European Chemicals Agency

Committee for Risk Assessment (RAC)

Committee for Socio-economic Analysis (SEAC)

Background document
to the opinions on the Annex XV dossier
proposing restrictions on
Mercury in measuring devices

ECHA/RAC/ RES-O-0000001363-81-02/F
ECHA/SEAC/[reference code to be added after the adoption of the SEAC opinion]

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

This Background Document (BD) shall be regarded as further reference material to the opinions of the Committees for Risk Assessment and Socio-economic Analysis. It contains further details and assessment in addition/beyond the justifications provided in the opinions including, where relevant, information that has been received during the opinion making process and may be used to better understand the opinions and their justifications. The BD is a supporting document based on the Annex XV restriction report submitted by MS, and updated to support the opinions of the Committees.

1 July 2011

Preface

The existing restriction in Entry 18a of Annex XVII to the REACH Regulation on mercury in measuring devices includes a review clause. According to the clause, the Commission was to carry out a review of the availability of reliable safer alternatives that are technically and economically feasible for mercury containing measuring devices and where such alternatives are available present, if appropriate, a proposal to extent the existing restriction. The Commission sent its review report to ECHA on 20 November 2009 and requested ECHA to prepare a corresponding Annex XV restriction report.

This Background Document (BD) concerns the industrial and professional uses of mercury in measuring devices as the existing entry in Annex XVII already restricts the placing on the market of mercury containing measuring devices for general public. The following measuring devices are covered:

- Barometers
- Manometers (including tensiometers)
- Metering devices for the determination of softening point
- Mercury electrodes (used in voltammetry)
- Mercury probes used for capacitance-voltage determinations
- Porosimeters
- Pycnometers
- Sphygmomanometers
- Strain gauges (used with plethysmographs)
- Thermometers (including hygrometers)

Barometers, manometers, sphygmomanometers and strain gauges are used to measure pressure and thermometers temperature. Porosimeters, pycnometers and metering devices for determination of softening point measure different parameters related to the structure and porosity of a sample. Mercury electrodes are used with specific devices like polarographs, for instance to determine trace elements in the environment and in biological fluids. Mercury probes are used to measure several parameters related to the purity of the material such as permittivity, doping, oxide charge and dielectric strength.

Barometers, manometers, sphygmomanometers, strain gauges and thermometers contain mercury as an integral part of the device whereas metering devices (for determination of softening point), mercury probes (for capacitance-voltage determinations), polarographs (using mercury electrodes), porosimeters and pycnometers use mercury during the measurement. This difference has an effect on the assessment of the devices as will be described later in this report. The devices included in the BD are also significantly different with regard to other factors, such as number of devices in the EU, the amount of mercury involved, the type of users (private practitioners, laboratories and research institutions, meteorological stations, airfields, ships, different industries etc), and reasons for the continued use.

The main focus of this document is on the assessment of the technical and economic feasibility of alternatives for the mercury devices. This emphasis on possibilities to transfer to alternatives stems from the review clause in the existing restriction. Furthermore, extensive amount of work has already been carried out on the hazard properties, fate, emissions of and exposures to mercury at international, EU and national levels and there is a wide agreement on the human health and the environmental concerns related to mercury and on the need for further actions where technically and economically possible. Based on this, the hazard profile is discussed only briefly. Furthermore, a qualitative approach is taken to the emission and exposure assessment. The approach taken to describe the hazard, emissions and exposure in this report is presented and justified in Section B.2. Based on this approach taken, Part B of the BD deviates from the standard format for an Annex XV restriction report, as published by ECHA (2009).

Furthermore, the number and different nature of the devices covered in this BD have led to the development of device specific annexes that discuss the following information:

- Technical description of the device
- Description of release and exposure
- Available information on the alternatives (Part C)
- Justification why the proposed restriction is the most appropriate Community-wide measure (Part E).

Consequently, Part E in the main document is in practise a summary of the proposed restrictions and provides a short justification for proposed actions / non-actions on different devices while Part C in the main document is reduced to a general introduction.

The main information source used for the assessments of the technical and economic feasibility of alternatives to mercury measuring devices is Lassen et al. (2008). This report called "*Options for reducing mercury use in products and applications, and the fate of mercury already circulating in society*" was commissioned by the European Commission (DG Environment). Lassen et al. (2008) and other information sources have an extensive amount of data on mercury in measuring devices, but still there were some data gaps for the remaining specific uses. Therefore, ECHA complemented this information by commissioning a consultant for the preparation of this restriction report. The results from the additional work are referred to as Lassen et al. (2010) in this report and can be found as Appendix 3. In addition, ECHA staff carried out literature and internet searches. These are reported in the relevant sections as well as in Appendix 2. To keep the workload proportionate, the efforts were targeted to gather data that could support the conclusion as to whether technically and economically feasible alternatives exist.

Content

A. Proposal

A.1 Proposed restriction(s)

A.1.1 The identity of the substance(s)

- Substance name: Mercury
- IUPAC name: Mercury
- EC number: 231-106-7
- CAS number: 7439-97-6
- Index number: 080-001-00-0

A.1.2 Scope and conditions of restriction(s)

For transparency reasons the original scope and conditions of the restriction as presented by the ECHA as dossier submitter in the original Annex XV restriction report is presented below. The opinions of RAC and SEAC are presented below in Chapter A.1.2.2.

Original Annex XV restriction report

Based on the justifications summarised in Section A.2 and discussed in the report, the following restrictions with derogations are suggested for mercury measuring devices in professional and industrial uses[1]:

1. Barometers, hygrometers, manometers, sphygmomanometers, tensiometers, thermometers and other non-electrical thermometric applications containing mercury shall not be placed on the market. This applies also to measuring devices placed on the market empty intended to be filled with mercury.

   It is suggested that the placing on the market of devices containing mercury for the following uses are derogated from the restriction described above:

   (a) Sphygmomanometers that are used (i) in long-term, epidemiological studies which are on-going at entry into force; (ii) as reference standards in clinical validation studies of mercury-free sphygmomanometers.

   (b) Mercury-in-glass thermometers used in industrial applications for temperature measurements above 200°C as demonstrated by the reading scale.

   (c) Thermometers exclusively intended to perform tests according to standards that require the use of mercury thermometers. It is suggested that this derogation will be valid until five years after the date of the adoption of this restriction.

[1] These suggested restrictions and related derogations concern only professional and industrial uses of the devices. 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.

(d) Mercury triple point cells that are used for the calibration of platinum resistance thermometers.

2. Plethysmographs designed to be used with mercury strain gauges, mercury pycnometers and mercury metering devices for determination of the softening point shall not be placed on the market.

It is suggested that the restrictions mentioned under paragraphs 1 and 2 will apply 18 months after the adoption of the respective Commission proposal.
Furthermore, it is suggested that these restrictions would not apply to measuring devices mentioned above that are more than 50 years old.

Opinion of RAC and draft Opinion of SEAC

The following Opinion of RAC and draft Opinion SEAC are identical excluding the derogation in paragraph 4. In addition to the derogation proposed by RAC for measuring devices which are to be displayed in exhibitions for cultural and historical purposes, SEAC proposes to have derogation for measuring devices more than 50 years old on 3 October 2007. This derogation is consistent with the existing entry 18a of Annex XVII to the REACH Regulation on mercury in measuring devices intended for sale to general public and on mercury in fever thermometers.

Opinion of RAC:

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.

3. 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.
4. 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.

5. 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].
6. 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.

Draft Opinion of SEAC:

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 exhibitions for cultural and historical purposes.

A.2 Summary of the justification

Identified hazard and risk

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 identyfied for methylmercury.

It is estimated that 3.5 to 7.6 tonnes of mercury is placed on the market in mercury containing measuring devices in 2010 (see Table 1). These amounts are used to describe the maximum potential for mercury emissions to the environment that might ultimately occur. This is considered appropriate for the purpose of this BD as the low separate collection rate and resulting inadequate waste treatment of a substantial part of the devices, leads in the long term to a relatively high share of mercury used in these devices being released to the environment.

Table 1: The amount of mercury estimated to be placed on the market in the EU in mercury containing measuring devices in 2010

Measuring device containing mercury	**Amount of Hg placed on the market in the EU in 2010 (t/y)**
Barometers	0.1-0.5
Manometers (including tensiometers)	0.04-0.4
Sphygmomanometers	2.6-5.1
Strain gauges (used with plethysmographs)	0.014
Thermometers (including hygrometers)	0.7-1.6
Total	**3.5-7.6**

Source: Lassen et al. (2008) as updated in device specific annexes 1 – 5.

In addition, around 5-15 tonnes of mercury is supplied annually to be used with porosimeters, pycnometers, devices using mercury electrodes in voltammetry, mercury probes used for capacitance-voltage determinations and metering devices for determining the softening point (see Table 2).

The annual amounts presented (in Tables 1 and 2) are not comparable. The figures in Table 2 are the amount of mercury the laboratories purchase and cannot be used to estimate maximum potential for emission as is the case in Table 1. To estimate emissions several additional factors need to be considered. These include number of measurements carried out, practices to purify and regenerate used mercury and the risk management measures and operational conditions applied to control the emissions and exposures. Furthermore, available information indicates that the hazardous waste legislation requirements are generally complied with when handling the mercury contaminated waste generated during these measurements.

Table 2: The amount of mercury estimated to be purchased in the EU to be used with measuring devices in 2010

Measuring device using mercury	**Amount of Hg purchased to be used for measurements (t/y)**
Mercury electrodes (used in voltammetry)	0.1-0.5
Mercury probes used for capacitance-voltage determinations	0.001-0.005
Metering devices for the softening point determination	not available
Porosimeters	5-14
Pycnometers	not available
Total	**5-15**

Source: Lassen et al. (2008), device specific annexes 6-10

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.

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.

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.

Justification that action is required on a Community-wide basis

The main reason to act on a Community-wide basis is the cross boundary human health and environmental problem related to mercury. Furthermore, the fact that the goods need to circulate freely within the EU stresses the importance of the Community-wide action. Thus, the use of mercury in these devices needs to be controlled 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 proposed restriction is the most appropriate Community-wide measure

Tables 3 and 4 summarise the justifications for the proposed restriction as well as the justification for not proposing any regulatory action for each device. The main purpose of the proposed restrictions is to reduce the mercury pool in the society, thus avoiding negative impacts on human health and environment. Nevertheless, based on the review clause, the justification is focused on the technical and economic feasibility of the alternatives.

Table 3: Proposed restrictions and summary of justification for measuring devices containing mercury

Measuring device containing mercury	Proposed restriction	Summary of justification
Barometers	Restriction on the placing on the market of mercury barometers.	Technically and economically feasible alternatives are available.
Manometers (including tensiometers)	Restriction on the placing on the market of mercury manometers and tensiometers.	Technically and economically feasible alternatives are available.
Sphygmomanometers	Restriction on the placing on the market of mercury sphygmomanometers with limited derogations.	Technically and economically feasible alternatives are available in most applications.
Strain gauges (used with plethysmographs)	Restriction on the placing on the market of mercury strain gauges to be used with plethysmographs.	Technically and economically feasible alternatives are available.
Thermometers (including hygrometers)	Restriction on the placing on the market of mercury thermometers with derogations for i) thermometers to perform specific analytical tests according to established standards and ii) mercury triple point cells that are used for the calibration of platinum resistance thermometers	Technically feasible alternatives are available for majority of applications. Reasons for derogations: i) some current standards refer to mercury thermometers and time is needed to revise them ii) mercury is one of the reference points needed in the International Temperature Scale (ITS-90)

Table 4: Proposed restrictions and summary of justification for measuring devices using mercury

Measuring device using mercury	**Proposed restriction**	**Summary of justification**
Mercury electrodes (used in voltammetry)	No restriction proposed	Technically feasible alternatives are not available in all applications. In addition, two main alternatives seem not to be economically feasible.
Mercury probes used for capacitance-voltage determinations	No restriction proposed	Technically and economically feasible alternatives are not available.
Metering devices for the softening point determination	Restriction on the placing on the market of mercury metering devices for the softening point determination	Technically feasible alternatives are available and in use. The alternatives also seem to be economically feasible.
Porosimeters	No restriction proposed	High uncertainties in the technical feasibility of the alternatives. Consequently the economic feasibility was not assessed in detail.
Pycnometers	Restriction on the placing on the market of mercury pycnometers.	Technically feasible alternatives are available and in use. The alternatives also seem to be economically feasible.

B. Information on hazard and risk

B.1 Name and other identifiers of the substance

Name of a substance: Mercury
EC Number: 231-106-7
CAS Number: 7439-97-6
Molecular weight: 200.59
The classification and labelling of mercury is provided in Appendix 1.

B.2 Scope and approach

Scope
The existing restriction in Entry 18a of Annex XVII to the REACH Regulation for mercury in measuring devices includes a review clause[2]. According to that clause, the Commission was to carry out a review of the availability of reliable safer alternatives that are technically and economically feasible for mercury containing measuring devices and where such alternatives are available to present, if appropriate, a proposal to extend the existing restriction. The Commission services have collected a significant amount of new information from stakeholders on measuring devices and have received the SCENIHR opinion on the safety, availability and quality of alternative methods for blood pressure measurements (SCENIHR, 2009). The Commission has sent ECHA its review report (see Appendix 5) and requested the European Chemicals Agency to prepare an Annex XV dossier as foreseen by Article 69 of REACH.

<u>Export</u>
Regulation (EC) No 1102/2008[3] bans the export of metallic mercury and certain mercury compounds from 15 March 2011. Furthermore, Article 8(1)(a) of this Regulation calls for examining the need to extend the export ban to products containing mercury naming in particular thermometers, barometers and sphygmomanometers. For reasons of legal consistency it has not been considered whether there is a need to ban the export of mercury in measuring devices in the framework of the REACH Regulation in the course of preparing the restriction report. Consequently, the BD did not further address the need or possibilities to limit export of mercury in measuring devices. Since the submission of the report on the 15th of

[2] Paragraph 4 of Entry 18a of Annex XVII of the REACH Regulation as amended by Commission Regulation (EC) No 552/2009
"By 3 October 2009 the Commission shall carry out a review of the availability of reliable safer alternatives that are technically and economically feasible for mercury containing sphygmomanometers and other measuring devices in healthcare and in other professional and industrial uses. On the basis of this review or as soon as new information on reliable safer alternatives for sphygmomanometers and other measuring devices containing mercury becomes available, the Commission shall, if appropriate, present a legislative proposal to extend the restrictions in paragraph 1 to sphygmomanometers and other measuring devices in healthcare and in other professional and industrial uses, so that mercury in measuring devices is phased out whenever technically and economically feasible."
[3] Regulation (EC) No 1102/2008 on the banning of exports of metallic mercury and certain mercury compounds and mixtures and the safe storage of metallic mercury, OJ L 304, 14.11.2008, p.75.

June 2010, a stakeholders meeting was held in Brussels by the Commission (DG ENV) on the 18th of June 2010 on the review of the Community Strategy Concerning Mercury. In part, this meeting was also an information exchange as required by Article 8 of Regulation (EC) No 1102/2008. A new Communication on the review of the Community Strategy Concerning Mercury was adopted by the Commission on 7/12/2010.[4] According to Article 8(4) of Regulation (EC) No 1102/2008, the Commission has to submit to the European Parliament and the Council a report by 15 March 2013, if appropriate accompanied by a proposal for a revision of Regulation (EC) No 1102/2008, which shall reflect and evaluate the outcome of amongst others the information exchange required by Article 8(1).

Electrical and electronic equipment

Several mercury containing measuring devices are dependent on electric currents in order to work properly, and thus fall under the definition of 'electrical and electronic equipment' in the RoHS Directive[5]. For reasons explained in Appendix 4, they are not covered by this BD. This is in line with recital 1 of the Directive 2007/51/EC that introduced the restriction on mercury in measuring devices, now subject to revision and reads: "*The Commission communication of 28 January 2005 on the Community strategy concerning mercury, which considered all uses of mercury, concluded that it would be appropriate to introduce Community-level marketing restrictions on certain **non-electrical or non-electronic** measuring and control equipment containing mercury, which is the main mercury product group not covered by Community action so far*." (emphasis added).

Exemption for scientific research and development

According to article 67(1) of the REACH Regulation, restrictions "*shall not apply to the manufacture, placing on the market or use of a substance in scientific research and development*". Article 3(23) defines scientific research and development (SRD) as "*any scientific experimentation, analysis or chemical research carried out under controlled conditions in a volume less than 1 tonne per year*". Based on this definition the SRD exemption may also cover any analysis, e.g., those carried out for quality control or environmental monitoring purposes, provided that the conditions set out in Article 3(23) are met.

With regard to these conditions, Article 3(23) explicitly limits activities covered by the SRD exemption to those "*carried out under controlled conditions in a volume less than 1 tonne per year*". Based on this explicit requirement, analytical activities that are not run under controlled conditions and substances that are used for research purposes in quantity of more than 1 tonne per year, cannot benefit from the exemption.

The SRD exemption would apply in all the cases where the above conditions are satisfied, and where the substance is used directly in analysis, on its own or in a

[4] The text of the new Communication is available on:
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2010:0723:FIN:EN:PDF

[5] 'electrical and electronic equipment' or 'EEE' means equipment which is dependent on electric currents or electromagnetic fields in order to work properly and equipment for the generation, transfer and measurement of such currents and fields falling under the categories set out in Annex IA to Directive 2002/96/EC (WEEE) and designed for use with a voltage rating not exceeding 1 000 volts for alternating current and 1 500 volts for direct current (Article 3(a) of Directive 2002/95/EC).

preparation, including in conjunction with analytical equipment, such as measuring devices using mercury (metering devices for determination of softening point, polarographs using mercury electrodes, porosimeters and pycnometers).

Contrary to substances used directly for analytical purposes, on their own or in preparation (or in conjunction with measuring devices), substances forming an integral part of an analytical device cannot benefit from the SRD exemption in so far as it is not the substance which is directly used in the analysis but the article. In these cases, the main purpose of the substance is not directly related to the analytical operation but to another function, even though sometimes a crucial function. This is the case of mercury in measuring devices, which forms an integral part of the device but is not used and delivered as such during the analytical process (e.g., barometers, manometers, sphygmomanometers, strain gauges and thermometers).

In summary, this BD covers placing on the market and use of mercury for non-electrical or non-electronic measuring devices in professional and industrial uses. The need for marketing or use restrictions for other uses of metallic mercury or other mercury compounds is not within the scope of this BD.

Background

Several international governance bodies have undertaken action to address the global human health and environmental concerns related to emissions of and exposure to mercury. The existing restriction on mercury in measuring devices, and the current restriction proposal to extend this restriction, is part of this overall action.

<u>United Nations</u>

The UNEP mercury programme has been established and strengthened by a series of Governing Council decisions. In February 2003, the UNEP Governing Council decided that "*national, regional and global actions, both immediate and long-term, should be initiated as soon as possible to protect human health and the environment through measures that will reduce or eliminate releases of mercury and its compounds to the environment*", and urged "*all countries to adopt goals and take national actions, as appropriate, with the objective of identifying exposed populations and ecosystems, and reducing anthropogenic mercury releases that impact human health and the environment*" (UNEP, 2003).

In February 2009 the UNEP Governing Council adopted a decision, where it recalled the findings of the 2002 global mercury assessment that mercury is a substance of global concern due 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 and the environment. The Governing Council further requested to continue and enhance, as part of the international action on mercury, the existing work in reducing mercury use in products and processes and raising awareness of mercury free-alternatives.

The organisation of activities concerning mercury at the United Nations level is described in the following quotes:

"The UNEP mercury programme has been established and strengthened by a series of Governing Council decisions since decision 21/5 in 2001. The UNEP mercury programme delivers activities on mercury through the UNEP Global Mercury Partnership, and will also support the negotiations of an internationally legal instrument for control of mercury." (UNEP, 2010)

"The overall goal of the UNEP Global Mercury Partnership is to protect human health and the global environment from the release of mercury and its compounds by minimizing and, where feasible, ultimately eliminating global, anthropogenic mercury releases to air, water and land." (UNEP, 2010)

One of the Partnership Areas focuses specifically on products containing mercury, also covering measuring devices:
"*The goal of the Mercury-Containing Products Partnership Area is to phase out and eventually eliminate mercury in products and to eliminate releases during manufacturing and other industrial processes via environmentally sound production, transportation, storage, and disposal procedures. Key product areas identified under this partnership area include: batteries, dental amalgams, measuring and control (largely medical sector), electric and electronic switches, fluorescent lamps, cosmetics*." (UNEP, 2010)

The UNEP Governing Council agreed to elaborate a legally binding instrument on mercury and gave a mandate to an intergovernmental negotiating committee (INC) to prepare this (UNEP, 2010). Two sessions of this committee have been held: INC-1 in Stockholm, Sweden, in June 2010 and INC-2 in Chiba, Japan, in January 2011.

European Community
In the EU, mercury has been under different policy actions. The Community Strategy Concerning Mercury (COM(2005) 20 final) has 20 action points with the aim to reduce mercury levels in the environment and human exposure, especially from methylmercury in fish.

In October 2007, the Commission adopted a restriction for mercury in all fever thermometers and in other measuring devices intended for sale to the general public (Directive 2007/51/EC, current Entry 18a of Annex XVII to REACH). This restriction established that as soon as new information on reliable safer alternatives for sphygmomanometers and other measuring devices becomes available, the Commission shall consider extending the restriction.

Other regional and global actions
In addition to the described actions on the UN and EU-level, several other regional and global initiatives are active in identifying sources of mercury emissions and exposures, monitoring concentrations of mercury in the environment, defining protection objectives and recommending measures to address the mercury problem. Examples are the UNECE Convention on Long Range Transboundary Air Pollution (CLRTAP); the OSPAR Convention for the Protection of the Marine Environment of the North-East Atlantic; the Helsinki Convention on the Protection of the Marine Environment of the Baltic Sea Area; the UNEP Mediterranean Action Plan (MAP); the Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal; the Rotterdam Convention on the Prior Informed Consent

(PIC) Procedure for Certain Hazardous Chemicals and Pesticides in International Trade; The Arctic Council Action Plan to Eliminate Pollution of the Arctic (working groups ACAP and AMAP); and Nordic Co-operation.
Also, without going into the details, it is noted that there are restrictions and other legal measures on individual country or state level, such as for instance national restrictions of some EU-countries (see section B.5), the Mercury Export Ban Act in the US[6], and the ban for mercury added products in Canada[7].

Approach
As mentioned above, Entry 18a of Annex XVII requests the Commission to present a legislative proposal to extend the restrictions where reliable safer alternative substances or technologies that are technically and economically feasible are available for mercury containing sphygmomanometers and other measuring devices in healthcare and in other professional and industrial uses. Based on this entry, the Commission prepared a review report on the technical and economic feasibility of alternatives (see Appendix 5) and requested ECHA "*to evaluate new scientific evidence concerning the availability of reliable safer alternatives that are technically and economically feasible for mercury-containing sphygmomanometers and other measuring devices in healthcare and in other professional and industrial uses*", and to present the outcome in an Annex XV restriction report.

Therefore, the focus of the BD is on the technical and economic feasibility of the alternatives, while the hazards and exposure are described in general and qualitative terms.

The risks related to the use of mercury measuring devices cannot be assessed in isolation, and further restrictions related to these devices has to be seen as one of the means in the Community Strategy Concerning Mercury to reduce the overall mercury emissions.

Hazard
The hazardous properties and risks of mercury and methylmercury have been extensively studied and described in different scientific reports and have been acknowledged at high policy levels. A systematic literature survey would be unlikely to deliver new information that would change the consensus at the EU and international level on this hazard profile and the need for reduction of the mercury pool in the society. Hence, since a comprehensive description of the hazardous properties of mercury would mean duplicating the extensive work already carried out and agreed upon and taking into account the fact that the focus of the dossier is on the technical and economic feasibility of alternatives, the hazard assessment in this BD is brief and qualitative, and the technical dossier (IUCLID 5 –file) does not contain robust study summaries.

Exposure
Annex XV of REACH calls for the assessment of risks in accordance with the relevant parts of Annex I. Mercury as an element is persistent and has extremely

[6] http://www.epa.gov/mercury/regs.htm#laws
[7] http://www.gazette.gc.ca/rp-pr/p1/2011/2011-02-26/html/reg4-eng.html#41

complex processes of bioaccumulation and biomagnification that involve complicated biogeochemical cycles and ecological interactions (see section B.3 and UNEP, 2002). Therefore, it is not possible to carry out a quantitative exposure estimation with sufficient reliability, and a qualitative characterisation of risks in accordance with section 6.5 of Annex I to REACH is considered appropriate.

Since release estimates would not serve a quantitative exposure assessment or risk characterisation and would have to be expressed in exceedingly broad ranges to take into account all accumulated uncertainties[8], no quantitative release estimates are made either. The focus of the exposure assessment is on the minimisation of mercury emissions to the environment, which is also supported by the objectives in the Community Strategy Concerning Mercury to '*reduce mercury emissions'* and *'reduce the entry into circulation of mercury in society by cutting demand*' and the decision of the UNEP GC to '*reduce or eliminate releases of mercury and its compounds to the environment*' (UNEP, 2003).

As described above the main focus of this BD is on the technical and economical feasibility of the alternatives. The estimated amounts of mercury placed on the market in different devices are used to illustrate the risk reduction capacity of the restriction options. Where available, the risk reduction capacity is expressed as amount of mercury (kg Hg) which would not be placed on the market per year. This is then used when assessing the proportionality of the restriction options. Where technical or economic feasibility of alternatives cannot be established and consequently restrictions are not proposed in this BD the estimated amounts together with other considerations can be used to describe the remaining concern related to mercury included in or used with measuring devices.

Measuring devices covered by this BD can be divided to two categories i) devices containing mercury as an integral part of the device (barometers, manometers, sphygmomanometers, strain gauges and thermometers) and ii) devices using mercury during the measurements (porosimeters, pycnometers, mercury electrodes used in voltammetry, mercury probes used for capacitance-voltage determinations and metering devices). This difference is crucial for the description of releases and emissions in this BD as explained below and in Section B.4.

Release from measuring device containing mercury

The total estimated amount of mercury placed on the market in measuring devices containing mercury is used to describe the maximum potential for mercury emissions to the environment that might ultimately occur.

---

[8] See section B.4 and the ECHA Guidance on information requirements and chemical safety assessment, Chapter R.18 (ECHA, 2010) that mentions the following with respect to the use or release estimates for mercury: "*Note: Release estimates based on the release factors for mercury, lead and cadmium should not be used for exposure quantification and/or quantitative risk characterisation. A qualitative assessment is more appropriate here. Such qualitative assessment is needed to take into account the uncertainties around the environmental behaviour of the metal (for mercury) and/or the hazard profile of the substances related to human health (carcinogenic and reproductive toxicity with regard to cadmium and lead).*"

This estimation is obviously not to be confused with a quantitative estimate of actual emissions which would require in particular detailed information on the current waste management practices and emissions resulting from the waste stage (see section B.4.1). Mercury is an integral part of these devices and they normally operate without a need to handle mercury[9]. Mercury is disposed of together with the devices at the end of their service life. Therefore, the emission estimation related to measuring devices containing mercury concentrates on the release of mercury to the environment during the waste stage. Also the existing restriction covering mercury containing devices focused on the waste stage as described in recital 2 of Directive 2007/51/EEC which states: '*(2) There would be benefits for the environment and, in the long term, for human health, through* ***preventing mercury from entering the waste stream****, if restrictions on the marketing of measuring devices containing mercury were introduced.* (emphasis added).

In addition to the amounts placed on the market also the dispersiveness of use, proportion of proper waste collection and disposal, was well as other factors described in the BD (including also occupational exposure during production and service-life of the devices), are taken into account when illustrating the emissions and exposures related to different devices.

Release from measuring devices using mercury

The situation is more complex for devices using mercury during the measurements. The amount of mercury placed on the market cannot be used for these devices as a proxy for maximum potential for emissions in a similar way as it is used for mercury containing devices. The annual amount of mercury purchased by the laboratories to be used in the measurements is given to illustrate the volumes involved. However, for reasons given in section B.4.2 this amount alone does not describe the potential releases and exposures related to the measuring devices using mercury. Further parameters and qualitative descriptions are used to give a more complete picture.

Technical and economic feasibility of the alternatives

The technical and economic feasibility of alternatives is assessed in the device specific annexes based on the available information and the information collected in the stakeholder and public consultations. For technical feasibility, the argumentation is based on a qualitative description of the devices and their technical properties. For economic feasibility quantitative information is presented if available, including both investment and recurrent costs. When the annualised costs of alternatives are estimated to be lower than the annualised costs of the mercury device, it is straightforward to conclude that alternatives are economically feasible. When the annualised costs of alternatives are estimated to be higher, additional argumentation on the feasibility is provided. These comprise the relevance of i) the additional cost of mercury-free devices compared to the total costs of measurement (including the working time needed to measure) or ii) the additional cost of mercury-free devices compared to the total cost of purchases of goods and services by the user.

[9] With the exception of filling devices with mercury prior to their first use and during maintenance (e.g. of sphygmomanometers, barometers and manometers).

Proportionality

The total amount of mercury placed on the market in the measuring devices is used to assess the proportionality of the restriction options. The cost-effectiveness (€/kg Hg) of avoiding mercury is calculated for different devices by dividing the cost of using an alternative device by the amount of mercury that is avoided (for details, see Annexes 3b and 5b). A literature review on the compliance costs of other policies to reduce mercury and the human health benefits of reduced mercury emissions, as well as restoration costs in the EU and elsewhere is provided in Appendix 2. These costs give an order of magnitude comparison with the cost-effectiveness of the reduction of mercury in measuring devices estimated in this BD.

Summary

In summary, the approach to describe hazard in brief and to focus the exposure assessment on the minimisation of emissions was deemed warranted considering:

- that this BD supports the extension of the existing restriction on mercury in measuring devices where technically and economically feasible alternatives are available;
- the common understanding on the hazardous properties of mercury and its transformation products; and
- it would not be possible to perform a reliable quantitative estimation of releases, and especially of the resulting exposure levels.

Information sources for hazard and risk

The hazard and fate of mercury and its compounds are described in numerous peer-reviewed reports. The following reports were considered key documents:

- *'Global Mercury Assessment',* published by UNEP in 2002 (and UNEP 2008a and b);
- '*Methylmercury'* (WHO, 1990) ;
- '*Risks to Health and the Environment Related to the Use of Mercury Products*' prepared for the Commission by RPA in 2002.

It is noted that references used and cited in these key documents are not explicitly referred to in this BD.

For the qualitative description of potential releases and exposure, amounts of mercury included in or used with the measuring devices are mainly taken from Lassen et al. (2008). Additional information on release and exposure situations for porosimeters is gathered during the preparation of this dossier (Lassen et al., 2010 in Appendix 3).

B.3 General description of hazard and fate

Fate

Elemental mercury (Hg(0)) is a shiny, silver-white metal that is a liquid at room temperature. At room temperature some of the metallic mercury will evaporate and form mercury vapours. Mercury vapours are colourless and odourless.

After release, mercury persists in the environment, where it circulates between air, water, sediments, soil and biota in various forms (UNEP, 2002).

Elemental mercury vapour is transported on a hemispherical/global scale making mercury emissions a global concern. Elemental mercury in the atmosphere can undergo transformation into inorganic mercury forms[10], 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 (WHO, 1990). Emitted mercury vapour is converted to soluble forms, these soluble forms have residence times of a few weeks (WHO, 1990). Soluble forms of mercury are deposited by rain into soil and water.

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 periods of time, possibly hundreds of years.

Various chemical reactions can return mercury to the elemental form which can be readily re-emitted. Thus, mercury that has been deposited can be re-emitted and continue travelling through the atmosphere from source regions to receptor regions in a series of ‘hops’ (so called grasshopper effect). Mercury may be accumulated in polar regions, where colder conditions may be less favourable to re-emissions (UNEP, 2008b).

A portion of the inorganic mercury is methylated (particularly within sediments) to methylmercury, which enters the water column (RPA, 2002). Methylmercury is by far the most common organic mercury compound in the environment (UNEP, 2002). The rate of mercury methylation depends on factors such as the activity of mercury methylating bacteria (e.g. sulphate reducers), concentration of bioavailable mercury (UNEP, 2002). These factors in turn are influenced by parameters such as temperature, pH, redox potential and the presence of inorganic and organic complexing agents (UNEP, 2002). Chemical methylation of mercury is also possible, and biotic demethylation occurs as well (UNEP, 2002). Methylation and demethylation processes are in fact determining the actual methylmercury concentrations in the environment (UNEP, 2002).

[10] Oxidation states +I and +II

Although all forms of mercury can accumulate to some degree, methylmercury is absorbed and accumulates to a greater extent than other forms (UNEP, 2002)[11]. Marine and freshwater fish, as well as marine mammals, bioaccumulate[12] methylmercury in their muscle tissue (UNEP, 2008). Fish bind methylmercury strongly, and elimination of methylmercury from fish is very slow, which causes fish to accumulate methylmercury over time (UNEP, 2002).

Moreover, methylmercury biomagnifies[13] throughout the many aquatic trophic levels (UNEP, 2002). 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 (UNEP, 2008a). Other fish-eating species, such as seabirds, but also humans are situated at top level of the trophic chain through eating (predator) fish and other seafood (UNEP, 2002).[14]

On a global scale, the Arctic region and its species has been in focus because of the tendency of mercury to be transported over a long-range. However, the impacts of mercury are by no means restricted to the Arctic region. The same food web characteristics and similar dependence on mercury contaminated food sources are found in specific ecosystems and human communities in many countries around the world, particularly where a fish diet is predominant. (UNEP, 2002)

The bioaccumulation factor[15] for methylmercury in edible freshwater and saltwater fish and marine mammals can mount to many thousands (UNEP, 2002), and can even be well above one million (SCHER, 2008). In other words, low concentrations in the environment can still lead to high dietary exposure. Much is known about mercury bioaccumulation and biomagnification, but because of the complexity of the processes involved, the <u>extent</u> of mercury biomagnification in fish is not easily predicted (UNEP, 2002).

---

[11] Inorganic mercury can also be taken up, but generally at a lower rate and with lower efficiency compared to methylmercury (UNEP, 2002).

[12] Bioaccumulation refers to uptake from all environmental sources including water, food and sediment. UNEP (2002) gives the following description: “The term bioaccumulation refers to the net accumulation over time of metals within an organism from both biotic (other organisms) and abiotic (soil, air, and water) sources.”

[13] Biomagnification refers to accumulation via the food chain. UNEP (2002) gives the following description: “The term biomagnification refers to the progressive build up of some heavy metals (and some other persistent substances) by successive trophic levels – meaning that it relates to the concentration ratio in a tissue of a predator organism as compared to that in its prey (AMAP, 1998).”

[14] In EU the maximum levels for mercury in fishery products, in muscle meat of fish and in crustacae are given in the Commission Regulation (EC) No 1881/2006, amended No 629/2008. In addition, the Joint FAO/WHO Expert Committee on Food Additives (JECFA), established a provisional tolerable weekly intake (PTWI) of 1.6µg/kg bw, and the US National Research Council (NRC) established an intake limit of 0.7µg/kg bw (EFSA, 2004). According to EFSA, estimated intakes of mercury in Europe varied by country, depending on the amount and the type of fish consumed. The mean intakes in some countries exceeded the NRC-limit, and high intakes may also exceed the JECFA-limit (EFSA, 2004). Several EU Member States have issued advice to vulnerable populations to avoide or limit the frequency of intake of certain fish species (COM, 2008). The Commission advises that women who might become pregnant, woman who are pregnant or women who are breastfeeding, as well as young children, should not eat more than 100g per week of large predatory fish, such as swordfish, shark, marlin and pike (COM, 2008).

[15] The overall bioaccumulation factor is the ratio between the concentration in the organisms and the concentration in water (SCHER, 2008).

Hazard

Each form of mercury has its own toxicological profile, although, in general terms, the organic mercury compounds have the highest toxicity, followed by elemental mercury and inorganic mercury compounds. The focus is on the description of the hazards of methylmercury, since it is the most toxic form and, as described earlier, is of highest concern since it biomagnifies in food webs (UNEP, 2008). Elemental mercury is described in brief since mercury in measuring devices might result in direct human exposure to elemental mercury. Inorganic mercury compounds are not described here, since they are of less relevance.

<u>Methylmercury</u>

Humans

Methylmercury is highly toxic especially to the nervous system. Methylmercury toxicity has been demonstrated at low exposure levels (EFSA, 2004). In adults, the first effects at the lowest doses are non-specific 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 construction of the visual field, deafness, dysarthria and ataxia, and ultimately leading to coma and death (UNEP, 2002).

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 (UNEP, 2002). Some studies suggest even small increases in methylmercury exposures may cause adverse effects on the cardiovascular system, thereby leading to increased mortality (UNEP, 2002).

The examples of mercury poisoning in Japan and Iraq have shown on a population scale the severe neurological effects of methylmercury to humans. At first the poisoning in Minamata, Japan, was regarded as an epidemiological disease of unidentified causes (Minamata Disease), first seen in abnormal behaviour in animals, and in 1956 reported first in humans. In 1959 the cause was officially recognized as being methylmercury foodpoisoning. The methylmercury originated from discharged mercury containing wastewater from an acetaldehyde production factory into Minamata bay. According to the National Institute for Minamata Disease, there are 2955 legally recognized patients. (National Institute for Minamata Disease, 2010).

In Iraq, the poisoning incidents in 1956 and 1959-1960 and in 1971-1972 were due to the consumption of seed grain that had been treated with fungicides containing methyl- and ethylmercury. After the incident in 1971-1972 it was reported severe damage to the central nervous system in infants prenatally exposed to methylmercury (WHO, 1990 and UNEP, 2002). In adults the symptom was paresthesia and in more severe cases ataxia, blurred vision, slurred speech and hearing difficulties (UNEP, 2002).

In addition there are number of other epidemiological studies with pregnant women having marine diets and their children which provide some supporting evidence to the previous findings related to the neurological effects (WHO, 2007).

Environment

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. (UNEP, 2002)

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). UNEP (2002), reported eggs of certain Canadian species to be in this range, and concentrations in the eggs of several other Canadian species were said to continue to increase and are approaching these levels (UNEP, 2002).

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 (UNEP, 2002).

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 (UNEP, 2002).

<u>Elemental mercury</u>

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.

The EU harmonised classification and labelling of mercury is described in Appendix 1.

B.4 General qualitative description of potential release and exposure

More than 60 different applications for mercury have been identified in the EU. Lassen et al. (2008) estimated that in 2007 between 320 and 530 tonnes of mercury was used in industrial processes and products in the EU27+2. The biggest annual tonnages are used in chlor-alkali production and in dental amalgams representing 47 % and 27 % of the total amount of mercury used in the EU for all applications. The demand of mercury for chlor-alkali production is steadily declining as a result of a phase-out of the mercury-cell process[16]. The Figure 1 presents the shares of each application areas, including measuring devices, from the total annual use of mercury in products and industrial processes in the EU. For measuring devices the estimated share is currently 4 %. This does not correspond to the estimate for the risk reduction capacity of the proposed restriction (see general part E), as not all the measuring devices are covered by the proposal. The proposed restrictions represent around 1.5 % of the annual use.

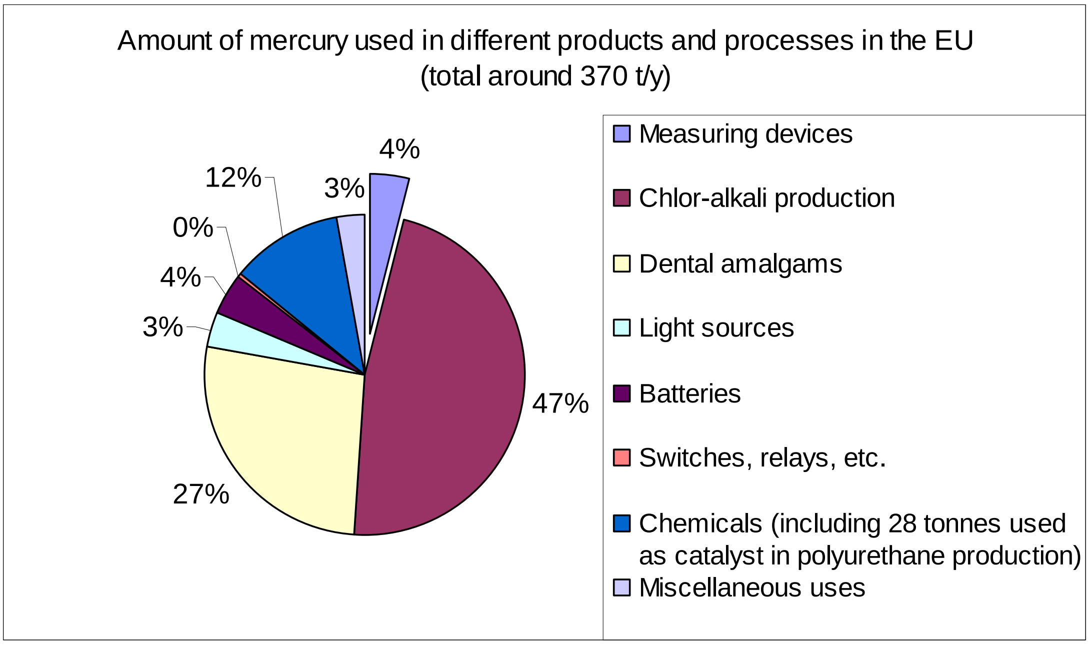


Figure 1: The amount of mercury used in products and industrial processes in

[16] The OSPAR Decision 90/3 of 14 June 1990 on reducing atmospheric emissions from existing chlor-alkali plants recommended that "*existing mercury cell chlor-alkali plants be phased out as soon as practicable. The objective is that they should be phased out completely by 2010*". Euro Chlor and its members state that they continue implementing a voluntary agreement on the gradual conversion to membrane technology. According to Eurochlor, the final phase out for the chlor-alkali production should be completed by 2020. (http://www.eurochlor.org/news/detail/index.asp?id=272) The chlor-alkali industry is also covered by the IPPC Directive, which requires installations to have permit conditions based on best available techniques (BAT). The mercury-cell process is not considered to be BAT for the chlor-alkali sector.

the EU annually. Source: Figures based on Lassen et al. (2008) and device specific Annexes for measuring devices[17].

To put the amounts of mercury used in products in a wider perspective, this paragraph gives an overview of the order of magnitude of emissions from anthropogenic and natural sources occurring in Europe and globally. It is estimated that around 1930 tonnes of mercury was released to the atmosphere from anthropogenic sources globally in 2005. Around 45% of this volume stems from the burning of fossil fuels. Europe is responsible for 150 tonnes, i.e. 8% of the global emissions. Emissions from natural sources (including releases from volcanoes and geothermal activity, wildfires and weathering of rocks and soils) are situated between 900 and 2300 tonnes for the year 2005. In addition, 900-2500 tonnes of mercury is estimated to return to the atmosphere as re-emissions. (UNEP, 2008b)

The following subsections describe the potential mercury releases and exposure during the life-cycle of mercury containing measuring devices and devices using mercury. Details for specific devices are given in Annexes 1 to 10.

B.4.1 Mercury emissions from measuring devices containing mercury

The amount of mercury placed on the market in the EU in different measuring devices containing mercury is estimated to be between 3.5 and 7.6 tonnes in 2010. Device specific figures are summarised in Table 5. The service-life of the measuring devices containing mercury is usually longer than 1 year, and consequently the accumulated pool of mercury in measuring devices in use is higher than the amount placed on the market annually. The estimates on the accumulated pool are also presented in Table 5. The estimate for accumulated pool considers the average life-time of the device and also possible trend in the number of devices placed on the market before 2010.

Table 5: The amount of mercury estimated to be placed on the market in the EU in mercury containing measuring devices in 2010

Measuring device containing mercury	Amount of Hg placed on the market in the EU in 2010 (t/y)	The estimated accumulated pool of Hg in the devices in 2010 (t)
Barometers	0.1-0.5	3
Manometers (including tensiometers)	0.04-0.4	4
Sphygmomanometers	2.6-5.1	39
Strain gauges (used with plethysmographs)	0.014	0.014
Thermometers (including hygrometers)	0.7-1.6	88

[17] The estimates for the measuring devices have been updated based on the information gathered in the stakeholder consultation.

Total	**3.5-7.6**	**134**

Source: Lassen et al. (2008)[18] as updated in device specific Annexes 1 – 5[19].

Mercury emissions to the environment and direct human exposure may occur during all life-cycle stages of mercury containing measuring devices, but in particular emissions to the environment from the waste stage are of concern. Figure 2 shows the life cycle of mercury containing devices and indicates the relative size of mercury losses from different life cycle stages. The size of the arrows illustrates the importance of emissions in the different stages.

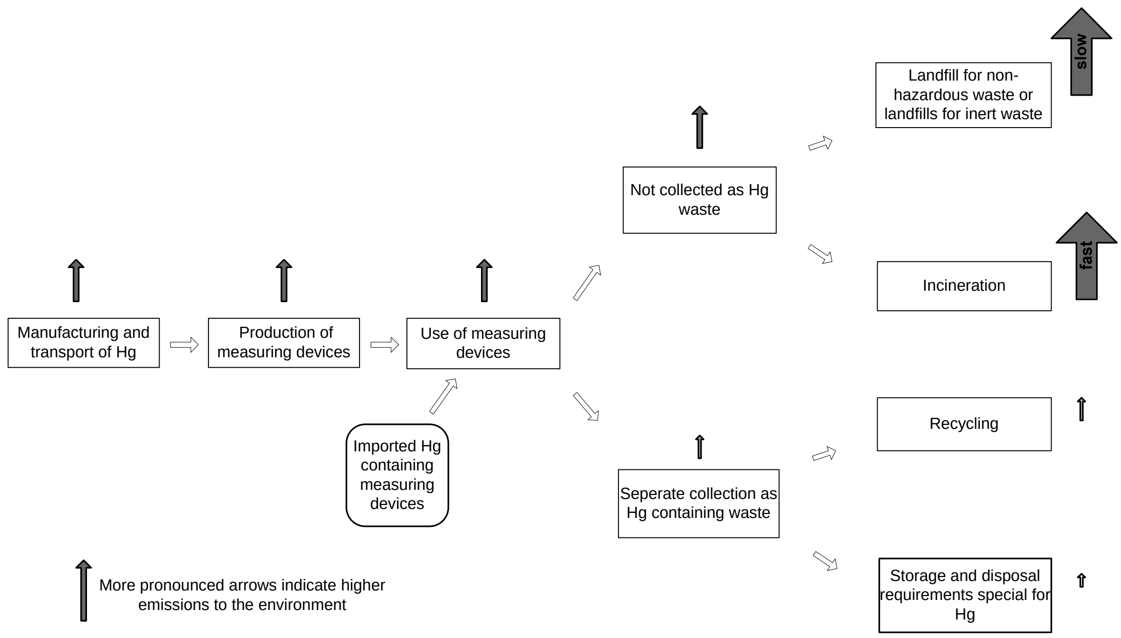


Figure 2 Scheme of the life-cycle of mercury in measuring devices

Production of measuring devices

In the production phase of mercury containing devices occupational exposure and emissions to the environment may occur during the handling of mercury, filling of the devices, breakage of devices, and the handling of mercury contaminated waste.

[18] Lassen et al. (2008) estimated the amount of mercury placed on the EU market in measuring devices containing mercury to be between 7 and 17 tonnes in 2007 (this amount included also devices for consumer use). Of this amount, 3 – 8 tonnes per year are covered by the existing restriction on the placing on the market of mercury containing measuring devices for sale to general public and placing on the market of fever thermometers and therefore not anymore available on the EU market (the measures in entry 18a of Annex XVII of REACH apply since 3 April 2009). Based on these figures the amount of mercury placed on the market in mercury containing measuring devices not covered by the existing restriction is roughly estimated to have been between 4 and 9 tonnes per year in 2007.

[19] The estimates for some of the measuring devices have been updated based on the information gathered in the stakeholder consultation (see Part G and Appendix 3 for information on stakeholder consultation).

To prevent occupational exposure via air –the most important route of exposure for workers, a Community-wide IOELV has been adopted (see section B.5). However, the IOELV might not be effective in preventing or reducing exposure from accidental breakage, spillage of mercury, and leakage.
In addition, emissions to the environment (to air and water, direct or indirect via waste disposal) arising from the production of measuring devices does not seem to be covered by Community legislation specifically setting limits on mercury emissions to air or water (see section B.5).

Service-life of measuring devices

During the service-life of the devices emissions of and exposure to mercury may occur during professional and industrial uses of mercury containing measuring devices, including maintenance, filling devices with mercury (e.g. sphygmomanometers, barometers and manometers) and breakage of devices. Exposure of workers (professional and industrial users)[20] occurs mainly via air, and emission to the environment include direct or indirect (via waste disposal) emissions to air and water. Existing occupational health and environmental legislation (see section B.5) is not considered to be effective in preventing or reducing emissions or exposure related to professional and industrial use of mercury containing measuring devices.

Waste stage of measuring devices

Mercury containing measuring devices are legally required to be collected separately from other (hazardous and non-hazardous) waste streams at the end of their service life (see also section on waste legislation in B.5).

Typically, after separate collection, the mercury containing waste has to undergo pretreatment (which can consist of sorting out, breaking of glass devices, etc). Subsequently the mercury can be separated from the other waste material and concentrated by vacuum distillation. The off gases can be treated with dust filters and activated carbon filters. The dust and the contaminated carbon from the gas treatment can be returned into the process used to isolate the mercury from the other parts of the devices (BREF Waste Treatments Industries, 2006). The resulting mercury can be refined and used as a secondary material or disposed of in compliance with amongst others the very specific rules for mercury waste storage in Regulation No 1102/2008.

Proper separate collection of mercury containing devices is a way to reduce emissions, but is challenging and costly, especially for devices where discarding is not very regular (e.g. as a result of a long life-time) and where devices are geographically widely spread. Promoting and organising collection is very dependant on priorities in

[20] For illustrative purposes, in the Netherlands 72 cases of human exposure to mercury have been reported to the National Poisons Information Centre in 2009, and 50 cases in 2010 (until 21 October). About one third of the cases concerns the breakage of fever thermometers. The remaining part concerns several applications like other thermometers, barometers and lamps (pers. comm.).

individual Member States (Lassen et al., 2008). As a rough figure[21], collection efficiencies of mercury in measuring devices in accordance with requirements set out in the hazardous waste legislation are estimated to be as low as approximately 20%. Collection efficiencies above 50% should in general not be expected (Lassen et al., 2008).

If not collected and treated in accordance with hazardous waste legislation, mercury containing waste is fed to landfill or incineration, which results in higher emissions compared to treatment according to hazardous waste legislation as described above. So called 'secondary techniques' for the abatement of mercury emissions from installations for incineration and landfills are briefly described in Box 1.

The low separate collection rate and resulting inappropriate waste treatment of a substantial part of measuring devices, leads in the long term to a relatively high share of mercury in measuring devices being released to the environment. Figure 2 represents the possible routes of mercury release to environment from measuring devices.

In principle it would be possible to make release estimates for the incinerated and landfilled waste fraction by estimating the mass flows going to the different fractions and by applying release factors to those estimates. However, the mercury volumes placed on the EU market in measuring devices and the fraction that is not specifically treated as mercury containing hazardous waste are rather uncertain. Also, it is unknown what fractions are incinerated and what fractions are landfilled. In addition, the reported release factors[22] are very variable and entailed with high uncertainty, and no good models exist to predict the releases from landfills[23].

[21] For (amongst others) the following reasons it is very difficult to obtain good information on rates of separate collection of mercury measuring devices.
According to the list of wastes (LoW), established by Commission Decision 2000/532/EC, mercury containing measuring devices fall under code "20 01 21* fluorescent tubes and other mercury-containing waste" (the asterisk points to classification as hazardous waste). Within this code, the mass of measuring devices is overshadowed by the mass of fluorescent tubes. Moreover, waste statistics reporting by Member States is done according to 'aggregated' waste categories. Fluorescent tubes and other mercury-containing waste is added together with 6 other entries under code 08.43.1 (Other discarded machines and equipment components, Hazardous), and it seems even that the actual reporting is only required on the level of "08 Discarded equipment, hazardous".
In addition, uncertainty on the quantity and mercury content of devices brought on the market in the past and uncertainty on when they are discarded (life times of devices) further complicates estimating the rate of separate collection (needed to compare with the estimated amount of separately collected mercury waste measuring devices).
Questionnaires were sent out to Member States as part of the study by Lassen et al. (2008), to obtain information on the individual waste codes (which is as explained not generally available). Only a few Member States submitted detailed waste data, and only 3 Member States submitted information on waste of mercury in measuring and control equipment.

[22] Kindbom and Munthe (2007) assumed a release factor of 0.5 to air for mercury in measuring devices that are incinerated in municipal solid waste **incineration**. A tenfold lower default release factor of 0.05 is suggested for municipal solid waste incineration in the draft ECHA Guidance on information requirements and chemical safety assessment, Chapter R.18 (ECHA, 2010). The guidance however also notes that metals are not destroyed and could be emitted to a rather high extent to air, even if flue gas is cleaned.
Kindbom and Munthe (2007) assumed an emission factor of 0.05 to air for the 1st year for mercury measuring devices in **landfills**, and a factor of 0.001 for the 9 consecutive years. Emissions for the years after were not estimated, but assumed to be very low as the waste will be covered with more

To sufficiently remove all these uncertainties, very extensive surveys on the market for all mercury devices, and on the compliance rate with the hazardous waste legislation in all Member States and on country-specific waste management practises would have to be carried out, without guarantee of success.

In other words, the release estimates would have to be expressed in exceedingly broad ranges to take into account all the accumulated uncertainty. Since such estimates would not serve any quantitative exposure assessment or risk characterisation[24], it was not judged useful to attempt to quantify emissions entailed with such high uncertainty, whereas the actual aim is to minimise exposure and emissions. The total estimated amount of mercury included in the measuring devices (see Table 5) was considered to be more useful to describe what emissions to the environment might ultimately occur, and therefore in what follows only a qualitative description of releases and risk management measures is given.

It is assumed that releases from waste incineration and landfills will at least be significant, and mercury measuring devices ending up in incineration are assumed to contribute to peaks that overload flue-gas cleaning system capacities for mercury removal (see also Box 1).

Virtually all handling of mercury can lead to emissions[25]. To some limited extent this will also be the case during the management of properly collected mercury containing measuring devices according to the hazardous waste requirements (see section B.5). However due to all the provisions and requirements for treatment of hazardous waste, these emissions are in magnitude incomparable to the emissions that may occur when mercury containing measuring devices go to installations for incineration or disposal of non-hazardous waste.

layers. It is not clear whether the authors take into account emissions through flaming of gasses. The draft ECHA Guidance on information requirements and chemical safety assessment, Chapter R.18 (ECHA, 2010) does not report a specific release factor for mercury.

23 The ECHA Guidance on information requirements and chemical safety assessment, Chapter R.18 (ECHA, 2010) mentions in this respect the following: "*Since no good models exist to predict the releases from landfills, the registrant should demonstrate control of risk based on a qualitative argumentation as to why the substance is unlikely to be released under landfill conditions. This argumentation may be based on volatility, water solubility, degradability and adsorption behaviour.*"

24 As described in section B.2, it is not possible to carry out a quantitative exposure estimation for mercury with sufficient reliability because of the properties of mercury.

25 As also indicated in Figure 2, mercury can be released to air during all waste handling operations (collection, transport, and temporary storage) prior to disposal or recovery operations; during dumping, spreading, compacting and burial of waste in landfills; from landfill gas vents and from the surface of landfills; during pretreatment prior to incineration; through exhaust of waste incineration; and to a limited extent also during recovery and permanent storage operations. In addition to the emissions to air, mercury is released to soil and (ground)water via leachate from landfills.

Box 1 Abatement of mercury emissions

Waste incineration
(source: BREF Waste Incineration, 2006)

There is a direct linear relationship between the amount of mercury in the *raw* flue-gases and the amount of mercury in the waste. Typical concentrations for municipal waste incineration plants are 0.05 – 0.5 mg/m³ in crude flue-gas. There are two ways to satisfy the mercury emission limit of 0.05 mg/m^3 in the waste incineration Directive (Directive 2000/76/EC). The most important means is limiting the input of mercury in the installation by proper collection, the other being an efficient mercury removal.

The majority of installations need special gas cleaning measures in order to meet the mercury emission limit value for air (but note that continuous monitoring of mercury emission levels is not required by Directive 2000/76/EC). Especially when the waste stream contains significant amounts of metallic mercury emissions are more difficult to control, since removal of metallic mercury is more challenging compared to ionic mercury. The precise abatement performance and technique required will depend on the levels and distribution of mercury in the waste. Under certain conditions such as a high input rate of mercury, the removal capacity limits of a flue gas cleaning systems may be exceeded, leading to temporarily elevated mercury emissions. Some short-term high loads have been noted in municipal solid waste. These are generally associated with the presence of batteries, electrical switches, thermometers, laboratory wastes, etc.

At high enough chlorine content, mercury in the crude flue gas will be increasingly in the ionic form which can be deposited in wet scrubbers. Volatile mercury compounds, such as $HgCl_2$, will condense when flue-gas is cooled, and dissolve in the scrubber effluent. To maintain scrubbing efficiency and prevent clogging in the wet scrubber system, a portion of the scrubber liquor must be removed from the circuit as waste water. This waste water must be subjected to special treatment (neutralisation, precipitation of heavy metals), before discharge or use internally.

Many waste streams contain relatively high amounts of mercury in metallic form, and therefore generally require adsorption by the use of carbon based reagents to achieve the emission levels, or alternatively by transformation into ionic mercury by adding oxidants that are subsequently deposited in the wet scrubber. Injected activated carbon is filtered from the gas flow using bag filters, and when saturated, the used activated carbon is often landfilled as hazardous waste. However, saturated active carbon is sometimes burnt in the incinerator in order to further remove dioxins (PCDD/F), what might lead to re-circulation of metallic mercury.

Landfill
According to recital 8 of Directive 1999/31/EC on the landfill of waste, both the quantity and hazardous nature of waste intended for landfill should be reduced where appropriate. This can only be achieved by proper collection. Mercury measuring devices that end up in landfills will result in emissions to air, soil and water.

Certain general requirements for landfills in respect to location, water control, leachate management, bottom and surface sealing and stability can to a certain extent limit the release rate for mercury emissions from landfills. Due to its properties it is nevertheless likely that in the course of time the mercury will be slowly emitted to the environment.

B.4.2 Mercury emissions from measuring devices using mercury

Around 5-15 tonnes of mercury is annually purchased by laboratories to be used with porosimeters, pycnometers, devices using mercury electrodes in voltammetry and metering devices for determining the softening point. These devices do not contain mercury, but mercury is used during the measurements and consequently the devices need to be refilled with mercury regularly. The estimated amount of mercury purchased for the use with measuring devices is presented in Table 6. It is stressed that these amounts are not comparable to the amounts placed on the market in mercury containing measuring devices (Table 5). Below, it is explained how the amounts in Table 6 as well as other parameters, are used to describe the mercury cycle related to these measurements.

Table 6: The amount of mercury estimated to be purchased in the EU to be used with measuring devices in 2010

Measuring devices <u>using</u> mercury	**Amount of Hg purchased to be used in the measurement (t/y)**
Mercury electrodes (used in voltammetry)	0.1-0.5
Metering devices for the softening point determination	not available
Mercury probes used for capacitance-voltage determinations	0.001-0.005
Porosimeters	5-14
Pycnometers	not available
Total	**5-15**

Source: Lassen et al. (2008), device specific Annexes 6-10[26]

The devices described in this section use mercury as ‘an analytical chemical’ for their functioning. They have to be filled with mercury regularly and mercury is not an integral part of these measuring devices. Without rigorous risk management measures and use conditions, mercury emissions and exposure of workers and environment

[26] The estimates for some of the measuring devices have been updated based on the information gathered in the stakeholder consultation, and consequently may differ from what is reported e.g. in the Lassen et al. (20008).

occur when carrying out measurements with porosimeters and similar devices, when handling the used mercury (including its regeneration or purification for reuse) and as a result of handling of mercury contaminated waste. Therefore, risk management measures and operational conditions recommended by the producers of the devices and reported to be used by the laboratories performing the measurements are used to qualitatively describe the minimisation of releases.

There is no single parameter to describe the potential release and exposure from the measuring devices using mercury. Therefore, several parameters are used in device specific annexes. The amount of mercury purchased by the users is used to describe the flow of mercury between the users and the suppliers of mercury (including companies offering regeneration or purification services).

As the same mercury can be used several times (after in-house or outsourced regeneration or purification) the amount of mercury used annually in the measurements is reported to describe the magnitude of the mercury involved in the use phase of devices. The available information suggests that the emissions to the environment during the use phase are likely to be low. The same applies to exposure of workers. It is stressed that the laboratories concerned will have to ensure that the newly established occupational exposure limit value for mercury and the requirements of hazardous waste legislation will be complied with (see section B.5).

The amount of mercury containing waste disposed of annually is estimated where possible. These amounts are considerably lower than the amount purchased by the users. This is because the purchased amount includes also mercury purified and regenerated by specialised companies and resold to the users. The available information (see Annex 7, and Lassen et al. 2010), suggests that compliance with the hazardous waste legislation is considerably higher for devices using mercury than for devices containing mercury. The main reason for this difference in compliance would be that handling of mercury and mercury waste is part of normal use of porosimeters and other similar devices. Consequently the standard operation procedures of laboratories performing measurements with these devices should cover treatment of mercury containing wastes.

It is stressed that the main focus of this BD is on the assessment of technical and economic feasibility of alternatives. The potential releases and exposures are described primarily to illustrate the risk reduction capacity of the restriction options. Although the releases and exposures related to the use of mercury with these four types of measuring devices appear to be relatively low, it is stressed that the objective expressed in the Community mercury strategy to reduce the entry into circulation of mercury into society still applies. Consequently the use of mercury with the remaining measuring devices should be phased out as soon as technically and economically feasible alternatives are available.

B.5 Summary of existing legal requirements and their effectiveness

Several existing pieces of legislation aim to reduce or control risks arising from chemicals in their different life-cycle phases. In the following sections the effectiveness of this legislation to specifically address the concerns with mercury in measuring devices is assessed.

Waste legislation

Mercury-containing measuring devices are classified as dangerous according to the European List of Waste (Commission Decision 2000/532/EC)[27], and should be handled according to the rules under Directive 91/689/EEC on hazardous waste (the directive was repealed by the Waste Framework Directive 2008/98/EC with effect from 12 December 2010). These rules in both the old and new framework, relate to amongst others a ban for mixing hazardous waste with other waste streams and record keeping and permit requirements for waste treatment establishments.

Landfill of mercury containing waste has to be dealt with according to the requirements for the ‘hazardous waste’ class in Directive 1999/31/EC on the landfill of waste, and according to the acceptance criteria for landfills in Decision 2003/33/EC. Some specific rules for mercury waste are laid down in Regulation No 1102/2008. The Regulation contains rules on the safe storage of metallic mercury. Until special requirements and acceptance criteria are adopted under a Comitology procedure, only temporary above-ground storage is permitted. The concern is that eventually mercury in landfills may slowly be remobilised over time (UNEP, 2008b). These concerns for remobilisation are in particular related to the indefinite persistence of mercury, but also to the liquid status of mercury, high vapour pressure, and solubility in water. Storage in salt mines, and storage in deep underground, hard rock formations are under assessment as options for final disposal.

Mercury in measuring devices that are not collected separately and are received in landfills for non-hazardous waste or for inert waste, will not be sufficiently contained. Certain general requirements for landfills in respect to location, water control, leachate management, bottom and surface sealing and stability do exist, and can to a certain extent abate mercury emissions from these landfills, although it is likely that eventually a significant proportion of the mercury slowly will be emitted - if not all in the course of time.

Similarly, mercury in measuring devices that are not collected properly and are incinerated, will lead to significant emissions. Nevertheless, according to the waste incineration Directive (Directive 2000/76/EC) both hazardous as non-hazardous waste incineration has to satisfy an air emission limit value of 0.05 Hg mg/m^3 [28], and an emission limit value for mercury and its compounds in discharges of waste water of 0,03 mg/l (from the cleaning of exhaust gases). However, in contrast to continuous monitoring of dust, HCl, SO_2, CO, C_xH_y, NO_x, and HF, the waste incineration Directive only requires a minimum of two measurements each year for mercury compounds. Local authorities can require more frequent measurements, and in some Member States, such as Austria and Germany, continuous monitoring is required.

Despite these legal provisions, in particular because of low separate collection rates of mercury containing measuring devices, significant emissions occur in the waste phase

[27] Code “20 01 21* fluorescent tubes and other mercury-containing waste”
[28] Average value over the sample period of a minimum of 30 minutes and a maximum of 8 hours

from all mercury containing measuring devices covered by this BD. The problems with regard to these emissions are described more in detail in the section B.4. It can be concluded that the risk management measures provided for in the waste legislation do not sufficiently address the concerns with mercury arising from the waste phase of mercury containing measuring devices. The efforts needed from the enforcement authorities to ensure that the existing requirements in the waste legislation are complied to are difficult to estimate and would vary between the Member States. However, taking into account the relatively high awareness with regard to the environmental and human health risks related to mercury (compared to many other hazardous wastes) and the fact that the requirements have been in place for a relatively long time it does not seem plausible to rely only on better enforcement of waste legislation to address the issue of placing new mercury measuring devices on the market.

With regard to measuring devices using mercury, the available information indicates that the hazardous waste legislation requirements are generally complied with to a substantially higher extent (see Annex 7 and Appendix 3).

Occupational health legislation

Several pieces of occupational health legislation are in place to manage the risks of the use of mercury in the working environment during the production of measuring devices containing mercury, filling of devices by the users, professional use of mercury with devices such as porosimeters, and during the treatment of mercury contaminated waste.

An 8-hour TWA for mercury and divalent inorganic mercury compounds of 0.02 mg/m^3 is included in the 3rd list of IOELVs[29] under the Chemical Agents at Work Directive (Directive 98/24/EC). Several Member States had already established national exposure limits before the Community-wide IOELV had been adopted (e.g., BE, IE, LT and UK). The IOELV will have to be implemented in all Member States by 18 December 2011 at the latest. The relevant biological monitoring techniques that complement the IOELV should be taken into account by MSs during health surveillance.

Finally, the Young People at Work Directive 94/33/EEC and the Pregnant Workers Directive 92/85/EEC apply to work with mercury (Repr. Cat. 2). They are targeted towards protection of vulnerable populations.

Although occupational health legislation has a crucial role to play in avoiding occupational exposure from mercury in general, measures such as IOELVs are not effective in preventing or reducing exposure resulting from certain events related to the measuring devices containing mercury, such as accidental breakage, spillage or leakage. With regard to measuring devices using mercury, based on available information, there are no reasons to assume that the newly established occupational exposure limits for mercury would be insufficient to protect workers.

[29] List of Indicative Occupational Exposure Limit Values established by the Commission Directive 2009/161/EU of 17 December 2009

Legislation controlling emissions to the environment during production

Production of mercury containing measuring devices does not seem to be covered by Community legislation specifically setting limits on mercury emissions to air or water. Production does not seem to be covered by the IPPC Directive (Directive 2008/1/EC) or the Council Directive 84/156/EEC on limit values and quality objectives for mercury discharges by sectors other than the chlor-alkali electrolysis industry.

Medical devices directive

Sphygmomanometers and strain gauges fall under the scope of the medical devices directive (Directive 93/42/EEC concerning medical devices). The directive foresees that devices must meet a series of "essential requirements", such as for example a requirement to be designed and manufactured in such a way as to reduce to a minimum the risks posed by substances leaking from the device. However the existence of these requirements has not prevented that breakage and leakage still occurs in real-life, with emission, exposure and costs associated with cleaning the spills as consequences.

National restrictions

Denmark, The Netherlands, Norway and Sweden have national restrictions on mercury in measuring devices. The following provides an overview of the information received from these Member States and Norway. An effort is made to summarise the elements of importance for mercury in measuring devices. For the full description of the restrictions, the national legislation should be consulted. The metering devices for the softening point determination are not mentioned in the national restrictions.

<u>Denmark</u>

Denmark prohibits import, sale and export of mercury and mercury-containing products. The Danish restriction entered into force in 1994, was expanded in 1998 and 2003, was prolonged in 2008, and subsequently has been amended to take into account the entries 18 and 18a of Annex XVII to the REACH regulation. The legislation foresees a possibility for the Danish EPA to allow derogations, but according to information received from the Danish EPA this possibility has never been put to practise. The legislation foresees a list of exemptions to the general ban that are relevant to mercury measuring devices.

Thermometers for special applications, i.e. calibration of other thermometers and analysis equipment are exempted. According to the Danish EPA, in practise this can be translated to an exemption of thermometers for laboratory use. Manometers for calibration of other pressure gauges, barometers for calibration of other barometers, products for research, products for teaching, and products for the repair of existing mercury-containing equipment are exempted as well. Also an exemption is foreseen for ‘mercury-containing chemicals for special applications’. According to the Danish EPA, mercury-intrusion porosimetry would, depending on the actual use, fall under one of the exemptions to the restriction.

The Danish EPA reported not to have experienced any particular problems introducing the national restriction.

The Netherlands

The Netherlands restrict production and import of mercury containing products since 1 January 2000. Possession of a product containing mercury or use for trading (2nd hand market) or production purposes is restricted since 1 January 2003 (unless it was already in use before that date). The restriction is not applicable to antiques (>100 years old).
The restriction does not apply to pycnometers or porosimeters, a McLeod compression manometer meant for measuring absolute pressures lower than 20kPa, thermometers exclusively intended to perform specific analytical tests according to established standards, equipment for the calibration of platinum resistance thermometers using the triple point of mercury (the Netherlands would have only one such device).

Norway

The sale of mercury thermometers is prohibited in Norway since 1 October 1998. Thermometers for professional use for meteorological, hydrological and oceanographical measurements and for control measurements and calibrations in laboratories were exempted until 1 January 2001.

Since 1 January 2008 there is a prohibition to manufacture, import, export and sell compounds and articles containing mercury. It is also prohibited to use compounds containing mercury. The restrictions do not apply to analysis and research purposes, but mercury thermometers for analysis and research purposes are specified not to be exempted from the prohibition, and polarographs are said to be exempted for analysis and research purposes only until 31 December 2010. According to information received from the Norwegian Climate and Pollution Agency (Klif), mercury used with porosimeters would fall under ‘analysis and research’, and thus is not restricted in Norway. Import and sales are however forbidden. Suppliers have to apply for an exemption in order to place mercury on the market for analysis and research.

Exemptions can be granted to the prohibitions. The most common cases with exemptions to buy mercury thermometers are for the following:

- Analyses according to ASTM[30] in cases where mercury thermometers are specified;
- Calibration thermometers (where very high precision is essential);

[30] ASTM International is one of the main standardisation organisations, see also section 3.3 of Annex 5a.

- Maximum thermometers to be placed inside older autoclaves (without thermo-couples). The applicants claim that data loggers cannot stand the high temperatures.

According to Klif, Norway has received only very few such applications during the last few years, less than ten a year. All ASTM standards referred to concerned testing of oil products (pour point, flash point open cup and closed cup, and possibly also cloud point were thought to be amongst these standards).

Sweden

Sweden prohibits the placing on the market, use and export of mercury and chemical compounds and mixtures containing mercury. It is prohibited to place on the market or to export goods containing mercury. The Swedish Chemicals Agency (KemI) may issue regulations to derogate from the general restriction, and in addition can grant exemptions in individual cases. The original version of the restriction dates from 1991. In what follows is described how the Swedish mercury restriction affects individual mercury measuring devices (based on information received from KemI).

Thermometers

In Sweden, the production, sale and export of mercury thermometers is restricted since 1993. The granted exemptions concerning mercury containing thermometers are:

- Use for flash point determination according to standard method ASTM D93 (granted in 2006, expired);
- Import of two thermometers ASTM D97, which were then exported to be used according to 2381 Cloudpoint (granted in 2007, expired);
- Export of 10 thermometers to be used for flash point determination according to dir. 67/548/EEG (granted in 2007, expired);
- Export of thermometers to be used for flash point determination according to dir. 67/548/EEG (granted in 2007, will expire 30 June-2011).

KemI is not aware of any other problems to replace mercury containing thermometers and is not aware of particularly high costs when replacing them.

Porosimeters

The Swedish restriction applies to mercury containing devices as well as devices that make use of mercury. Until end of year 1995 there was an exemption to import, to manufacture and to place porosimeters on the market. According to an investigation made by a consultant 2004, commissioned by KemI, feasible alternative technology for pore sizes exceeding 2000 Å (0.2 µm) was not available at that time. There are further two exemptions granted in 2006 for two porosimeters sold to a company and to a university respectively. The intended uses were pore sizes exceeding 1000 Å mainly for research and development.

Strain gauges

The translation of the current exemption for strain gauges (2007) reads:

> "*The applicant may manufacture and sell up to 150 mercury containing strain gauges each year and these must be used in already existing equipment*

- to measure blood flow in a muscle within clinical routine activities up to 2010-12-31
- for other uses within clinical routine activities up to 2009-12-31
- for research and development up to 2012-12-31 given that the project started prior to 2007-12-31. If the research concerns blood flow in a muscle the project may start not later than 2010-12-31.
- to validate mercury free alternatives up to 2010-12-31.

The applicant has the duty to keep records on the uses."

Manometers
KemI reports that there have not been any applications for exemptions to the restriction from 2005 up to now. As far as they are aware of, there have been no applications for exemption before 2005 either.

B.6 Summary of hazard and risk

Mercury and its compounds are highly toxic to humans, ecosystems and wildlife, with amongst others serious chronic irreversible adverse neurotoxic and neurodevelop-mental 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 identyfied for methylmercury.

It is estimated that 3.5 to 7.6 tonnes of mercury is placed on the market in mercury containing measuring devices in 2010 (see Table 7). These amounts are used to describe the maximum potential for mercury emissions to the environment that might ultimately occur. This is considered appropriate for the purpose of this BD as the low separate collection rate and resulting inadequate waste treatment of a substantial part of the devices, leads in the long term to a relatively high share of mercury used in these devices being released to the environment. Although not the primary concern, it is worth mentioning that direct exposure of workers can occur during production, professional/industrial use of the devices and during waste management operations.

Table 7: The amount of mercury estimated to be placed on the market in the EU in mercury containing measuring devices in 2010

Measuring device containing mercury	**Amount of Hg placed on the market in the EU in 2010 (t/y)**
Barometers	0.1-0.5
Manometers (including tensiometers)	0.04-0.4
Sphygmomanometers	2.6-5.1
Strain gauges (used with plethysmographs)	0.014
Thermometers (including hygrometers)	0.7-1.6
Total	**3.5-7.6**

Source: Lassen et al. (2008) as updated in device specific annexes 1 – 5.

In addition around 5-15 tonnes of mercury is supplied annually to be used with porosimeters, pycnometers, devices using mercury electrodes in voltammetry and metering devices for determining the softening point (see Table 8).

The annual amounts presented (in Tables 7 and 8) are not comparable. The figures in Table 8 are the amount of mercury the laboratories purchase and cannot be used to estimate maximum potential for emission as is the case in Table 7. 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. Furthermore, the available information indicates that the hazardous waste legislation requirements are generally complied with when handling the mercury contaminated waste generated during these measurements.

Table 8: The amount of mercury estimated to be purchased in the EU to be used with measuring devices in 2010

Measuring device using mercury	Amount of Hg purchased to be used for measurements (t/y)
Mercury electrodes (used in voltammetry)	0.1-0.5
Metering devices for the softening point determination	not available
Mercury probes used for capacitance-voltage determinations	0.001-0.005
Porosimeters	5-14
Pycnometers	not available
Total	**5-15**

Source: Lassen et al. (2008), device specific annexes 6-10

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.

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.

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.

C. Available information on the alternatives

As explained in the Preface, a deviation from the reporting format is made to improve the flow and readability of the text as several different measuring devices are assessed in this BD. In this general part C, information on risks related to alternatives that is relevant for all devices is reported. In addition, information on technical and economic feasibility from the Annexes 1-10 is summarised.

It is reminded that the emphasis lays on the identification of potential alternative substances and techniques, and their technical and economic feasibility.

C.1 Identification of potential alternative substances and techniques

Potential alternatives have been identified for all devices and are described in Annexes 1-10.

C.2 Human health and environment risks related to alternatives

C.2.1. Measuring devices containing mercury -Comparison of risks posed by mercury devices and their alternatives

In the following, a semi-quantitative comparison of the risks of alternatives compared to measuring devices containing mercury is made for each stage in the life-cycle. The potential for risk is described with semi-quantitative indicator scores ranging from 1 to 4.[31]

Alternative liquids

Alternative liquids used in thermometers are ethanol (ethyl alcohol), methanol, pentane, pentanol, toluene, kerosene, creosote, petroleum, i-amyl benzoate (isoamyl benzoate or isopentyl benzoate), and 'citrus-extract-based solvents' (see section 3.1 of Annex 5a). The market share of these alternatives is unknown, and this information seems not to be readily available. From a product catalogue it appears that the choice of liquid depends in the case of thermometers amongst others on the lower and upper limits of temperature measurement and that many liquids are to a certain extent interchangeable (see section 3.1 of Annex 5a).

For barometers 'a red silicone fluid' is used, but other liquids might be used as well. Alternative liquids in use for manometers are most commonly water or alcohols.

There might be some direct human exposures and release to the environment arising from the *production phase* of organic liquid filled thermometers, barometers, and manometers, from filling barometers or manometers by the end-users, or from the *use phase* (breakage). Since many of the liquids are volatile, such exposure would be

[31] 1 = negligible risk potential; 2 = low risk potential; 3 = moderate risk potential; and 4 = high risk potential.

similar to mercury in terms of route of exposure and exposure levels, but would for most liquids be in comparison insignificant on the basis of intrinsic properties (e.g. ethanol). Most liquids could thus be scored 1. For creosote (classified as carcinogen cat. 1B according to Annex VI to the CLP Regulation), and possibly some other alternative liquids it suffices to say that the risks might in the worst case be of a comparable order to mercury (both creosote and mercury could be scored 3). Note that creosote seems only to be used as an alternative liquid in thermometers, and represents only a fraction of the alternatives used to replace mercury thermometers. On the whole, replacing mercury containing measuring devices with the spectrum of alternatives, clearly results in a reduction of risk. Overall, the production and use phase of the alternatives is scored as a range of 1-2, in order to reflect that the risk potential will depend on the share of each liquid that replaces mercury (the score of 2 would be conservative, acknowledging that the share of ethanol and other alcohols are many times higher than creosote).

As described in section B.4, the main risk of the use of mercury in measuring devices is related to the *waste phase* and the persistency of mercury as an element. There is no legal requirement to separately collect devices with alternative liquids, and thus these devices will go to either municipal waste incineration or landfill. In contrast to mercury devices, the share of devices filled with organic liquids that is incinerated does not cause risks to the environment (the organic substances are entirely oxidised). Thus, a score of 1 could be attributed for the share of liquids that are incinerated.

When diverted to landfill, substances such as ethanol and pentane are not considered to pose environmental risks in the waste phase since they are readily biodegradable (EU RAR n-pentane, 2003) (EC JRC, 2000a). Also, pentanol quickly degrades (EC JRC, 2000b). Such substances are given a score of 1. Substances such as kerosene, creosote and petroleum, might degrade slower when landfilled or released to the environment (to air or as leachate), but still much faster than mercury (which is an element). These specific substances could be accorded a scoring of 3. In order to reflect the dependence on the share of each liquid that replaces mercury, an overall score of 1-2 could be attributed to landfilling of the alternatives.

The use of water as an alternative liquid in manometers poses no risks (score 1 for all life-cycle stages).

One of the several alternatives to mercury strain gauges are strain gauges containing gallium-indium alloys. Annex 4 describes the comparably low to negligible risks related to the use of gallium and indium in strain gauges for plethysmography[32].

[32] Gallium is also used in some thermometers, but as explained in Annex 5a, these thermometers are currently only used for niche-applications. Gallium thermometers are not considered a direct replacement of mercury thermometers for economical reasons, and it seems likely so also for technical reasons (such as precision and wetting of glass).

Electronic alternatives

Background

Electronic alternatives (electronic thermometers, sphygmomanometers, barometers, manometers and strain gauges) to mercury measuring devices would contribute with a very small fraction to the overall volume of Waste Electrical and Electronic Equipment (WEEE)[33]. All WEEE or 'e-waste' can contain small amounts of heavy metals, flame retardants, phthalates, and other substances with hazardous properties. Especially the very large volumes of e-waste in society makes the presence of these small amounts of hazardous substances significant, and causes e-waste to be of concern to the environment and human health.

RoHS[34] and WEEE[35] Directives are a pair of legislation working in synergy, essentially to overcome emissions from hazardous substances present in e-waste.

The RoHS Directive restricts currently the presence of lead, mercury, cadmium, hexavalent chromium, polybrominated biphenyls (PBB) and polybrominated diphenyl ethers (PBDE) in new electrical and electronic equipment put on the market[36]. However, it currently does not (yet) cover the categories 'monitoring and control instruments'[37] and 'medical devices'[38]. The proposed RoHS recast[39] includes the above mentioned currently omitted category in its scope, and consequently also electronic alternatives to mercury measuring devices would be covered by the RoHS Directive in the future. The European Parliament voted in the first reading on 3 February 2011 and the council reached Political Agreement on 14 March 2011. Both support inclusion of the two categories in the scope of RoHS.

The WEEE Directive provides for the creation of collection schemes, thus preventing electronic waste ending up in unsorted municipal waste. The collection requirements are applicable to the categories 'monitoring and control instruments' and 'medical devices'.

Comparison of exposure and release between mercury containing devices and their alternatives

[33] A small fraction of the category 'monitoring and control instruments', which itself is estimated to be 0.2% of the 8.3 - 9.1 million tonnes e-waste produced in 2005 (http://ec.europa.eu/environment/waste/weee/pdf/final_rep_unu.pdf)

[34] Directive 2002/95/EC on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS).

[35] Directive 2002/96/EC on waste electrical and electronic equipment (WEEE).

[36] The concentration limit for the restriction is 0.1% by weight, with the exception of cadmium where a 0.01% by weight in homogeneous materials shall be tolerated.

[37] Directive 2002/96/EC mentions under 'monitoring and control instruments': smoke detectors; heating regulators; thermostats; measuring, weighing or adjusting appliances for household or as laboratory equipment; and other monitoring and control instruments used in industrial installations (e.g. in control panels).

[38] Directive 2002/96/EC mentions under 'medical devices': radiotherapy equipment; cardiology; dialysis; pulmonary ventilators; nuclear medicine; laboratory equipment for in-vitro diagnosis; analysers; freezers; fertilization tests; and other appliances for detecting, preventing, monitoring, treating, alleviating illness, injury or disability.

[39] Proposal for a Directive of the European Parliament and of the Council on the restriction of the use of certain hazardous substances in electrical and electronic equipment (recast), COM(2008) 809 final.

It is difficult to make an assessment of the risk potential of the production of electronic alternatives. Both in the production of mercury containing measuring devices and the electronic alternatives, occupational health legislation has to be complied with. Production of semi-conductor parts of electronic alternatives occurs under 'clean room' conditions, however environmental releases might occur. In the production of plastics, substances might be used, potentially in less controlled conditions than in the semi-conductor industry. It can be concluded that during production of both mercury containing measuring devices and their electronic alternatives, exposure of workers and release to the environment can occur. Notably, mercury devices such as manometers and barometers have to be filled with mercury by the customer before use, which entails occupational exposure of a concern that is not comparable to exposures or releases during the production of electronic alternatives. A scoring of 1-2 is attributed to the production stage of electronic alternatives and 3 to mercury devices.

Importantly, during the service-life of the mercury measuring devices, breakage of devices and normal maintenance leads to release to the environment and exposure of workers to the highly toxic and volatile elemental mercury. No comparable exposure or release exists during the service-life of electronic alternatives, and thus professional exposure and environmental releases are comparably negligible. The scoring of the service-life is therefore 1 for the electronic alternatives, and 3 for mercury devices.

Similarly to mercury measuring devices, the main concern of electronic goods are risks related to the waste stage. At the end of service-life, both electronic alternatives and mercury devices legally have to be collected separately, and for both compliance with the legal requirement is poor[40]. Poor compliance has an important detrimental effect on the level of control in the subsequent waste treatment, and the principal risks arise from the fractions that are not collected separately.

There are however a number of important differences between electronic alternatives and mercury devices to be noted:

- Amounts
  Most importantly, the amounts of hazardous substances per electronic alternative are comparably negligible to mercury containing measuring devices where the mercury content is several gram per device or much higher. This consideration is important in each life-cycle step.
- Collection, transport and pre-treatment
  In the course of collection, transport and pre-treatment[41] of mercury measuring devices and the resulting breakage, some mercury will be released to the air. No similar releases of hazardous substances exist during such activities carried out with waste electronic alternatives.

[40] According to the Commission "*only one third of electrical and electronic waste in the European Union is reported as separately collected and appropriately treated. A part of the other two thirds is potentially still going to landfills and to sub-standard treatment sites in or outside the European Union.*" (DG ENV website http://ec.europa.eu/environment/waste/weee/index_en.htm, retrieved on 26 August 2010.). Concerning the collection of mercury devices, see part B.4.

[41] Pre-treatment is understood as mixing, shredding, and sorting activities that are typically carried out on municipal wastes before it is landfilled or incinerated.

For these reasons, a score of 1 can be attributed to the share of electronic alternatives that are collected separately and are subsequently treated properly, whereas mercury devices that are collected separately would be attributed a score of 3.

For both mercury devices and their alternatives, the fractions that are *not* collected separately, can go to landfills for non-hazardous waste or incineration plants for non-hazardous waste. Again, there are a number of important differences to be noted:

- Landfill
  As a result of landfill activities (spreading, compacting, etc.) and the destructive pre-treatment (see previous indent) most devices will be present in broken state in the landfill, thus allowing a large volume of uncontained liquid mercury per device to evaporate or leach out of landfills. In contrast, the small amounts of hazardous substances present per waste electronic alternative device are generally not liquid or volatile, are bound in the matrix of the device, or otherwise relatively well contained, and are thus released and leaching out only very slowly. A score of 2 is attributed to landfill of electronic alternatives, and a score of 4 to mercury devices.
- Incineration
  During incineration in plants for non-hazardous waste, from both mercury devices as from their electronic alternatives emission to air and water occurs. Here again, the quantities of hazardous substances emitted from the waste electronic alternatives is low in comparison with mercury devices. A score of 2 is attributed to incineration of electronic alternatives, and a score of 4 to mercury devices.

Mechanical alternatives

Mechanical alternatives (aneroid sphygmomanometers, aneroid barometers, aneroid manometers and bi-metal dial thermometers) have a composition similar to any other everyday article. According to product catalogues, materials used for these articles are plastics (PC, Polyamide, TP-Elastomer, PMMA, etc.), metals (stainless steel, galvanized steel, aluminium, anodized aluminium, brass, nickel-plated metal, copper-beryllium-alloy, bronze, NiFe-alloy, etc.), coatings, glass, silicone, and other common materials (Ludwig Schneider, 2010; Omega, 2010; Trerice, 2010; WIKA, 2010; Palmer Wahl, 2010; Jumo, 2010; ARMATURENBAU, 2010; Wittich & Visser, 2010; HEINE Optotechnik, 2010). As a consequence, and especially in comparison with mercury containing measuring devices, there are no known notable risks related to these devices (score 1 for all life-cycle stages).

Table 9 gives an overview of the potential for risk by means of semi-quantitative indicator scores. The overview makes clear that the risks of every alternative type is lower than mercury containing measuring devices in all life-cycle stages.

Table 9 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****		

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

C.2.2 Measuring devices using mercury

Gas pycnometers use an inert gas such as helium or nitrogen to measure the replacement volume. The alternative methods to mercury metering devices for the softening point determination use water or glycerol, mechanical and/or electronic parts. No significant risks have been identified related to the use of these alternatives.

There are several potential alternative methods to mercury porosimetry, mercury probes and to mercury electrodes used in voltammetry. Since technical feasibility could not be established, the risks of all potential techniques have not been assessed in great detail. Some alternative methods make use of liquids (such as water, hexane, gallium and indium) or gas (such as nitrogen, argon, krypton and CO_2). Use of some other methods, such as X-Ray Tomography, might present a higher risk than methods using gas or liquids.

More information on alternatives can be found in Annexes 6 to 10.

C.3 Technical feasibility of alternatives

According to Annexes 1-10, technically feasible alternatives are available for mercury barometers, 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[42].

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

[42] 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.

determinations, none of the alternatives are both technically and economically feasible.

C.4 Economic feasibility

According to Annexes 1-10, economically feasible alternatives are available for mercury barometers, manometers, sphygmomanometers, strain gauges, thermometers, pycnometers and metering devices.

For mercury porosimeters and devices using mercury electrodes in voltammetry, the technical feasibility of alternatives could not be established and thus the economic feasibility was not fully assessed. For mercury probes used for capacitance-voltage determinations, none of the alternatives are both technically and economically feasible.

D. Justification for action on a Community-wide basis

As stated in part B of this report the need to consider the extension of the current restriction on mercury in measuring devices at Community level was already established in Directive 2007/51/EC.

D.1 Considerations related to human health and environmental risks

As explained in section B, the hazard properties of mercury and its transformation products are widely recognized. It is difficult for any Member State to act alone to effectively protect its environment or its population from mercury exposure, because the human health and environmental problem related to mercury is cross boundary. This is also well recognised by the Community mercury strategy and by the activities of UNEP and regional organisations.

As reported in Section B.4 mercury measuring devices are used throughout the EU, although some Member States have already established national restrictions (see section B.5). Consequently, the mercury emissions originating from the entire life cycle of measuring devices, and in particular their waste stage, take place in most of the Member States, even though the amount of emissions in different parts of the EU varies depending on the amounts of devices used and disposed of, and on the waste management practices.

Therefore, the risks need to be controlled on a Community-wide basis.

D.2 Considerations related to internal market

The proposed restrictions cover devices that are extensively traded among and used in all Member States most of which have not established national restrictions. The devices containing mercury are both produced in and imported to the EU as reported in Annexes 1 to 10. The justification to act on a Community-wide basis stems from the fact that the goods need to circulate freely within the EU. The proposed restriction would remove the potentially distorting effect that current national restrictions may have on the free circulation of goods. The second justification is that regulating mercury through Community-wide action ensures that the producers of the devices in different Member States are treated in an equitable manner. Furthermore, acting at Community level would ensure a ‘level playing field’ among all producers and importers of the devices.

D.3 Other considerations

The Community is currently promoting measures at international level[43] that aim to address human health and environmental problems relating to mercury (see section B.2). Mercury is both a regional and a worldwide problem. Therefore, acting at Community level strengthens the Community's and its Member States' possibilities to cooperate constructively with other countries and relevant institutions.

D.4 Summary

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 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 of policymakers to address the adverse impacts of mercury at worldwide level.

[43] For instance, the Community is active in the United Nation's Environment Programme's Mercury Programme (see http://www.chem.unep.ch/mercury/).

E. Justification why the proposed restriction is the most appropriate Community-wide measure

As explained in the Preface, a deviation from the reporting format is made to improve the flow of the restriction report as several different measuring devices are assessed in one report. In this general part E, a summary of the justifications why the proposed restrictions are the most appropriate Community-wide measure is reported. It starts with an overview of the assessment of the proposed restrictions against their effectiveness, practicality and monitorability. This is followed by device specific summaries for the proposed restrictions as well as summaries for justifications for not proposing restrictions for certain devices. Finally, the justification for derogations and conditions common for all devices are provided.

The details of the assessment are provided in device specific Annexes 1 to 10.

Summary of the assessment of the proposed restrictions

While the major part of the assessment of the options and reasons for proposals can be found in the device specific annexes, some common issues and a summary are discussed below.[44]

The main purpose of <u>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</u>. While the main benefits of these restriction proposals result from the prevention of mercury from entering the waste stream, the proposed restrictions on the placing on the market would also result in additional other benefits related to reduction of possible exposure of workers during production and use of the devices. There may be also some further co-benefits (e.g. during waste handling).

Based on the review clause in the existing restriction on mercury in measuring devices, the justification for proposing further restrictions focuses on the technical and economic feasibility of the alternatives. The costs of avoiding mercury in euros per kilogramme (€/kg Hg) are presented to assess and conclude on the proportionality of the restriction options, when data exist to allow such estimation. For the purposes of this restriction report a literature review has been carried out of the compliance and other costs, as well as human health benefits of regulating mercury. This review has been used to support the assessment of the proportionality of restriction options. For details, see Appendix 2.

[44] Note that it has not been considered appropriate to make a distinction between professional and industrial users for assessing possible restrictions on mercury measuring devices in this report. Nevertheless, the typical groups of users are described in the device specific annexes.

Assessment of effectiveness

For the reasons mentioned in section B.2, a quantitative exposure assessment or risk characterisation was not carried out in this BD. Instead, the total estimated amount of mercury placed on the market in measuring devices containing mercury is used to describe the maximum potential for mercury *emissions to the environment* that might ultimately occur. The proposed restriction is estimated 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[45]. 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.

It is recognised that the time when the restriction becomes effective depends on the decision making process and the transitional periods after the decision is taken by the Commission. For the purpose of the risk reduction capacity and cost calculations of this report it is assumed that the restrictions would apply from the beginning of 2015.

The temporal scope of the analysis was selected in the following manner. Taking into account the uncertainties related to the available data and the assumed declining trend in the number of mercury devices placed on the market, 20 years scope is regarded appropriate. As the average lifetime of mercury containing devices is around 10 years in most applications, the restriction would have its full effect 10 years after adoption, i.e. in 2024, when all the existing mercury containing devices would be replaced. Thus, year 2024 was selected as a representative year to illustrate annualised impacts.

Table 10 gives details of the amount of mercury that is estimated not to be placed on the market in the EU as a result of the proposed restriction. Both the representative year (2024) and the total effect of the 20 years (i.e. 2015-2034) are presented.

Table 10: 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**

Source: Derived from Annexes 1-10

Notes: * Number of the mercury containing devices projected to decline by 5% per annum as described in the device specific annexes 3a and 5a

[45] 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.

** 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.

The compliance costs of the proposed restrictions are estimated to be €13.3 million in 2024, or cumulatively €129 million for 2015-2034 (Table 11). The compliance costs for barometers, manometers, metering devices, pycnometers and strain gauges are not (fully) quantified. Nevertheless, in the case of barometers and manometers the qualitative evidence strongly suggests that the alternatives to mercury devices cost the same as mercury devices. In other words, the additional cost is about €0 in this case. For metering devices and pycnometers no information was available on the costs of alternatives. However, there does not seem to be remaining markets for these devices in the EU and thus, costs would be close to €0.

Table 11: Estimated compliance costs of the proposed restriction in 2015-2034 as well as in 2024

Device	2024 per annum € million	2015-2034 cumulative € million
Sphygmomanometers	3.2	29
Thermometers *	9.0	97.4
Barometers	0	0
Manometers (including tensiometers)	0	0
Strain gauges	0.13	2.6
Pycnometers**	~0	~0
Metering devices**	~0	~0
Total	**12.3**	**129**

Source: Annexes 1-10
Note: * Labour time savings when using electronic alternatives are included in this figure, see Annex 5a and 5b.
** There does not seem to be remaining markets for these devices in the EU and thus, costs would be close to €0

As the environmental and human health impacts are not quantified, no further comparison between the benefits and costs of the proposal is possible. However, it was possible to quantify the reduction in the amount of mercury placed on the market in the EU as a result of the proposed restrictions. Based on these estimates the cost-effectiveness of the proposed restrictions is estimated. These are given in Table 12. Overall the cost-effectiveness of the proposed restriction is estimated to be €4,100/kg Hg but naturally there are variations between the different measuring devices.

Table 12: Estimated cost-effectiveness of the proposed restrictions

Device	Cost-effectiveness (€/kg)
Sphygmomanometers	1,300
Thermometers*	19,200**
Barometers	0
Manometers (including tensiometers)	0
Strain gauges	9,600
Pycnometers***	not available
Metering devices***	not available
Total*	**4,100**

Source: Annexes 1-10
Note: * Weighted average (kg of mercury used as the weight) excluding hygrometers
** Labour time savings when using electronic alternatives for industrial thermometers measuring temperatures above 200ºC are included in this figure, see Annex 5a and 5b.
*** There does not seem to be remaining markets for these devices in the EU

Assessment of practicality

All the device specific restriction proposals concern the placing on the market of the mercury included in or used with the measuring devices. No use or other conditions are proposed, even though for some devices they are assessed to some extent. In general, no problems related to the implementability and manageability of the proposed restriction were identified.

The enforcement of the placing on the market of the mercury measuring devices can be assessed mainly by inspecting producers, and by verifying if importers and distributors still supply mercury measuring devices.
However, enforceability of the proposed derogations in the restriction for thermometers might be more problematic (see Annex 5a).

Adding a concentration limit to the restriction proposal for devices containing mercury is not considered necessary since it is clear in the context of the restriction that metallic mercury or alloys of metallic mercury are used in closed columns. It is clearly not the purpose that enforcement authorities would verify if a device would contain in e.g. its plastic or glass parts a certain concentration below a threshold. As explained in the Annexes 1-5, visual inspection suffices to determine if mercury is used as a liquid in the column. The sole exception to this would be mercury dial thermometers that have a mercury filled metal bulb. In the latter case a non-destructive analytical method named X-ray fluorescence (XRF) can be used. See also the First Advice of the Forum on the enforceability of the proposed restriction on mercury measuring devices, adopted 19 November 2010. For the reasons mentioned above, it could even be considered confusing for the actors to introduce a concentration limit, and thus would reduce the clarity of the restriction proposal.

Assessment of monitorability

The monitoring of the restriction for all the devices will be done through enforcement and no additional monitoring is envisaged. Therefore, the monitorability of the restriction options for different measuring devices is not discussed further in the device specific Annexes. The current monitoring of environmental concentrations of mercury or methylmercury does not give information on the effectiveness of the existing restriction for mercury measuring devices and it is not feasible to target the monitoring to provide such information. This is because of the share of mercury measuring devices is only about 4% of the total amount of the mercury used in the EU. The share of measuring devices of the emissions caused by the intentional use in the EU is not known. Furthermore, there are mercury releases from other sources than intentional use in articles and processes (e.g. power plants).

Other community-wide measures than restriction

Other community-wide measures are not assessed in detail in the device specific annexes. This approach is taken as the review clause in the existing restriction asks for extension of the current restriction where technically and economically feasible alternatives are available.

Mercury is already covered by several pieces of Community legislation. On the basis of assessment described in Section B.5 (and B.4), the current legislation and in particular waste legislation is not sufficient to address the concerns related to placing on the market of *new* measuring devices containing mercury. In other words, action under waste legislation is considered not to be the most appropriate risk management option to address the concerns with placing on the market of *new* mercury measuring devices. Moreover, it should be noted that restriction is an important waste prevention instrument, thus satisfying the top priority in the waste hierarchy[46].

It is acknowledged that low separate collection of existing devices is of concern. Action to improve the separate collection rate of the *existing* mercury measuring devices in society that have reached the end of their service life could be undertaken as a separate and additional measure to the proposed restriction. Analysis of the possibilities for and appropriateness of such action is not in the remits of this BD, but can be considered by the Commission and Member States in the appropriate fora under e.g. the framework of waste legislation and the Community Strategy Concerning Mercury.

Based on available information, as described for instance in Box 1 of Annex 7 (Porosimeters) and in Appendix 3, with regard to measuring devices using mercury hazardous waste requirements appear to be complied with to a substantially higher extent. In addition, there are no indications that the newly established occupational exposure limits for mercury would be insufficient to protect the workers. Restriction options 2 and 3 in Annex 7 (Porosimeters) discuss the needs and possibilities to strengthen the compliance with the existing obligations under waste and occupational health legislation by introducing conditions in Annex XVII of REACH. However, such conditions are not proposed due to reasons given in Annex 7.

[46] 'prevention' means measures taken before a substance, material or product has become waste, that reduce: (a) the quantity of waste, including through the re-use of products or the extension of the life span of products; (b) the adverse impacts of the generated waste on the environment and human health; or (c) the content of harmful substances in materials and products (Dir 2008/98/EC).

The proposed restrictions and summary of the device specific justifications

<u>Measuring devices containing mercury</u>

- *<u>Barometers</u>*

Proposal: Restriction on the placing on the market of mercury barometers.

Justification: Technically feasible alternatives are available and electronic alternatives already dominate the market. The alternatives are available at approximately the same price as mercury barometers. Consequently restricting the placing on the market of mercury barometers would not introduce additional costs (cost-effectiveness is around €0 per kg Hg not placed on the market).

- *<u>Manometers (including tensiometers)</u>*

Proposal: Restriction on the placing on the market of mercury manometers and tensiometers.

Justification: Technically feasible alternatives are available and in use. The alternatives are available at approximately the same price as mercury manometers. Consequently restricting the placing on the market of mercury barometers would not introduce additional costs (cost-effectiveness is around €0 per kg Hg not placed on the market).

- *<u>Sphygmomanometers</u>*

Proposal: Restriction on the placing on the market of mercury sphygmomanometers with limited derogations for (i) on-going epidemiological studies and (ii) using mercury sphygmomanometers as reference standards in clinical validation studies of mercury-free sphygmomanometers.

Justification: Technically feasible alternatives are available with very limited exemptions based on the opinion of SCENIHR. Based on the assessment of compliance costs (in Annex 3b), the alternatives are also regarded as economically feasible. The cost of avoiding mercury (around €1300/kg Hg) is considered to be proportional.

- *<u>Strain gauges (used with plethysmographs)</u>*

Proposal: Restriction on the placing on the market of mercury strain gauges to be used with plethysmographs.

Justification: Technically feasible alternatives for mercury strain gauges used with plethysmographs are available. The alternatives are also economically feasible.

- *Thermometers (including hygrometers)*

Proposal: Restriction on the placing on the market of mercury thermometers and other non-electrical thermometric applications containing mercury with derogations for i) thermometers to perform specific analytical tests according to standards that require the use of a mercury thermometer (time-limited); and ii) mercury triple point cells that are used for the calibration of platinum resistance thermometers.

Justification: Technically feasible alternatives are available for all applications, with the exception of: thermometers used for testing according to analysis standards that prescribe mercury thermometers, because some time is needed to amend those standards; and mercury triple point cells because mercury is needed as a reference point in the 1990 International Temperature Scale. Economically feasible alternatives are available for all applications.

Measuring devices using mercury

- *Mercury electrodes (used in voltammetry)*

Proposal: No restriction.

Justification: Technically feasible alternatives are not available in all applications. The technical limitations are related, for instance, to mobility and sensitivity of the alternative devices and to the parameters measured. In addition, two main alternatives seem not to be economically feasible due to higher price and recurrent costs and requirements on the laboratory infrastructure.

- *Metering devices for determination of softening point*

Proposal: Restriction on the placing on the market of metering devices for determination of softening point.

Justification: Technically feasible alternatives are available and they seem to dominate the market. No information has been found indicating that the alternatives would be economically infeasible.

- *Porosimeters*

Proposal: No restriction.

Justification: Technical feasibility of the alternatives could not be established under the framework of this report. The alternatives may not be feasible for the users as they do not measure exactly the same parameters. The comparability of the measurement results is difficult to be assessed. In addition the applicability of the alternatives is limited in terms of pore sizes covered and the type of sample (e.g. applicable only to hydrophobic samples). Assessment of technical feasibility is complicated by the fact that porosimeters are used in several application areas which all have their own technical features. As the technical feasibility could not be established, the economical feasibility was not assessed in details. In addition, waste management of mercury and mercury contaminated samples and other materials is part of the normal operation of the laboratories performing measurements with these devices. The reported practices in laboratories appear to support the view that the waste handling of mercury used in the measurements would be conducted in accordance to the requirements of the hazardous waste legislation (see Annex 7 and Appendix 3).

- *Pycnometers*

Proposal: Restriction on the placing on the market of mercury pycnometers.

Justification: Technically feasible alternatives are available and they seem to dominate the market. No information has been found indicating that the alternatives would be economically infeasible.

- *Mercury probes used for capacitance-voltage determinations*

Proposal: No restriction

Justification: None of the alternatives for mercury probes used in capacitance-voltage or current-voltage measurements are both technically and economically feasible. This is mainly because in most of the cases the replacement of a mercury probe used for capacitance-voltage determinations would require several other measuring devices.

Justification for derogations and conditions common for all devices

Justification to propose a transitional period of 18 months

The actors need some time to adapt after a regulation has entered into force. The reasons are technical, economic, practical and regulatory.

Examples of technical adaptation are: when measuring devices change, industry, laboratories and their customers may need to adapt the processes where the measurement takes place. In some cases the products using measuring devices need to be changed, too.

Examples of reasons for adaptation due to economic reasons are: it would seem economically disproportionate if manufacturers, importers, wholesale and retail sellers could suddenly not place on the market their existing stocks of devices. These considerations are particularly important due to the fact that many operators in measuring device market are small and medium sized companies.

Examples for practical reasons for a transitional period are: responsible authorities may need to make arrangements to be able to enforce the new restrictions. It takes some time for them to inform each other as well as the suppliers and customers in all markets about the change in legislation. This is also a specific issue for importers who need to inform non-EU suppliers about the change in EU regulation.

Theoretically, the length of the transitional period could be different for different devices. However, for reasons of clarity to enforcers and to the actors who have to comply with the restrictions, there is a merit of having one single transitional period, unless there are good grounds to do otherwise.

For some devices like barometers, manometers, pycnometers and metering devices where the alternatives already dominate the market, a shorter transitional period could be justified. However, as only relatively small amounts of mercury, if any, is currently placed on the EU market in these devices, an earlier date would not reduce the mercury placed on the market considerably. Therefore, risk reduction capacity would not be significantly higher (due to low tonnages) and it is regarded to be more valuable to have a more coherent entry with the same transitional period for all the devices.

For the above reasons a transitional period of 18 months is considered reasonable for the market operators and administration to adapt to the requirements of the proposed restriction. A shorter period could imply implementation problems and there seems to be no need for a longer one, apart from the issue relating to the use of mercury thermometers prescribed by analysis standards. In this latter case a transitional period of 5 years is suggested.

<u>Derogations for devices with cultural and historical value</u>

In addition to device specific derogations, a general derogation for placing on the market of old devices (more than 50 years old) was proposed by the dossier submitter. This derogation is similar to the one in the existing restriction on consumer devices (Entry 18a).

The derogation is meant to allow a general selling and buying of old, historically valuable mercury containing devices which can be regarded as antiques or cultural goods. The negative impact of this derogation on the risk reduction capacity is insignificant. As the continued use of the existing devices is proposed to be allowed, the derogation would simply allow a very limited number of old devices to be placed on the market, if needed.

The same date as in the equivalent derogation in the existing restriction (more than 50 years old on 3 October 2007, paragraph 3 a) in entry 18a of Annex XVII of REACH) is proposed to be used. Setting the same date for all devices keeps the entry simpler and clearer, and thus easier to comply with and more enforceable.

However, based on information received during the public consultation, a need for an additional derogation for measuring devices which are to be displayed in exhibitions for cultural and historical purposes was identified. Some of the devices for which restrictions are proposed may not fulfil the prerequisite of being 50 years old, but nevertheless have historical or cultural value. For instance technical museums should be able to obtain or lend professional and industrial measuring devices to be displayed in the exhibitions. This would not be possible without additional derogation as placing on the market also covers the second hand market, and placing on the market of devices free of charge.

In the Opinion of RAC, the general derogation for old measuring devices (more than 50 years old) was replaced by the derogation for measuring devices which are to be displayed in exhibitions for cultural and historical purposes. However, in the draft Opinion of SEAC, both derogations are proposed.

Justification for not proposing a review clause

During the preparation of this report it has been considered whether a review clause would be helpful for mercury devices for which a restriction had not been proposed. Such review clause could be focussed on the availability of technically and economically feasible alternatives for mercury devices and it could promote the development of the alternative devices, substances and methods. However, it was recognised that it is difficult to estimate the impact of such a review clause.

A Member State or ECHA can propose a re-examination of an existing restriction in accordance with Article 69(5) of REACH when this is deemed necessary.

In conclusion, for reasons of legislative coherence and clarity, a review clause was not proposed in this restriction report.

F. Socio-economic assessment

F.1 Human health and environmental impacts

For the reasons explained in Part B, the risk reduction capacity of the proposed restriction has been described by using as a proxy the amount of mercury placed on the market in the EU included in or to be used with the measuring devices. These amounts have been described in the device specific annexes. It is important to note that the specific human health or environmental impacts of introducing a restriction could not be quantified. Furthermore it was not considered proportionate to even aim at such quantification given the reasons explained in the Part B.4. As human health and environmental impacts could not be quantified, it is also not possible to monetise these impacts.

The proposed restriction is estimated to reduce the amount of mercury placed on the EU market (in devices or to be used in measurements) by 60 tonnes between 2015 and 2034. Table 10 in Part E gives details. It is evident that not placing 60 tonnes of mercury on the market has a positive impact on the environment and human health. These effects have been discussed in the Part B.3.

F.2 Economic impacts

Apart from the assessment the economic feasibility of alternatives and for some devices assessing the compliance costs, no additional economic impacts from introducing the proposed restrictions have been assessed. Detailed compliance cost assessments for sphygmomanometers and thermometers can be found in Annexes 3b and 5b.

The administrative costs related to the proposed restrictions have been qualitatively reflected in device specific annexes, where this has been possible and regarded proportional. In general administrative costs both to authorities and market operators concerned are assumed to be low.

The compliance costs of the proposed restrictions are estimated to be €12.3 million in 2024, or cumulatively €129 million for 2015-2034. Table 11 in Part E gives details. Furthermore Table 12 gives the average cost-effectiveness of replacing mercury devices with mercury-free ones. Overall the proposed restrictions would cost about €4,100 per kg Hg on the average. Note that this average has been calculated using kilograms as weights. A simple, unweighted average would have given misleading information about the economic impact.

Based on a literature review, Appendix 2 presents the compliance costs, human health benefits and restoration costs of reduced mercury emissions to better understand the estimated compliance costs in relation to other actions and policies to reduce mercury.

F.3 Social impacts

Restricting the placing on the market of mercury measuring devices affects the employment of those who are currently producing them. Table 13 presents the number of identified producers of each measuring device in and outside the EU, number of employees in production of mercury devices in the EU and the share of production in the EU to internal markets. Unfortunately, the number of employees producing mercury measuring devices is not known for all devices, as such information is not easy to collect.

Table 13: Number of producers of mercury measuring devices in EU in 2007

Measuring device	Number of identified producers in the EU	Number of identified producers outside the EU	Number of employees in production of mercury devices in the EU	Share of production in the EU to internal markets
Barometers*)	1 (possibly a couple)	Unknown	2-20	not available
Devices using mercury electrodes	1	1 (Switzerland)	not available	not available
Manometers (incl. tensiometers)	2**)	Unknown	not available	not available
Mercury porosimeters	0	4 (USA)	0	not applicable
Mercury probes***)	0	2 (USA)	not available	not available
Mercury pycnometers	0	1 (USA)	0	not applicable
Metering devices*)	1	Unknown	not available	not available
Sphygmomanometers *)	4	Unknown	30-50	15%
Strain gauges (used with plethysmographs)	1	1 (USA)	not available	100%
Thermometers (incl. hygrometers) *)	11	Unknown	1000-1500	50%

Source: Lassen et al. (2008), Lassen et al. (2010), see Appendix 3

Notes: *) Manufacturers are known to produce also mercury free devices

**) The production of mercury tensiometers may be discontinued in the EU (Lassen et al., 2008)

***) The mercury probes used for capacitance-voltage determinations were recognized as a mercury measuring device based on the information received in the last day of the public consultation on the Annex XV restriction report. The two producers in the USA were identified by ECHA via internet search.

All identified producers of mercury barometers, metering devices (for determination of softening point), sphygmomanometers and thermometers in EU produce also the mercury-free alternatives. Mercury porosimeters and pycnometers are not produced in the EU. For manometers and barometers, the markets of mercury containing devices are very small compared to mercury-free alternatives.

Given that the restriction proposal does not cover restriction of exports of measuring devices, and given that exports are not restricted by Regulation (EC) No 1102/2008 (see also part B.2), European companies will be allowed to continue producing mercury containing measuring devices for exports. Since in addition most producers of mercury devices are also producing or placing on the market mercury-free alternatives, the social impacts of the proposed restriction would be minimal.

In conclusion, the proposed restriction is estimated to have either no or very small social impacts, in particular on the employees in companies as well as on the aggregate employment of companies producing measuring devices. For the users of the restricted mercury containing measuring devices, no negative social impacts have been identified.

F.4 Wider economic impacts

Specific care has been taken to ensure that the proposed restriction on mercury containing measuring devices is compatible with the international trade rules under the World Trade Organisation. This has been done by adhering to the following principles.

Restricting the placing on the market of mercury measuring devices means that the non-EU producers will no longer be able to export them into the EU. However, these producers can export the alternatives to mercury containing devices into the EU. Thus, the competitiveness of the EU measuring device producers is not affected to the detriment of their competitors outside the EU. In sum, devices containing mercury produced in as well as imported to the EU are regulated exactly in the same manner.

F.5 Distributional impacts

Mercury containing measuring devices are used in laboratories, small and large industry installations, hospitals as well as private practitioners. Thus, regulating the placing on the market of new devices will affect both small or micro (also self-employed) enterprises[47] as well as big companies. Nevertheless, as mercury-free devices cost normally around the same as the mercury device and as the use of existing devices until the end of their service-life is allowed, the impacts on users (including SME's) is small. Therefore any distributional impact would also be small.

Most of the companies producing mercury containing measuring devices are small or medium sized, i.e. are categorised as SME companies (Lassen et al., 2008). As the restriction treats all of these in the same manner all across the EU and as no

[47] In "micro" entreprises, there are less than 10 staff, in "small" entreprises there are less than 50 staff.

economies of scale exist in the production of measuring devices, no specific SME related impacts have been identified.

It is not known to what extent the mercury containing measuring devices are used more in the new Member States compared to the EU15. In some Member States (see Section B.5) there have been national measures to move away from the mercury measuring devices. Thus, these Member States have already partly replaced the mercury devices so it is possible that this restriction proposal would induce relatively speaking slightly higher implementation costs to new Member States. It should also be considered that some devices may be used more in relative terms in the EU15 compared to new Member States. This is due to for instance economic structure. Thus the distributional impacts in terms of costs across different Member States are estimated to be minor.

F.6 Main assumptions used and decisions made during analysis

Throughout the analysis a 4% discount rate has been used as this is in line with ECHA (2008) and the Commission (2008a). The time period of the analysis is 20 years (between 2015-2034) as this represents a period during which most of the direct impacts of the restriction will occur. Results are also presented as annualised using the year 2024 as a representative year, when most of the proposed restrictions would be in full effect.

The causal chain from production or use of mercury devices to health impacts has been explained in Part B. Given that the health and environmental impacts of the proposed restriction have not been estimated (see Section B.2), the methodology used in SEA has been that of cost-effectiveness. As a proxy for effectiveness of risk reduction, the amount of mercury included in the measuring devices sold annually in EU has been used. For the measuring devices using mercury similar assumption has not been needed for two reasons:

- There seems not to markets for mercury pycnometers and mercury metering devices anymore, and consequently no compliance costs.
- For porosimeters and mercury electrodes no compliance cost calculations were conducted as the technical feasibility could not be established.
- For mercury probes no compliance cost calculations were conducted due to strong qualitative evidence supporting that none of the alternatives (or set of alternatives) are both technically and economically feasible.

G. Stakeholder consultation

Public consultation on the Annex XV restriction report (September 2010 - March 2011)

After submission of the original Annex XV restriction report, ECHA organised a public consultation on the restriction report. During the consultation, comments were received from 28 stakeholders, representing individuals, industry, NGO's and Member States. The comments received, as well as the responses from the dossier submitter (ECHA) and from the rapportteurs of the Committees for Risk Assessment and Socio-economic Analysis will be made available on the ECHA website. Furthermore, the Background Document was updated based on the received comments.

Stakeholder consultation during the preparation of the restriction report (beginning of 2010)

In December 2009, ECHA contracted Cowi consulting company, together with ENTEC and IOM to carry out a focussed stakeholder consultation on mercury measuring devices (Lassen et al. 2010, see Appendix 3). The consultation took place between January and May 2010. The objective was mainly to collect input data to assess the proportionality of the restriction options and for socioeconomic analysis – in particular on costs of alternatives as well as technical and economic feasibility of replacement.

In this consultation questionnaires tailored to each equipment type were sent to identified producers. An example of the questionnaire is available in Appendix 3 of this BD. In some cases more detailed information was requested through follow-up questions. Based on (Lassen et al., 2008) it was deemed that the contacted producers represent the majority of producers in the EU. Still, in segments where import from countries outside the EU takes place, it was not always possible to consult the non-EU producers. It was considered unnecessary to consult the producers of barometers due to earlier work giving already an adequate information basis.

In addition to work by Lassen et al (2010), during January-April 2010, ECHA consulted those Member States that were identified to have national bans for mercury measuring devices. The data are reported in Section B.5. Other Member States were not approached when preparing this report. Nevertheless, Commission has consulted Member States in summer 2008.

Commission's consultation (summer 2008)

The review by Commission (see Appendix 5), describes the consultation of Member states and stakeholders as follows:

> "In summer 2008, DG-Enterprise & Industry has launched a consultation with Member States and other interested stakeholders. More specifically, questionnaires were prepared and circulated to the Members of the Commission Experts Working Group on Limitation of Chemicals (LWG) and to the Experts

Working Group on Medical Devices (MDEG) asking them to provide input concerning:

- the availability of alternatives to mercury-containing sphygmomanometers in the Member States and whether these are adequately validated and calibrated;
- essential uses of mercury-containing sphygmomanometers that are required in Member States (e.g. treatment of special medical conditions);
- other mercury-containing measuring devices used for research and in industrial uses and the availability of alternatives for such devices.

In addition, the Commission sent the questionnaires to interested NGOs, industry trade associations, and scientific organisations requesting them to submit any information (reports of relevant studies/clinical trials etc.) which would be helpful for the purposes of the review."

Other consultations (before 2010)

In addition to the stakeholder consultation carried out in the framework of preparing this B.D. and to the review of Commission (see Appendix 5), a lot of information on mercury containing measuring devices had been collected by the Commission and stakeholders in recent years. During the preparation of these reports stakeholders have also been consulted. The following reports have been used as a main source when preparing the original restriction report and this Background Document:

- Lassen et al. (2008), published by DG ENV: Options for reducing mercury use in products and applications, and the fate of mercury already circulating in society
- Concorde (2009) published by EEB: Turning up the pressure: Phasing out mercury sphygmomanometers for professional use
- SCENIHR (2009) opinion on Mercury Sphygmomanometers in Healthcare and the Feasibility of Alternatives.

References

ACI Alloys (2010). Website from ACI Alloys, Inc., consulted on 26 March 2010. Available at http://www.acialloys.com/msds/ga.html

Amarell (2005). Catalogue from 2005 Amarell GmbH & Co. KG.

Amarell (2010). Laboratory thermometers. Website from Amarell GmbH & Co. KG, consulted on 26 March 2010. Available at http://www.amarell.de/thermometers/laboratorythermometers.htm

Amel (2001). *Introduction to Modern Voltammetric and Polarographic Analisys Techniques, Edition IV, Amel Electrochemistry, 2001*. Amel srl., Milano, 2001. http://www.amelchem.com/download/items/voltammetry/manuals/eng/manual_eng.pdf

Anderson (2010). Website from Anderson Instrument Co., consulted on 29 March 2010. Available at http://www.andinst.com/PDFs/5052.pdf

Anghel S. (2004), Pressure measurement, available at http://www.phys.ubbcluj.ro/~sorin.anghel/teaching/SIS/diverse_materiale/senzori_presiune_engl.pdf

Answers.com (Sci-Tech Dictionary) (2010). Website visited in the beginning of 2010.

ARMATURENBAU (2010). Website from ARMATURENBAU GmbH consulted on 15 November 2010. Available at http://www.manotherm.com/Products1f.htm http://www.manotherm.com/Datenblaetter-pdf/1201-eng.pdf

ASTM (2009). *Replacing Mercury-in-Glass Thermometers in ASTM Test Methods - Some Guidelines for a Complex Task*. Mercury Task Group of ASTM Committee E20 on Temperature Measurement, ASTM International, November/December 2009. Article published online, available at http://www.astm.org/SNEWS/ND_2009/enroute_nd09.html

ASTM (2010). Mercury Removal Initiative. Website from ASTM International, consulted on 13 April 2010. Available at http://www.astm.org/COMMIT/mercury.html

Benedek, I. and Feldstein, M.M. (2009). *Technology of Pressure-Sensitive Adhesives and Products*. CRC press, Taylor and Francis group LLC, Florida, 2009.

Brannan (2010). Website from S. Brannan & Sons Ltd., consulted on 7 April 2010. Available at http://www.brannan.co.uk/products/pro_vline.html

BREF Waste Incineration (2006). *Integrated Pollution Prevention and Control Reference Document on the Best Available Techniques for Waste Incineration*. European Commission, Joint Research Centre, Institute for Prospective Technological Studies, Seville, August 2006.

BREF Waste Treatments Industries (2006). *Integrated Pollution Prevention and Control Reference Document on Best Available Techniques for the Waste Treatments Industries*. Formally adopted by the European Commission. European Commission, Joint Research Centre, Institute for Prospective Technological Studies, Seville, August 2006

Burns Engineering (2010). FAQs on the website from Burns Engineering Inc., consulted on 21 March 2010. Available at http://www.burnsengineering.com/faq/

Cadwallader, L.C., (2003) Gallium safety in the Laboratory, DOE Scientific and Technical Information, INEEL/CON-03-00078 available at www.osti.gov

Camlab (2010). Website from Camlab, consulted on 7 April 2010. Available at http://www.camlab.co.uk

Chamois (2010), Website from Chamois, consulted on 3 November 2010. Available at http://www.chamois.net/_userfiles/pages/image/dpg10A.pdf

Chandler et al (1994). *Cytotoxicity of Gallium and Indium Ions compared with Mercuric Ion*, Journal of dentistry research, 73:1554

Channa, H. and Surmann, S. (2009). Voltammetric analysis of N-containing drugs using the hanging galinstan drop electrode. *Pharmazie,* **64**: 161-165.

Collery et al., Gallium in cancer treatment Critical Reviews in Oncology/Hematology 42 (2002) 283–296

Commission (2006). *Proposal for a Dirctive of the European Parliament and of the Council amending Council Directive 76/769/EEC relating to restrictions on the marketing of certain measuring devices containing mercury*. European Commission, COM(2006) 69 final, Brussels, Februari 2006.

Commission (2008). *Methyl mercury in fish and fishery products. Information Note.* European Commission, D/530286, Brussels, 21 April 2008

Commission (2009a). *Impact Assessment Guidelines*. SEC(2009) 92, Brussels, 15 January 2009. Available at http://ec.europa.eu/governance/impact/commission_guidelines/docs/iag_2009_en.pdf

Commission (2009b). Minutes of mercury workshop, held on April 2009. European Commission, Brussels, July 2009.

Concorde East/West (2009). *Turning up the pressure: Phasing out mercury for professional use*. Concorde East/West for the European Environmental Bureau, Brussels, June 2009. Available at http://www.eeb.org/publication/2009/SphygReport_EEB_Final-A5_11Jun2009.pdf

CUWVO (1990). Coördinatiecommissie uitvoering wet verontreiniging oppervlaktewateren, werkgroep VI. *Afvalwaterproblematiek in de tandheelkundige verzorging, aanbevelingen met betrekking tot de sanering van de lozingen afkomstig van tandartspraktijken, tandheelkundige faculteiten en tandtechnische laboratoria.*

Difference Between Similar Terms and Objects (2010), consulted on 3 November 2010, available at http://www.differencebetween.net/science/

Dingens Barometers & Clocks (2011). Consulted on 4 January 2011. Available at http://www.barometers.com/index.htm

Ebro (2010). Website from ebro Electronic GmbH und Co. KG, consulted on 8 April 2010. Available at http://www.ebro.de/

EC JRC (2000a). IUCLID chemical data sheet for ethanol, CAS nr. 64-17-5. European Commission, Joint research centre, Februari 2000. ECB-European chemical substance information system.

EC JRC (2000b). IUCLID chemical data sheet for pentanol, CAS nr. 30899-19-5. European Commission, Joint research centre, Februari 2000. ECB-European chemical substance information system.

ECHA (2007). *Guidance for the preparation of an Annex XV dossier for restrictions*. European Chemicals Agency, Helsinki, June 2007. Available at http://guidance.echa.europa.eu/docs/guidance_document/restriction_en.pdf?vers=19_09_08

ECHA (2008). *Guidance on Socio-Economic Analysis – Restrictions*. European Chemicals Agency, Helsinki, May 2008. Available at http://guidance.echa.europa.eu/docs/guidance_document/sea_restrictions_en.pdf

ECHA (2009). *Addendum to the Guidance on Annex XV for restrictions and to the guidance on Socio-economic Analysis (SEA) – Restrictions. Explanatory note – Format of Annex XV restriction report*. Available at http://guidance.echa.europa.eu/docs/authorities/AXV_restriction_format_01102009.doc

ECHA (2010). Guidance on information requirements and chemical safety assessment, Chapter R.18: Estimation of exposure from waste life stage, draft version 2. European Chemicals Agency, Helsinki, 17 August 2010.

EFSA (2004). Opinion of the Scientific Panel on Contaminants in the Food Chain on a request from the Commission related to mercury and methylmercury in food.

Request N° EFSA-Q-2003-030, adopted on 24 February 2004. *The EFSA Journal*, **34: 1-14**.

EEB (2009). *Report from the conference EU Mercury phase out in Measuring and Control Equipment, Brussels, 18 June 2009*. European Environmenal Bureau, Brussels, October 2009. Available at http://www.zeromercury.org/EU_developments/091104EEB-HCWH-Meas-Dev-Conf-Rep.pdf

Electrochemistry Encyclopedia (2010), website visited in the beginning of 2010. Available at http://electrochem.cwru.edu/encycl/

Environment Canada (2010). Mercury and the Environment webpages, consulted on 25th of March, 2010. Available at http://www.ec.gc.ca/mercury/sm/en/sm-mcp.cfm?select=sm

ESH (2003). European Society of Hypertension – European Society of Cardiology guidelines for the management of arterial hypertension, Guidelines Committee, *Journal of Hypertension*, **21**: 1011-1053.

ESH (2008). European Society of Hypertension guidelines for blood pressure monitoring at home: a summary report of the Second International Consensus Conference on Home Blood Pressure Monitoring. *Journal of Hypertension*, **26**: 1505-1530.

EU RAR n-pentane (2003). European Union Risk Assessment Report n-PENTANE, CAS No: 109-66-0, EINECS No: 203-692-4. European Communities, 2003.

Finklin, A.I. and Fischer, W.C. (1990). *Weather Station Handbook - an Interagency Guide for Wildland Managers*. A publication of the National Wildfire Coordinating Group, Idaho, March 1990.

Geratherm (2010). Geratherm® *classic*, a mercury-free analogue thermometer containing Galinstan. Geratherm Medical AG website. Consulted on 26 March 2010. Available on http://www.geratherm.com/wp-content/uploads/2009/10/user-manual-Geratherm-classic2.pdf

Global Test Supply (2010). Retailer website Global Scientific Supply –the laboratory supply company of Global Test Supply, LLC. Consulted on 8 April 2010. Available on http://www.globalscientificsupply.com/

Hanna (2010). Website of Hanna Instruments Belgium. Available at: http://www.hannainst.be

HEINE Optotechnik (2010). Website from HEINE Optotechnik GmbH & Co. KG consulted on 4 November 2010. Available at
http://www.girodmedical.com/media/upload/notice/2/G/A/GAMMA_G-E.pdf

HERC (2010) – Healthcare Environmental Resource Center - Mercury in healthcare facilities, available at http://www.hercenter.org/hazmat/mercury.cfm#Galinstan

Hydraulics & Pneumatics (2010), Technology Zones - Bourden-tube designs, available at http://www.hydraulicspneumatics.com/200/TechZone/SystemInstrumen/Article/True/6438/TechZone-SystemInstrumen

Hylander, L.D. and Goodsite, M.E. (2006). Environmental costs of mercury pollution. *Science of the Total Environment* **368**: 352–370.

IAG (2005) *Report of the independent advisory group on blood pressure monitoring in clinical practise*.

IARC (2006) Cobalt in Hard Metals and Cobalt Sulfate, Gallium Arsenide, Indium Phosphide and Vanadium Pentoxide, IARC Monographs on the Evaluation of Carcinogenic Risks to Humans, volume 86, 2006

IUPAC Task Group (2010), Provisional document dated 15 February 2010 to be published as IUPAC TECHNICAL REPORT: *Liquid intrusion and alternative methods for the characterization of macroporous materials*. By Rouquerol, J., Baron, G., Denoyel, R., Giesche, H., Groen, J., Klobes, P., Levitz, P., Neimark, A.V., Rigby, S., Skudas, R., Sing, K., Thommes, M., Unger, K.

Jackson A.M., E.B Swain, CA Andrews and D.Rae (2000) Minnesota's mercury contamination reduction initiative. *Fuel Process Technol* 2000;65:79–99.

JUMO (2010). Website from JUMO GmbH & Co. KG consulted on 15 November 2010. Available at
http://www3.jumo.de/pio/JUMO/en_DE/cat/ee048e280a090a052d21932a67cccaf6/dial-thermometers-with-bimetal-measuring-system.html

KemI (2004). *Mercury –investigation of a general ban*. KemI Report No 4/04. Swedisch Chemicals Inspectorate (KemI), Stockholm, October 2004.

KemI (2005). *Mercury-free blood pressure measurement equipment – Experiences in the Swedish healthcare sector*. Swedish Chemicals Inspectorate. Available at: http://www.chem.unep.ch/Mercury/Sector-Specific-Information/Docs/Swedish_exp_Hg_free_bloodpressure_equip.pdf

KemI (2007). Decision on exemption from prohibition on certain mercury containing articles. Swedish Chemicals Agency. Reg. no. 660-1505-06.

Kindbom, K. and Munthe, J. (2007). *Product-related emissions of mercury to air in the European Union*. IVL Swedish Environmental Research Institute Ltd, sponsored by the Swedish Chemicals Agency (KEMI), Göteborg, June 2007. Available at: http://www3.ivl.se/rapporter/pdf/B1739.pdf

Labnewsletter.com (2010). Website consulted on 11 March 2010: http://www.labnewsletter.com/index.php?article_id=66&clang=0

Lassen, C. and Maag, J. (2006). *Alternatives to mercury-containing measuring devices*. Environmental Project No. 1102 2006. The Danish EPA, Copenhagen.

Lassen, C, Holt Andersen, B., Maag, J. and Maxson P. (2008). *Options for reducing mercury use in products and applications, and the fate of mercury already circulating in society*. COWI and Concorde East/West for the European Commission, ENV.G.2/ETU/2007/0021, December 2008. Available at http://ec.europa.eu/environment/chemicals/mercury/pdf/study_report2008.pdf

Lassen, C., McGonagle, C. and Corden, C. (2010). *Services to support preparing an Annex XV restriction report on mercury containing measuring devices. Results from the information gathering and stakeholder consultation*. Entec, Cowi and IOM for ECHA, June 2010. Published as Appendix 3 of this report.

Lowe (2009). Axillary Electronic and Galinstan Thermometer Measurements: A Comparison of Their Consistency. *Thyroid Science* **4**(3):CLS1-9.

Ludwig Schneider (2010). Catalogue Ludwig Schneider GmbH & Co. KG, received in March 2010.

MDC (Materials Development Corporation) (2011). Website available at www.mdc4cv.com www.4dimensions.com

Mercuryprobe (2011). Website available at http://mercuryprobe.com

Metrohm (2009), Mercury electrodes – Important applications of polarography and possible mercury-free alternatives, presentation made by Uwe Loyall at Mercury measuring devices in healthcare and other industrial / professional uses workshop April 2009, Brussels

Metrohm leaflet (2008): Polarography, voltammetry and CVS – The Whole World of Ion Analysis, available on line at http://www.google.ro/search?hl=ro&source=hp&q=Polarography%2C+voltammetry+and+CVS+%E2%80%93+The+Whole+World+of+Ion+Analysis&btnG=C%C4%83utare+Google&aq=f&aqi=&aql=&oq=&gs_rfai=

MicroDAQ (2010). Website from MicroDAQ.com, Ltd, consulted on 21 March 2010. Available at http://www.microdaq.com/accessories/choosing.php

Mitchell, J., Beau, J., Webber, W. and Strange, J.H. (2008). Nuclear magnetic resonance cryoporometry. Physics reports 461 (2008).

Morris, M. (2006). Soil Moisture Monitoring: Low- Cost Tools and Methods, available at www.attra.ncat.org.ceeldorado.ucdavis.edu/files/45069.pdf

National Institute for Minamata Disease (2010). Website of the National Institute for Minamata Disease, Minamata City, Japan. Consulted on 2 Februari 2010. http://www.nimd.go.jp/archives/english/index.html

NESCAUM (2005). *Economic Valuation of Human Health Benefits of Controlling Mercury Emissions from U.S. Coal-Fired Power Plants*. Northeast States for Coordinated Air Use Management (NESCAUM), February 2005. Available at http://www.nescaum.org/documents/rpt050315mercuryhealth.pdf

NEWMOA website (2010). Consulted on 8 March 2010. Available at http://www.newmoa.org/prevention/mercury/projects/legacy/healthcare.cfm#sg.

Omega (2010). Website of OMEGA Engineering, INC., consulted on 29 March 2010. Available at http://www.omega.com/Temperature/pdf/DIALTEMP_REF.pdf
http://www.omega.com/prodinfo/infraredthermometer.html
http://www.omega.co.uk/prodinfo/pt100.html

Palmer Wahl (2010). Catalogue retrieved from the website of Palmer Wahl Instrumentation Group on 24 February 2010. Available at http://www.palmerwahl.com/

Peruzzi, A., Bosma, R., and van den Hark, J. (2007). The Dutch National Realization of the ITS-90 over the Range 13.8033 K–273.16K. *Int J Thermophys* **28**:1882–1892.

Petrotest data sheet (2010). Available at http://www.petrotest.com/petrotest_product_10-0081_en.pdf

PMS instruments (2011). Website consulted on 4 April 2011. Available at http://www.pmsinstruments.co.uk/acatalog/Accessories_And_Spares_For_Hokanson_Vascular_Range.html

Porous materials (2010). Several product brochures visited 8 March 2010. Available at http://www.pmiapp.com/products/index.html

Rein K. von, Hylander L.D. (2000). Experiences from phasing out the use of mercury in Sweden. *Regional Environ Change* J 2000;1:126–34.

Repetto, G. and Peso, A. d. (2001). *Gallium, Indium, and Thallium*, Patty's Toxicology

Ripple, D.C. and Strouse, G. F. (2005). Selection of Alternatives to Liquid-in-Glass Thermometers. *J. ASTM International* **2**: JAI13404.

RPA (2002). Risks to Health and the Environment Related to the Use of Mercury Products. Risk & Policy Analysts Limited for the European Commission, 9 August 2002. Available on http://ec.europa.eu/enterprise/sectors/chemicals/files/studies/rpa-mercury_en.pdf

SCENIHR (2009). *Mercury Sphygmomanometers in Healthcare and the Feasibility of Alternatives*. Opinion of the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR), 23 September 2009. Available at http://ec.europa.eu/health/ph_risk/committees/04_scenihr/docs/scenihr_o_025.pdf

SCHER (2008). Opinion on the environmental risks and indirect health effects of mercury in dental amalgam. Scientific Committee on Health and Environmental Risks (SCHER), 6 May 2008. Available at http://ec.europa.eu/health/ph_risk/committees/04_scher/docs/scher_o_089.pdf

Schroder, D.K. (2006), Semiconductor material and device characterization, IEEE Press, Wiley-Interscience Publication, available at http://books.google.ro

Semilab (2011a). Information received in the public consultation (to be published in the ECHA website)

Semilab (2011b). Website available at www.semilab.com

SIKA (2010). On-line catalogue from SIKA Dr. Siebert und Kühn GmbH & Co. KG. consulted on 7 April 2010. Available at http://www.sika.net/eng/messgroessen/Thermometers.cfm

Smajstrla, A.G. and Harrison, D.S. (2002), Tensiometers for Soil Moisture Measurement and Irrigation Scheduling, available at http://edis.ifas.ufle.edu

Spadaro, J.V. and A. Rabl (2008). Global Health Impacts and Costs Due to Mercury Emissions. *Risk Analysis* **28**: 603-613.

Strouse, G. F., and Lippiatt, J. (2001), "New NIST Mercury Triple Point Cells", *Proceedings of Tempmeko 2001*, 2001, **1**: 453-458.

Surmann, S. and Zeyat, H (2005). Voltammetric analysis using a self-renewable non-mercury electrode. *Anal Bioanal Chem* **383**: 1009-1013.

Swain, E.B., Jakus, P.M., Rice, G., Lupi, P, Maxson, P.A., Pacyna, J.M., Penn, A., Spiegel, S.J. and Veiga, M.M. (2007). Socioeconomic Consequences of Mercury Use and Pollution. *Ambio* **36**: 45-61.

Thompson, J.A.J., Paton D.W (1991) Determination of Trace Metals in Estuarine Sediment Pore Waters Containing High Concentrations of Iron, Canadian Technical Report of Hydrography and Ocean Sciences, No 133.

Trerice (2010). Product catalogue retrieved from the website of Trerice on 29 March 2010. Available at http://www.trerice.com/pdfs/thumbnails/Complete%20Catalogs.pdf

UNEP (2002). *Global Mercury Assessment*. UNEP Chemicals, Geneva, Switzerland, December 2002. Available on http://www.chem.unep.ch/mercury/report/final%20assessment%20report.htm

UNEP (2003). Governing Council Decision 22/4, chemicals, mercury programme. Governing Council/ Global Ministerial Environment Forum 22nd session, Nairobi, Februari 2003. http://www.chem.unep.ch/mercury/mandate-2003.htm

UNEP (2008a). *Guidance for identifying populations at risk from mercury exposure*. UNEP Chemicals, Geneva, Switzerland, August 2008. Available on http://www.unep.org/hazardoussubstances/Mercury/MercuryPublications/GuidanceTrainingmaterialToolkits/GuidanceforIdentifyingPopulationsatRisk/tabid/3616/language/en-US/Default.aspx

UNEP (2008b). *The Global Atmospheric Mercury Assessment: Sources, Emissions and Transport*. UNEP Chemicals, Geneva, Switzerland, December 2008. Available at http://www.chem.unep.ch/Mercury/Atmospheric_Emissions/UNEP%20SUMMARY%20REPORT%20-%20CORRECTED%20May09%20%20final%20for%20WEB%202008.pdf

UNEP (2010). UNEP mercury programme website, consulted on 24th of February 2010. Available at http://www.chem.unep.ch/mercury/default.htm

US EPA (2009). *Elemental Mercury Used in Flow Meters, Natural Gas Manometers, and Pyrometers; Proposed Significant New Use Rule*. Federal Register Environmental Documents, September 11, 2009, Volume 74, Number 175. Available at http://www.epa.gov/fedrgstr/EPA-TOX/2009/September/Day-11/t21894.htm

US EPA (2010). Phase-Out of Mercury Thermometers Used in Industrial and Laboratory Settings. Website from United States Environmental Protection Agecy (US EPA), consulted on 13 April 2010. Available at http://www.epa.gov/hg/thermometer.htm

US EPA (2011). Phase-Out of Mercury Thermometers Used in Industrial and Laboratory Settings. Website from United States Environmental Protection Agecy (US EPA), consulted on 1 Februari 2011. Available at http://www.epa.gov/mercury/thermometer.htm

Vaisala (2010). Available at *http://www.vaisala.com/instruments/products/ptb110.html*.

Vargas-Florencia, D., Petrov, O.V. and Furó, I. (2006). NMR cryoporometry with octamethylcyclotetrasiloxane as a probe liquid. Accessing large pores. Journal of Colloid and Interface Science 305 (2007).

VWR LabShop (2010). Website of VWR LabShop (US), consulted on 29 March 2010. Available at http://vwrlabshop.com

WHO (1990). *Methylmercury. Environmental health criteria 101*. Published under the joint sponsorship of the United Nations Environment Programme, the International Labour Organisation, and the World Health Organization. World Health Organization, Geneva, 1990. Available on http://www.inchem.org/documents/ehc/ehc/ehc101.htm

WHO (2007). Health risks of heavy metals from long-range transboundary air pollution.

WIKA (2010). WIKA products webpages, consulted on 26 March 2010. Available at http://www.wika.nl/products_en_co.WIKA?ActiveID=11591

Wikipedia (2010a). Gallium information webpage on Wikipedia, consulted on 26 March 2010. Available at http://en.wikipedia.org/wiki/Gallium

Wikipedia (2010b). Thermocouple information webpage on Wikipedia, consulted on 31 March 2010. Available at http://en.wikipedia.org/wiki/Thermocouple#Types

Wikipedia (2010c). Bimetallic strip information webpage on Wikipedia, consulted on 31 March 2010. Available at http://en.wikipedia.org/wiki/Bi-metallic_strip

Wikipedia (2010d). Thermistor information webpage on Wikipedia, consulted on 31 March 2010. Available at http://en.wikipedia.org/wiki/Thermistor

Wikipedia (2010e). International Temperature Scale of 1990 information webpage on Wikipedia, consulted on 31 March 2010. Available at http://en.wikipedia.org/wiki/International_Temperature_Scale_of_1990

Wikipedia (2010f). Kraemer-Sarnow method webpage on Wikipedia, consulted on 2 June 2010. Available at http://en.wikipedia.org/wiki/International_Temperature_Scale_of_1990

Wikipedia (2011a). Gallium information webpage on Wikipedia, consulted on 14 Januari 2011. Available at http://en.wikipedia.org/wiki/Mercury_(element)

Wikipedia (2011b). Mercury probe webpage on Wikipedia. Available at http://en.wikipedia.org/wiki/Mercury_probe

Wittich & Visser (2010). On-line catalogue "Meteorological instruments, version EN0708" from Ingenieursbureau Wittich & Visser consulted on 15 November 2010. Available at http://wittich.nl/NL/PDF/TOEPASSINGEN/Catalogue_conventionalweatherinstruments.pdf

Welch Allyn website (2010). Consulted on 24 Februari 2010. Available at http://www.welchallyn.com/products/en-us/x-11-ac-100-0000000001023.htm

Woodall, J.M. (2008), Solid aluminium alloys: a high energy density material for safe energy storage, transport, and splitting water to make hydrogen on demand, Sept. 24, 2008, Princeton Plasma Physics Laboratory, available at www.pppl.gov

WMO (2008). *Guide to Meteorological Instruments and Methods of Observation, 7th Edition, WMO-No. 8*. World Meteorological Organization, Geneva, August 2008.

World Bank (2006) *Disease Control Priorities in Developing Countries*, 2nd edition Available at http://www.ncbi.nlm.nih.gov/bookshelf/br.fcgi?book=dcp2

Device specific Annexes

Annex 1: Barometers

Content

1. Technical description of mercury barometers

Mercury barometers are instruments used to measure atmospheric pressure by measuring the changes in the height of the mercury column. A mercury barometer is typically a glass tube filled with mercury. One end of the tube is sealed while the other end of the tube is submerged in a container filled with mercury. Large barometers for professional use (e.g. laboratory use) may contain up to 1.1 kg of mercury according to the Lassen et al. (2008). Typically the more precise equipment has wider columns and consequently more mercury.

As the placing on the market mercury barometers for the general public has been restricted in the EU from 3 October 2009 (Entry 18a in Annex XV of the REACH Regulation), the remaining uses are industrial and professional applications including weather stations, meteorological departments, airports and airfields, wind tunnels, oil refineries, engine manufacturing, sporting sites, offshore installations (e.g. windmill parks) and on ships. According to one supplier small local airfields may still use their old mercury-containing equipment, as the automatic reading of the meter is not essential (Lassen, C. and Maag, J., 2006).

2. Description of release and exposure

Based on the approach described in Part B of the main document, the estimations on i) the total amount of mercury accumulated in devices in the EU and ii) the amount of mercury placed on the market annually in the EU are used to describe the potential release and exposure during the waste phase of the devices (see Table A1-1). Furthermore, to get a more comprehensive picture, the annual amounts iii) used in the production of devices, iv) imported into the EU and v) exported from the EU are given to illustrate the potential for direct exposure of workers during the production and service-life of the devices. However, it is stressed that this report does not further assess the potential concerns related to workers as explained in Part B. If quantitative estimates are not available, a qualitative description is given.

Table A1-1: Amounts of mercury accumulated, used in production, placed on the market and imported and exported in barometers in 2010

Mercury	Estimated amounts
Pool accumulated in barometers (in industrial and professional use) in the EU	~ 3 t Hg Assuming 10 years lifetime for a barometer (Lassen et al., 2008) and no trend in number of devices placed on the market, results in 3 tonnes of Hg accumulated in barometers in industrial and professional applications.
Placed on the market in barometers in the EU	0.1-0.5 t Hg/y (Lassen et al., 2008)
Used in production of barometers in the EU	No data available to quantify. At least one (possibly few) producers of Hg barometers in the EU (Lassen et al., 2008).
Imported into the EU in barometers	No data available.
Exported from the EU in barometers	The producers of barometers also export devices. Up to 40 kg of Hg is exported from the UK annually in barometers. (Lassen et al., 2008)

Box 1: General qualitative description of potential release and exposure

Production phase

According to Lassen et al. (2008) there is at least one (possibly few) producer of mercury barometers in the EU. Nevertheless, there is no data available to quantify the amount of mercury used in the production. The producers also export mercury barometers outside the EU, for example up to 40 kg mercury per year is exported from the UK in barometers. It is estimated that in the EU around 2-20 persons are full-time employed in the production of mercury barometers for both the EU and non-EU markets. The only identified producer of mercury barometers is a SME size enterprise. (Lassen et al., 2008)

There is no data available on emissions and exposure during the production phase, but it is assumed that some emissions may occur during the production of these devices due to the volatile properties of mercury.

Service-life

There is no reliable information on the number of mercury barometers in industrial and professional use and thus on the related accumulated amount of mercury in the barometers. However, according to Lassen et al. (2008) the professional barometer market in the EU is estimated to use 0.1-0.5 tonnes of mercury per year. Assuming an average service-life of 10 years for barometers, and having no trend in the number of devices placed on the market, results in accumulated stock of around 3 tonnes. Nevertheless, according to Lassen et al. (2008) the market is estimated to be decreasing.

In the UK, the professional barometer market is estimated to use less than 10 kg mercury per year (Collin 2008 as cited in Lassen et al., 2008). The users are scientific, medical and special test laboratories, airfields as well as some educational institutes. Some scientific mercury barometers are used for calibration of other barometers such as aneroid and electronic types.

According to WMO (2008) the main risks to workers occur in laboratories where mercury barometers are frequently emptied or filled. Emissions might occur in meteorological stations if mercury is not cleaned up immediately after spillages or when the device is broken. However, WMO (2008) gives detailed instructions on how to clean up mercury spillages. Some companies in the EU are specialised in restoration of mercury barometers and some information on maintenance can be found on their websites:

> http://www.bafra.org.uk/html_pages/articles_mercurialbarometer.html
> http://www.quicksilver-barometers.co.uk/
> http://www.czajkowski-furniture.co.uk/barometer-restoration-and-conservation.htm

<u>Waste phase</u>

The amount of mercury to be disposed of as waste each year corresponds to the amount of mercury placed on the market in barometers 10 years earlier (assuming 10 years service-life). As the mercury barometer market is estimated to be declining (Lassen et al., 2008), the amount of mercury disposed of in barometers (in industrial and professional use) is assumed to be higher than annual amount of mercury placed on the market in the same year.

There is no specific information on how mercury barometers and the mercury content are collected and handled. However, WMO (2008) instructs the weather stations on how the collected mercury can be either disposed or recovered with a reference to contact local authorities and/or suppliers. Based on this, it is assumed that the collection rate might be somewhat higher for mercury in barometers than the roughly estimated average collection rate of 20 % as hazardous waste for mercury containing measuring devices as stated in Lassen et al. (2008).

3. Available information on alternatives (Part C)

3.1 Identification of potential alternatives

Several barometers have been identified by Lassen et al. (2008) as alternatives for mercury containing barometers. These include electronic barometers (e.g. aneroid displacement transducers and electronic resistance or capacitance barometers), aneroid mechanical barometers and mercury free liquid barometers.

3.2 Human health and environment risks related to alternatives

• *Electronic alternatives*
As described in general part C, the human health and environmental risks related to the use of electronic alternatives are insignificant in comparison with the potential emission and exposure associated with the amount of mercury in barometers.

• *Aneroid mechanical barometers*
Materials used for these articles are everyday materials such as plastics and stainless steel. There are no indications of risks to human health or the environment related to the use of bi-metal dial thermometers (see also description on mechanical alternatives in general part C).

• *Mercury free liquid barometers*
The filling liquids commonly used are mineral oils and coloured silicon-based fluids.
A barometer 'Eco-celli" is marketed as mercury free, "not hazardous" and 'environmentally safe', with a "red silicon-based fluid" and a gas filled in a U-shaped tube (Dingens Barometers & Clocks, 2011). The same company has introduced another mercury free liquid barometer; 'Innovacelli' which is also marketed as 'the barometer does not contain mercury or any other toxic agents'. Although the exact properties of the fluid are unknown, there are no known notable risks related to these devices and especially in comparison with mercury containing measuring devices, the risk associated with mercury free liquid barometers is considered to be negligible.

Overall the human health and environmental risks related to the alternative devices seems to be negligible compared to the risks of mercury containing devices.

3.3 Technical feasibility of alternatives

Lassen et al. (2008) state that: 'No specific applications for which mercury barometers cannot be replaced have been identified.' The reasons for using the mercury barometers seem to be that users are used to this barometer and that it is easy to recognise when the equipment is not functioning correctly.
Based on the available information, technically feasible alternatives to mercury barometers exist for all applications.

3.3.1 Electronic barometers

Barometers having an electronic read-out (with equivalent accuracy and stability) have many advantages compared to mercury barometers. These can be operated also remotely while mercury containing barometers need to be observed by people at the place of measurement. The ratio of purely automatic weather stations to observer-staffed weather stations increases steadily. (WMO, 2008)

Electronic barometers are already widely used by professionals in the EU. They use transducers which transform the sensor response into a pressure-related electrical quantity in the form of either analogue or digital signals. Many electronic barometers have automatic data logging. Such devices have currently the highest market share in the EU. Electronic barometers are marketed for different kind of professional applications like weather stations, aviation, laboratories and industrial pressure measurements. The electronic barometers are regarded as precise as the mercury barometers. (Lassen et al., 2008). The electronic barometers are used also for calibration of other barometers (personal communication with Lassen, 2010).

The following kind of electronic barometers are used:

> i) A cylindrical resonator barometer (or vibrating cylinder air-pressure transducer) is designed to measure absolute air pressure using the vibrating element principle. It provides a frequency output from which pressure is computed and it can be read by a computer. For example, in Denmark, this type of barometer is normally used for calibration of other barometers.
>
> ii) An aneroid displacement transducer contains a sensor with electrical properties (resistance or capacitance) that changes as the atmospheric pressure changes. In Denmark these barometers are today used e.g. by weather stations, ships, airports.
>
> iii) A modern version of the pressure transducer using piezoelectric transducer (digital piezoresistive barometer) determines two resonance frequencies of the piezoelectric element. By calculating a linear function of these frequencies and with an appropriate set of variables obtained after calibration, a pressure is calculated by a microprocessor which is independent of the temperature of the sensor.
>
> iv) Bourdon tube barometers consist of a sensor element that changes its shape under the influence of pressure changes and a transducer that transforms the changes into a form directly usable by the observer. Precise and stable digital instruments with quartz Bourbon tubes are used as working standard reference barometers in calibration laboratories (WMO, 2008).

According to a producer of mercury barometer for the professional market, electronic barometers can replace mercury containing barometers for all applications (Lassen et al., 2008*)*. According to the WMO (2008) mercury barometers are, in general, regarded as having good long-term stability and accuracy, but are now losing favour to equally accurate electronic barometers, which are easier to read.

The WMO (2008) guide specifies that electronic barometers should be calibrated about once a year. According to the guide this calibration is done more frequently than for mercury barometers.

3.3.2 Aneroid mechanical barometer

The mechanical aneroid barometer consists of an evacuated metal diaphragm linked mechanically to an indicating needle. These barometers have been used for 200 years and are considered just as accurate as the traditional mercury barometer. According to WMO (2008) the greatest advantages of conventional aneroid barometers over mercury barometers are their compactness and portability, which make them especially practical at sea or in the field.

3.3.3 Mercury-free liquid barometer

According to a producer in the EU, a mercury-free liquid barometer is a U-shaped glass tube filled with a red silicone fluid and gas. The principle to measure air pressure is based on the compressibility of gasses instead of the weight of liquid mercury. There is one producer of this type of barometer, and it is marketed for use in schools and hospitals. Adjacent to the barometer tube is a thermometer filled with blue coloured methanol (methyl-alcohol).

3.4 Economic feasibility

According to Lassen et al. (2008) the price of the mercury barometers varies from €100 to 1000 and non-electronic alternatives are available at the same price range. However, the prices are difficult to compare as some of them are affected by the decorative purpose of the given barometers. Even for professional users the barometers are sometimes regarded as a piece of furniture (personal communication with Lassen, 2010).

Electronic precision barometers based on vibrating element sensors are available at higher prices. However, these have many additional features (e.g. measuring more parameters than only air pressure) that explain the cost difference. Therefore, it is difficult to compare directly the price of an electronic precision barometer with the price of a mercury containing device. (Lassen et al., 2008)

Mercury-free liquid barometers are between 30 and 50 % cheaper than the comparable mercury containing barometers (Lassen et al., 2008). In spite of the cheaper price of mercury-free barometers, some users might be in favour of using the mercury containing barometer because of the tradition. E.g. it is easier to see if the mercury barometer functions correctly (Lassen et al., 2008).

Lassen et al. (2008) roughly estimated that changing to alternatives would not increase the costs to the users. This is supported by Gallican et al. (2003) who concluded that the aneroid and electronic barometers are cost-competitive and acceptable alternatives to the mercury barometers.

It is estimated that a waste treatment cost for mercury sphygmomanometers is €30 compared to the €2 for electronic alternative (Concorde, 2009). As industrial mercury barometers may contain more mercury than sphygmomanometers, the corresponding cost difference between mercury and mercury free barometers can be assumed to be the same or more. There are no mercury barometer specific estimates on waste treatment costs available.

Based on the information described above, alternatives are regarded as economically feasible.

4. Justification why the proposed restriction is the most appropriate Community-wide measure (Part E)

4.1 Identification and description of potential risk management options

4.1.1 Risks to be addressed – the baseline

As described in section B.2, the total estimated amount of mercury placed on the market in measuring devices containing mercury is used to describe the maximum potential for mercury emissions to the environment that might ultimately occur. The amount of mercury placed on the market in barometers for industrial and professional use is estimated to be 0.1-0.5 t per year in the EU. It is estimated that the amount of mercury barometers used by professionals is decreasing (WMO, 2008).

Although not the primary concern, it is worth mentioning that direct exposure of workers can occur during production, professional/industrial use of the devices and during waste management operations.

4.1.2 Options for restrictions

The following options for restriction were identified:

1) restriction on the placing on the market of new mercury containing barometers,
2) restriction on the placing on the market of new mercury containing barometers and the use of existing mercury containing barometers, and
3) restriction on the placing on the market of new mercury containing barometers with a derogation for calibration.

Only the option 1 has been taken for further assessment for the following reasons.

The banning of the use of existing mercury barometers is not assessed further based on the following reasons; It is estimated that the number of mercury barometers used by professionals has already been decreasing. In addition it is assumed that the collection rate for these specialised uses is higher than what has been assumed for instance for sphygmomanometers. Considering the relatively low risk reduction capacity and the costs related to replacing the barometer before the end of the service life, the use ban is not considered to be proportionate. In addition the enforcement of the use ban would require resources and might be in practice difficult to carry out in effective way.

Denmark has in its national ban a derogation for calibration purposes and the Danish Meteorological Institute has as a national reference a mercury containing barometer However, it has not been used in recent years and it seems that it has not been maintained either (Personal communication with Lassen, 2010). In the Netherlands, Sweden and Norway no derogation for the use of mercury barometers for calibration exists in their national bans. Therefore it can be concluded that there seems to be no need to introduce an exemption for calibration in this restriction proposal. The average life time of barometers is 10 years (Lassen et al., 2008) which gives flexibility to use existing mercury barometers for calibration purposes during this period.

4.2 Assessment of risk management options

4.2.1 Restriction of the placing on the market barometers

4.2.1.1 Effectiveness

Risk reduction capacity

The risk reduction achieved by introducing the restriction will be an annual reduction of metallic mercury entering the EU society of approximately 0.1-0.5 tonnes per year. According to Lassen et al. (2008) there are only one or few producers of mercury barometers in the EU. This volume is a measure for reduction of the maximum potential for mercury emissions to the environment that might ultimately occur. In addition, it can be mentioned that the volume also reduces direct exposure of workers in production, use and waste phase, with the exception of exposure related to remaining production for exports.

Emissions related to the use and waste phase of devices already on the market will not be affected by the proposed restriction.

It is assumed that compared to mercury devices the alternatives do not pose significant environmental or human health risks.

Proportionality

Technical feasibility

As stated in section 3.3 technically feasible alternatives are available (Lassen et al., 2008 and WMO, 2008). Electronic barometers dominate already the market for professional use in the EU.

Economic feasibility

Based on the information given in Section 3.4, it is concluded that the costs to the users would not increase if mercury barometers are replaced by alternatives. In some cases the costs are not comparable as for example electronic barometers have features like automatic data logging, the possibility to measure many parameters at the same time etc. that are different compared with the mercury barometer and might for these reasons result in higher prices. It depends on the case whether these additional features are of relevance (and of economic value).

In the EU at least one (possibly few) producer of mercury barometers exist. During the stakeholder consultation of the existing restriction of the placing on the market mercury barometers for sale to the general public, two producers[48] of mercury barometers were opposed to the proposal. Their claim was that if a restriction is introduced it would lead to a negative impact on their future business. However, the current EU markets are only for professional use. This is minor compared what the markets used to be before the placing on the market of mercury barometers to households was restricted[49]. Thus, the impact to the producers to further restrict the markets of mercury barometers is estimated to be small.

According to WMO (2008) the calibration of electronic barometers will need to be done more frequently than for mercury barometers, thus potentially increasing the cost to National Meteorological Services, particularly those with extensive barometer networks. However, as the trend has been to move away from mercury barometers these costs of calibration are not considered to cause major impacts among users, in particular since certain new features have been gained with this change.

Based on the information above, it is estimated that restricting the placing on the market of mercury barometers would not introduce compliance costs (i.e. the cost-effectiveness ~€0 per kg Hg not placed on the market).

Given that the additional costs of using mercury free barometers are ~€0, it is evident that these costs are proportionate to the risks related to mercury. To better understand the estimated compliance costs in relation to other actions and policies to reduce mercury, one can compare the cost effectiveness of the proposed restriction (~€0/kg Hg) with the policy options reviewed in Appendix 2.

[48] Five producers were identified, but only one produce mercury barometers for industrial and professional use

[49] Total mercury consumption in barometers in 2007 was estimated to be 2-5 tonnes Hg/year of which 0.1-0.5 tonnes was for professional use (Lassen et al., 2008). From 3 October 2009, the placing on the market of mercury barometers has been prohibited in the EU.

4.2.1.2 Practicality

Implementability and manageability

Technically feasible alternatives are available and it is estimated that the costs to the users would not increase significantly. As it is not proposed to restrict the current use, the mercury barometers may be used until the end of their service life.

Enforceability

The compliance with the restriction on the placing on the market of mercury barometers can be verified by following the fairly limited number of producers (one to few), importers and distributors of these devices.

4.3 The proposed restriction and summary of the justifications

Proposal:

Restriction on the placing on the market of mercury containing barometers after 18 months of entry into force of the amendment of Annex XVII.[50]

Summary of justification:

The main purpose of the proposed restrictions is to reduce the mercury pool in the society, thus avoiding negative impacts on human health and environment. Technically and economically feasible alternatives to mercury containing barometers are available and electronic barometers already dominate the market in the EU.

[50] The scope of the current entry related to barometers in the Annex XVII will become wider.

Annex 2: Manometers and tensiometers

Content

1. Technical description of manometers and tensiometers

Manometers are instruments for measuring pressure. The mercury containing manometers measure the difference in gas pressure between the measured environment and a reference.

Manometers usually consist of a U-shaped glass or plastic tube containing a liquid (usually water, alcohol or mercury). The surface of the liquid in one end of the tube moves proportionally with changes in pressure on the liquid in the other end. When pressure is applied, the liquid level in one arm rises, while the level in the other drops. A set of calibrated markings beside one of the arms permits a pressure reading to be taken, usually in inches or millimetres.

The column (U-tube) may be either vertical or inclined from the vertical to elongate the scale and further amplify the liquid movement. The inclined-tube manometer is used for smaller pressure measurements or where greater accuracy is required. One limb of the inclined tube manometer forms into a reservoir and the other is inclined at a known angle. Their accuracy relies less on the reader's skills, are more sensitive but unless the inclined limb is relatively long they cannot be used over a wide range of pressures. Inclined tube manometers cannot be read remotely and it is usually used with gases.

Manometers have a variety of laboratory, industrial and specific applications such as visual monitoring of air and gas pressure for compressors, vacuum equipment and special tank applications such as medical gas cylinders, fire extinguishers, etc. In addition, mercury manometers are used for calibration purposes.

Tensiometers are designed to measure the surface tension of liquids, to determine the soil moisture tension and for measuring the tension in a wire, fibre or beam (answers.com, 2010). The mercury containing tensiometers are devices used for measuring the suction or negative pressure of soil water (soil water potential). The reason why tensiometers are covered with manometers in this report is that the only part of tensiometer potentially containing mercury is the manometer. However, some alternatives for mercury tensiometers are based on totally different methods of measuring the soil moisture, and consequently these alternatives are not related to alternatives for manometers.

A mercury tensiometer comprises of capillary tubing linking to the mercury manometer. The capillary tubes have at the other ends, inserted in the soil, porous cups, normally constructed from ceramic.

Tensiometers are mainly used for research applications, in the scientific study of soils and plants, or in agriculture for planning the irrigation scheduling (Lassen et al., 2008, Smajstrla & Harrison, 2002).

2. Description of release and exposure

Based on the approach described in the Part B of the main document, the estimations on i) the total amount of mercury accumulated in devices in the EU and ii) the amount of mercury placed on the market annually in the EU are used to describe the potential release and exposure during the waste phase of the devices (Table A2-1). Furthermore, to get a more comprehensive picture, the annual amounts iii) used in the production of devices, iv) imported into the EU and v) exported from the EU are given to illustrate the potential for direct exposure of workers during the production and service-life of the devices. However, it is stressed that this report does not further assess the potential concerns related to workers as explained in Part B. If quantitative estimates are not available, a qualitative description is given.

Table A2-1: Amounts of mercury accumulated, used in production, placed on the market and imported and exported in manometers (including tensiometers) in 2010.

Mercury	Estimated amounts
Pool accumulated in manometers in the EU	~ 4 t Hg Assuming 20 years lifetime for a manometer and no trend in number of devices placed on the market, results in 4 tonnes of Hg accumulated in manometers.
Placed on the market in manometers in the EU	0.04-0.4 t Hg/y (Lassen et al., 2008)
Used in production of manometers in the EU	No data available to quantify. At least one producer of Hg manometers and one of Hg tensiometers[51] in the EU (Lassen et al., 2008).
Imported into the EU in manometers	No data available.
Exported from the EU in manometers	No data available.

Box 1: General qualitative description of potential release and exposure

<u>Production phase</u>

Only one producer of mercury manometers and one producer of mercury tensiometers have been identified in the EU and the production of tensiometers was discontinued in 2008. (Lassen et al., 2008)

As the manometers and tensiometers are supplied without mercury due to weight and transport costs (the customers fill them in with mercury before use), there are no

[51] According to Lassen et al. (2008), the production of tensiometers may be discontinued.

mercury emissions during the production phase.

Use phase

There is no reliable information on the number of mercury manometers in use and thus on the related accumulated amount of mercury in the manometers. However, around 10-15 tensiometers are estimated to be sold per year in the EU (Lassen et al., 2008). According to Lassen et al. (2008) the professional manometer and tensiometers market in the EU is estimated to use 0.04-0.4 tonnes of mercury per year. Assuming an average service-life of 20 years for manometers and tensiometers, and having no trend in the number of devices placed on the market, results in accumulated stock of around 4 tonnes.

In Denmark, before the Danish ban, the mercury use was estimated at 4-8 kg per year (Lassen et al., 2010).

The mercury content of a U-tube manometer may vary but it is estimated that normally a manometer contains 70-140g mercury. Nevertheless, special manometers may contain up to 10 kg of mercury e.g. mercury manometer used as reference instrument in Denmark. It contains a 6 m mercury column with up to 5-10 kg of mercury. It is read with a laser and data are processed electronically.

The mercury manometers and tensiometers are shipped without mercury and filled with mercury by the user. Thus the risks related to use phase may be more relevant for manometers and tensiometers than other devices filled during the production. In addition, some mercury may be released in case of breakage e.g. over pressuring the manometer can result in the mercury being blown out of the tube and contaminating the surroundings. Nevertheless, risks related to waste phase are regarded to be most relevant for manometers.

Waste phase

The appropriate collection of mercury manometers and the handling of these devices in accordance with hazardous waste legislation are crucial for the potential releases of mercury to the environment. According Lassen et al. (2008) around 20 % of mercury in measuring devices is collected as hazardous waste. This indicates that emissions during the waste phase are likely to occur.

3. Available information on alternatives (Part C)

3.1 Identification of potential alternative techniques

Different types of alternatives have been identified for mercury manometers: Liquid filled in tube manometers, elastic pressure sensors and electronic manometers (or digital manometers). The mercury manometers contained by the tensiometers are commonly replaced by elastic pressure sensors or electronic manometers. In addition, the moisture soil measurement can be carried out by quantitative methods like gravimetric soil sampling, neutron scatter, or dielectric constant methods (Morris, 2006).

Liquid filled in tube manometers are built on the same principle as the mercury ones, but they use other liquids, like water (most common used after the mercury) or alcohols. The pressure is expressed as depth of the fluid used. The density of the fluid can vary (diferencesbetween.net, 2011).

Mechanical alternatives / Elastic pressure sensors contain elements that flex, stretch, or temporarily deforms when a pressure is applied. They initially convert pressure into a displacement which is then read on a scale. The following two types of elastic pressure sensors have been identified:

Bourdon tube manometers consist of a tube of elliptical or oval cross section. A common design is the C-shaped tube sealed at one end and connected to a pointer. When increased pressure is applied to the open end, it deflects outwards proportionate with the pressure. This motion is transferred through a link to gear train connected to an indicating needle. Bourdon gauges are normally connected to gas cylinders to give an indication of the quantity of gas in the cylinders.

Pressure gauges with diaphragms contain a two sided flexible membrane with a known pressure. One side is an enclosed capsule containing air or other fluid at a predetermined pressure. The other side can be either opened or screwed into the system to be measured. The diagram is attached to a meter measuring how much the membrane bends when an outside pressure is applied. The pressure is expressed as the amount of force per unit (diferencesbetween.net, 2010). They are either:
- Mechanical pressure gauges are measuring devices containing a needle (pointer) attached to the diaphragm and rotating throughout a graduated dial.
- Electric resistance strain gauges uses a long strip of an electric resistor that resists the flow of electricity attached to the diaphragm. The bending diaphragm stretches out the resistor, increasing the resistance. The high variations of the diaphragm increase the resistance and drop the electric current. The outside pressure is determined by measuring the current.

Electronic manometers make use of transducers which transform the sensor response into a pressure-related electrical quantity in the form of either analogue or digital signals. They measure the pressure by use of pressure transducers, e.g. piezoelectric or capacitance pressure transducers which are connected via an analogue to digital converter to a display or data logger.

Other devices than manometers are available to measure both absolute & gauge pressure and for the calibration of high accuracy barometers and Air Data Test Sets. The modern devices like model DPG10A from Chamois (Chamois, 2010) combine the metrological performance of pressure balance (a combination of pistons and weights) with the convenience of digital instrumentation.

Other alternative methods (than tensiometers) for the soil moisture measurement

The gravimetric method is a direct technique for determining the water content of soils. It involves weighing soil samples, drying them to a constant value of mass at 105°C, and using the difference in weight to calculate the amount of water in soil. For the soil moisture measurements of high value crops, large farms and scientific research purposes there are other techniques available: *neutron scatter*, *di-electric constant methods*, *time-domain reflectometry (TDR)*, *frequency domain reflectometry (FDR)*, and *infrared thermometry*.

3.2 Human health and environment risks related to alternatives

Liquid filled in tube manometers

The risk associated with the use of alternative liquids in manometers, such as water or alcohols, is considered to be negligible.

Mechanical alternatives / Elastic pressure sensors

Materials used for mechanical systems such as Bourdon tube manometers and pressure gauges with diaphragms are everyday materials such as plastics and stainless steel. There are no indications of risks to human health or the environment related to these mechanical system (see also description on mechanical alternatives in general part C).

Electronic alternatives

As described in general part C, the human health and environmental risks related to the use of electronic alternatives are insignificant in comparison with the potential emission and exposure associated with the amount of mercury in manometers.

Tensiometers

When the soil moisture is measured by other quantitative methods than by mercury tensiometers, like gravimetric soil sampling, neutron scatter, or dielectric constant methods, the associated risks vary as the techniques are based on totally different principles. The apparatus needed by these methods could contain other hazardous substances or they can be given by the high electrical power used or due to radioactive sources contained. However, these alternatives are not considered as direct substitutes for mercury tensiometers (see reasons in section 3.3), and the related risks are not considered further.

Overall the human health and environmental risks related to the alternative devices seems to negligible compared to the risks of mercury containing devices.

3.3 Technical feasibility of alternatives

According to a European producer of mercury manometers, there is no application for which mercury manometers cannot be replaced by other devices (Giussani 2008 as cited in Lassen et al., 2008).

According to a report from 2004 (Kemi, 2004), a special type of pressure measurement is required in the polyethylene manufacturing industry where a precision measurement is made at high temperature. The polyethylene product is evaluated by this pressure measurement, which is an important quality-assurance parameter. Alternatives have been tested but none of them have given the required result. Nevertheless, Swedish Chemicals Agency (Kemi) reports that there have not been any applications for exemptions to their national restriction for mercury barometers from 2005 up to now. As far as they are aware of, there have been no applications for exemption before 2005 either. Based on this information, technically feasible alternatives are available in this application.

<u>Liquid filled in tube manometers</u>

Any fluid can be used in manometers instead of mercury, but the mercury has the advantages of high density and low vapour pressure. For low pressure differences well above the vapour pressure of water, water is commonly used (and "inches of water" is a common pressure unit).

<u>Mechanical alternatives / Elastic pressure sensors</u>

Bourdon tube manometers

Bourdon tube manometers are more robust than mercury manometers and more suitable for measuring higher pressures. They are today sold for applications, where U-tube manometers with mercury were previously used (Lassen and Maag, 2006).

Pressure gauges with diaphragm elements

Pressure gauges with diaphragm are considered just as accurate as the traditional mercury manometer. For low-pressure applications metallic diaphragms and bellows are used (hydraulicspneumatics.com, 2010). Diaphragm elements are often used in gauges to indicate absolute pressure. A variety of options and accessories are available to enhance life and operation of gauges.

<u>Electronic manometers (or digital manometers)</u>

Electronic manometers are already widely used by professionals and there is increasing market for them. They have many advantages compared to mercury manometer as they require less servicing and maintenance and far less expertise and can thus be used by less experienced users. Compared with electronic manometers, the mercury manometers are more difficult to handle. Electronic manometers are also more precise than a mercury manometer if properly calibrated. They can be used for automatic and remote control.

For the heating and sanitations sectors, a type of small hand-held electronic manometers is available from many suppliers. They may serve similar purposes as the mercury manometers and are more user-friendly.

Other devices than manometers are also available on the market mainly for calibration uses and for absolute and gauge pressure measurements. They are modern devices containing pressure balances and digital parts. This combination results in high accuracy measurements.

Other alternative methods for (tensiometers) the soil moisture measurement

The gravimetric method is regarded to be too time consuming, labor-intensive, requiring sample equipment, weighing scale and an oven to be used for day-to day management decisions, this highly accurate and low-cost method is often used to calibrate other tools and indirect methods, such as neutron probe or di-electric constant methods. The spatial variability of soils and their water content implies a large number of samples. Other identified available techniques, like *neutron scatter*, *di-electric constant methods*, *time-domain reflectometry (TDR)*, *frequency domain reflectometry (FDR)*, and *infrared thermometry*, are generally more expensive, providing more features and not comparable to the more narrowed use of tensiometers.

3.4 Economic feasibility

According to Lassen and Maag (2006), the price of a U-tube mercury manometer is around 108 €. All the other prices quoted below are based on internet search conducted in February 2010 by ECHA and are meant to be indicative only.

Alternatives can replace the mercury manometer in all applications and, even more, they are usually cheaper than the corresponding mercury manometer. Liquid filled in tube manometers are built on the same principle as the mercury ones and their prices are on the range of €16 to 20. The market prices of bourdon tube manometers are also typically lower than the price of the mercury one and they are more robust and more suitable for measuring higher pressures (Lassen and Maag 2006). Prices for them range from €54 to 122. Prices for pressure gauges range from €30 to 76, depending on the used material. Finally, the electronic manometers have many advantages over the mercury ones, and there is increasing market for them. However, the price of electronic manometers is about 3-4 times higher for similar pressure range. As the electronic manometers have the advantage of automatic measurements they cannot be directly compared to mercury manometers (Lassen and Maag 2006). The internet search suggested a price range from €110 to 350 for electronic manometers.

Since there is no application for which mercury manometers cannot be replaced by other devices and because alternatives are usually available at approximately the same price as that of a mercury manometer (see e.g. Lassen et al., 2008) there is no need for further compliance cost analysis to show that these devices are economically feasible options.

Two technically feasible devices, electronic tensiometers and bourden tube tensiometers, are already replacing the mercury tensiometers in all applications. According to Lassen et al. (2008) the prices of alternatives are below or equal to the prices of mercury tensiometers in the case of electronic devices and slightly higher for the tensiometers containing mechanical bourdon manometers. There is no evidence suggesting that there would be differences in recurrent costs between mercury and mercury-free tensiometers.

It is estimated that a waste treatment cost for mercury sphygmomanometers is €30 compared to the €2 for electronic alternative and €1 for mechanical alternative (Concorde, 2009). As mercury manometers contain around the same amount or more mercury than sphygmomanometers, the corresponding cost difference between mercury and mercury free manometers can be estimated to be the same or more. There are no manometer specific estimates on waste treatment costs available.

4. Justification why the proposed restriction is the most appropriate Community-wide measure (Part E)

4.1. Identification and description of potential risk management options

4.1.1 Risk to be addressed – the baseline

As described in section B.2, the total estimated amount of mercury placed on the market in measuring devices containing mercury is used to describe the maximum potential for mercury emissions to the environment that might ultimately occur. The maximum emission potential is estimated to be 0.04-0.4 tonnes per year in the EU including tensiometers (Lassen et al., 2008).

No response was received from the producers of manometers and tensiometers during the stakeholders consultation to assess the trend in the number (or the current number) of mercury manometers supplied annually to the EU markets.

Although not the primary concern, it is worth mentioning that direct exposure of workers can occur during production (but note that manometers are usually sold without mercury and are filled by the users), professional/industrial use of the devices and during waste management operations.

4.1.2 Options for restrictions

Since there is no application for which mercury manometers and tensiometers cannot be replaced by mercury-free alternatives already available, the only assessed restriction option is the restriction on the placing on the market of new mercury manometers and tensiometers for professional use. An exemption for mercury manometers which are to be displayed in exhibitions for cultural and historical purposes is proposed. In addition, SEAC proposes a derogation for devices that were more than 50 years old on 3 October 2007. These exemption are to allow the placing on the market of historically and culturally valuable devices.

4.2 Assessment of risk management option: Restriction of the placing on the market of mercury manometers and tensiometers

4.2.1 Effectiveness

Risk reduction capacity

The maximum risk reduction achieved by introducing the restriction will be an annual reduction of metallic mercury entering the EU society of approximately 0.04-0.4 tonnes per year. This volume is a measure for reduction of the maximum potential for mercury emissions to the environment that might ultimately occur. In addition, it can be mentioned that the volume also reduces direct exposure of workers in use and waste phase.

The emissions resulting from the use and waste phase of the mercury manometers already in use will not be affected.

Proportionality

Technical feasibility

Based on the information from Lassen et al. (2008) technically feasible alternatives are available and in use.

Economic feasibility

The alternatives are usually cheaper than mercury manometers. Electronic manometers are an exception being 3-4 times more expensive but also offering automatic measurement. Given that technically equivalent alternatives are cheaper, it is estimated that restricting the placing on the market of mercury manometers and tensiometers would not introduce additional costs. In other words the compliance costs of the restriction would be ~€0 (i.e. cost-effectiveness ~€0 per kg Hg not placed on the market).

Given that the additional costs of using mercury free manometers and tensiometers are ~€0, it is evident that these costs are proportionate to the risks related to mercury. To better understand the estimated compliance costs in relation to other actions and policies to reduce mercury, one can compare the cost effectiveness of the proposed restriction (~€0/kg Hg) with the policy options reviewed in Appendix 2

4.2.2 Practicality

Implementability and manageability

The technical feasible alternatives are already in use and it is not expected to have changes in the costs affecting the users. As it is not proposed to restrict the current use, the mercury manometers may be used until the end of the service life.

Enforceability

The compliance with restriction on placing on the market of mercury manometers can be verified by following the fairly limited number of producers, importers and distributors of these equipments.

4.3 The proposed restriction(s) and summary of the justifications

Proposal:

Restriction on the placing on the market of mercury manometers and tensiometers after 18 months of entry into force of the amendment of Annex XVII.

Summary of justification:

The main purpose of the proposed restrictions is to reduce the mercury pool in the society, thus avoiding negative impacts on human health and environment. Technically and economically feasible alternatives to mercury containing manometers (including tensiometers) are available and in use. The alternatives are available at approximately the same price as mercury manometers.

Annex 3a: Sphygmomanometers

Content

1. Technical description of sphygmomanometers

Mercury sphygmomanometers are devices used to measure blood pressure. They include a mercury manometer, an upper arm cuff, and a hand inflation bulb with a pressure control valve and require the use of a stethoscope. The method relies on the auscultatory technique, in which a clinician determines systolic and diastolic blood pressures (SBP and DBP) by listening (auscultating) for sounds that characterise different stages of blood flow during cuff deflation (Korotkoff sounds). Placing on the market of mercury sphygmomanometers intended for sale to the general public is already restricted by the existing restriction entry 18a in the Annex XVII of REACH Regulation. Thus, this report covers only professional uses.

2. Description of release and exposure

Based on the approach described in the Part B of the main document, the estimations on i) the total amount of mercury accumulated in devices in the EU and ii) the amount of mercury placed on the market annually in the EU are used to describe the potential release and exposure during the waste phase of the devices. (Table A3a-1). Furthermore, to get a more comprehensive picture, the annual amounts iii) used in the production of devices, iv) imported into the EU and v) exported from the EU are given to illustrate the potential for direct exposure of workers during the production and service-life of the devices. However, it is stressed that this report does not further assess the potential concerns related to workers as explained in Part B.

Table A3a-1: Amounts of mercury accumulated, used in production, placed on the market and imported and exported in sphygmomanometers in 2010

Mercury	Estimated amounts
Pool accumulated in sphygmomanometers in the EU	~ 26-51 t Hg
Placed on the market in sphygmomanometers in the EU	~ 2.6-5.1 t Hg/y
Used in production of sphygmomanometers in the EU	~ 6-9 t Hg/y (Based on EEB, 2009).
Imported into the EU in sphygmomanometers	~ 2-4 t Hg/y (Based on EEB, 2009)
Exported from the EU in sphygmomanometers	~ 5-8 t Hg/y (EEB, 2009), i.e. 85 % of production (Lassen et al., 2008)

Box 1: General qualitative description of potential release and exposure

Production phase

In addition to releases from the use and waste phase of sphygmomanometers, as described below, some emissions to the environment and exposure of workers occur in the production phase of mercury sphygmomanometers. It is estimated that around 6-9 tonnes of mercury is used annually in the production of sphygmomanometers in the EU. Around 5-8 tonnes of that is exported from the EU in sphygmomanometers. (EEB, 2009) According to Lassen et al. (2008) the production of mercury sphygmomanometers employ 30-50 persons in the EU.

Considering that the waste phase is seen as the main problem, and considering that having quantitative information on emissions would not impact the conclusions on the feasibility of alternatives, no further efforts were made to obtain such information.

<u>Service-life</u>

The current pool of mercury in sphygmomanometers in society is roughly estimated to be between 26 and 51 tonnes[52].

Mercury-containing measuring devices are used by private practitioners as well as in hospitals. The amount of mercury in each single place of use is small (around 85 g per device) and the use is geographically wide spread.

In the event of breakage or leaks occurring during the use of sphygmomanometers, workers and patients may be exposed (Lassen et al. (2008) and EEB (2009)). Cleaning up of spills is not likely to happen in an appropriate way, and proper ventilation of the room might be forgotten. In addition breakage and leakage can result in releases to the environment.

<u>Waste phase of sphygmomanometers</u>

The amount of mercury in sphygmomanometers placed on the market in the EU in 2010 is estimated to be between 2.6 and 5.1 tonnes. This amount is in the range estimated by Lassen et al. (2008) of 3-6 tonnes per year. This indicates also the amount of mercury disposed with sphygmomanometers annually. However, due to the assumed declining trend in the number of mercury sphygmomanometers placed on the market per year after 2010, also the amount of mercury disposed with these devices is declining (Lassen et al., 2010). Lassen et al. (2008) estimated the collection rate as hazardous waste for all the mercury containing measuring devices of 20%.

In particular the waste phase (separate collection of mercury sphygmomanometers and the handling of these devices in accordance with hazardous waste legislation) is crucial for the potential releases of mercury to the environment. The appropriate collection of sphygmomanometers at the end of their service life as hazardous waste has been reported to be poor in hospitals. A survey by the European Environmental Bureau (EEB) in 8 countries (Czech Republic, France, Germany, Greece, Hungary, Italy, Spain and United Kingdom) revealed that only half of the 37 interviewees

[52] Lassen et al. (2008) estimated that around 30 000 to 60 000 mercury sphygmomanometers are placed on the market annually in the EU 27. Assuming that there was no trend in number of devices sold annually between 2000 and 2010, and assuming a lifetime of 10 years for mercury sphygmomanometers gives an estimate of 300 000 to 600 000 mercury sphygmomanometers accumulated in the society in 2010. Assuming that one mercury sphygmomanometer contains in average 85 g of mercury gives an estimate of 26 to 51 tonnes of mercury accumulated in the society in sphygmomanometers.

(senior administrators, administrators, doctors, nursing directors, nurses, biomedical and technical specialists and other staff) were aware that mercury waste has to be collected separately to other waste streams. Some interviewees said that infectious hospital waste and hazardous waste streams were collected in the same bins. Even 30% of the interviewees stated that cleaning staff would discard mercury waste with the normal waste (Concorde East/West 2009). This relatively strong picture might need to be moderated bearing in mind the small sample size (n=37). Nevertheless the survey gives an indication that the awareness on how to dispose off mercury is poor, and that collection rates for mercury-containing measuring devices are low.

The sphygmomanometer waste ends-up partly in hospital waste for incineration, partly in municipal waste, and partly in hazardous waste. There is no information on how well the private practitioners take care of the separate collection and correct disposal of the mercury devices. However, it is not likely that the situation would be better than in hospitals. Overall this matches the general collection estimates for mercury-containing measuring devices in the report from Lassen et al. (2008) (estimated collection rate as hazardous waste of 20%).

3. Available information on alternatives (Part C)

The opinion of SCENIHR (2009) is the main basis for the information in this section and it provides more detailed information on mercury sphygmomanometers and mercury-free alternatives.

3.1 Identification of potential alternative techniques

There are several types of mercury-free alternatives on the market for blood pressure measurement to address the full range of functions required by the health care sector. These alternatives are based on either auscultatory or oscillometric techniques. There are also devices on the market utilising both techniques. Different types of sphygmomanometers in use can be categorised for instance in terms of inflation method, manometer type, need for using a stethoscope, blood pressure measurement frequency, placement of the pressure cuff, need for electrical current, etc.

The following categorisation into alternative devices is used in Sections 3.3 and 3.4 when assessing the technical and economic feasibility:

- Sphygmomanometers based on auscultatory technique
    - Non-automated aneroid sphygmomanometers (e.g. shock-resistant aneroid)
    - Non-automated electronic sphygmomanometers
    - Automated auscultatory sphygmomanometers

- Sphygmomanometers based on oscillometric techniques
    - Semiautomatic oscillometric sphygmomanometers
    - Automated oscillometric sphygmomanometers

3.2 Human health and environment risks related to alternatives

Mechanical alternatives

Materials used for mechanical systems (non-automated aneroid sphygmomanometers) are everyday materials such as plastics and stainless steel. There are no indications of risks to human health or the environment related to these mechanical system (see also description on mechanical alternatives in general part C).

Electronic alternatives

As described in general part C, the human health and environmental risks related to the use of electronic alternatives (non-automated electronic sphygmomanometers, automated auscultatory sphygmomanometers, and oscillometric sphygmomanometers) are insignificant in comparison with the potential emission and exposure associated with the amount of mercury in manometers.

Thus, in general, the human health and environmental risks are insignificant in comparison with the potential emission and exposure associated with the amount of mercury in sphygmomanometers. The accuracy and reliability of the blood pressure measurements with alternative devices is assessed and documented in Section 3.3 (technical feasibility of alternatives) below.

3.3 Technical feasibility of alternatives

3.3.1 Sphygmomanometers based on auscultatory technique

The auscultation method is based on the observation of the recurrence of the blood flow in the occluded artery (by using a cuff) of the upper arm by listening to the sounds when the occlusion is completely removed (by dilation of the cuff) and normal blood flow is restored. All the mercury containing sphygmomanometers are based on the auscultatory method.

Clinically validated, auscultatory mercury-free devices are equivalent to mercury sphygmomanometers, and are thus suitable also for specific groups of patients, including patients with arrhythmias, diabetes, pre-eclampsia and the elderly (SCENIHR 2009).

Compared to the mercury sphygmomanometers, the validated manual mercury-free sphygmomanometers allow, in some cases, obtaining a faster reading. In addition, the use of them obviously avoids all hazards and costs generated by the mercury. All manual mercury-free devices are prone to the problems related to the auscultatory technique, like observer bias and terminal digit preference, a phenomenon whereby an observer rounds off a measurement to a digit of his or her choosing. In this respect there is no difference to mercury-containing devices. (Concorde East/West, 2009)

Non-automated aneroid sphygmomanometers (e.g. shock-resistant aneroid)

The aneroid sphygmomanometers for manual reading work in a similar way as the mercury sphygmomanometers, but they contain an aneroid gauge that replaces the mercury manometer. Their accuracy and reliability vary with the design and quality of device. The aneroid sphygmomanometers have been in use for about 100 years and when used properly, and a proper maintenance protocol is followed, give accurate results.

The aneroid devices may be susceptible to calibration drift without this being apparent to the user. In general, aneroid sphygmomanometers should be calibrated according to the manufacturer's recommendation, or at least annually (IAG, 2005). According to Concorde (2009), the recommended calibration frequency by the British Hypertension Society (BHS) for aneroid shock-resistant sphygmomanometers is once a year, compared to the mercury devices typically needing calibration once every two years. Better designs to deal with this problem have recently appeared, after producers introduced a new concept with a resulting more shock resistant sphygmomanometer and a 5-year calibration warranty.

For the clinical use, several aneroid sphygmomanometers are validated by the British Hypertension Society (BHS 2008).

Non-automated electronic sphygmomanometers

The manual electronic sphygmomanometers work in a similar way to the mercury sphygmomanometers, but combine an electronic manometer (electrical transducer instead of mercury) with a digital display (numerical, circular/linear/bar graph) for manual reading. Validated manual electronic sphygmomanometers are available and provide the same accuracy as mercury devices. According to Concorde (2009), the BHS recommends electronic auscultatory sphygmomanometers to be calibrated once in three years.

Automated auscultatory sphygmomanometers

The automated auscultatory devices were designed in the 1970's to replace the observer and stethoscope with a microphone and some analogue electronics. These devices automatically display each detected Korotkov sound. Automated auscultatory sphygmomanometers are still used to replace oscillometric devices for patients with an irregular heart beat. The reliability of automated auscultatory devices depends on the correct placement of the microphone.

3.3.2 Sphygmomanometers based on oscillometric techniques

Oscillometric sphygmomanometers measure changes in artery pulsation during cuff inflation/deflation and then use software containing algorithms to calculate the systolic and diastolic values. As oscillometric devices operate on the bases of a different principle, they have not been considered as one-to-one alternatives for mercury sphygmomanometers.

Oscillometric devices have many advantages, and there is an increasing market for them. They require less servicing and maintenance than mercury sphygmomanometers, although they need to undergo regular checks. They also require far less expertise and can be used by patients themselves, thus removing the white-coat effect and offer more reproducible blood measurements. Oscillometric devices can also be used by patients with infirmities such as arthritis and deafness. They have also been reported to be more predictive of cardiovascular events.

Despite the above mentioned advantages of oscillometric devices, the auscultatory blood pressure measurements are necessary for some specific clinical conditions including arrhythmia, pre-eclampsia and certain vascular diseases. Thus, calibrated manual devices should be available in all clinical areas in case they are needed to check any non-auscultatory blood pressure measurements on individual patients.

<u>Semi-automatic oscillometric sphygmomanometers</u>

Semi-automatic devices based on the oscillometric technique include an electronic monitor with a pressure sensor, a digital display, an upper arm cuff and a hand-operated inflation bulb. The semi-automatic electronic devices are today standard for home/self assessment and also widely used by general medical practitioners.

According to SCENIHR (2009) opinion, some validated semi-automated sphygmomanometers based on oscillometry are available and partly replacing the mercury sphygmomanometers, even though they are not regarded as technically equivalent alternatives. They can be used by hospitals and general practitioners in most clinical conditions, but they are not suitable for measuring blood pressure of patients with pre-eclampsia, arrhythmias such as fibrillation, and for reasons that are not always apparent, probably influenced by arterial wall properties and pulse pressure (SCENIHR, 2009).

<u>Automated oscillometric sphygmomanometers</u>

Automated blood pressure devices for hospital use are more advanced equipment, which often combines the measurements of blood pressure with monitoring of temperature, heart rate and blood oxygen level. An accurate automated sphygmomanometer capable of providing printouts of systolic and diastolic blood pressure, together with heart rate and the time and date of measurement, should eliminate errors of interpretation, abolish observer bias and terminal digit preference. The devices for both 24-hour measurements and blood pressure measurements at home are more reproducible and predict cardiovascular events more precisely than blood pressure measurements in the clinic. The price of this equipment is typically on the order of 10 times the price of a mercury sphygmomanometer, but these advanced devices cannot be directly compared to mercury sphygmomanometers, as they have many more features.

3.3.3 Opinion of SCENIHR

SCENIHR (2009) recognised in its opinion that technically feasible alternatives exist, and that the mercury sphygmomanometers are gradually disappearing from clinical use. Clinically validated, auscultatory mercury-free devices are equivalent to mercury sphygmomanometers, and are thus suitable also for specific groups of patients, including patients with arrhythmias, diabetes, pre-eclampsia and the elderly (SCENIHR, 2009).

Mercury-free blood pressure measuring devices (when clinically validated) are generally reliable substitutes for mercury-containing sphygmomanometers in clinical practice. SCENIHR (2009) identified only two minor applications, where mercury containing measuring devices would still be needed.

- "For on-going, long-term, epidemiological studies currently using mercury sphygmomanometers it is advisable not to change the method of measurement. Therefore it will be necessary to keep mercury sphygmomanometers available in order to compare them with the alternatives in these studies." (SCENIHR 2009)

- "It is recommended that mercury sphygmomanometers remain available as a reference standard for clinical validation of existing and future mercury-free blood-pressure measurement devices. Therefore, the mercury sphygmomanometer should remain available as a reference standard until an alternative device is developed and recognised as such." (SCENIHR 2009)

3.4 Economic feasibility

Different models of sphygmomanometers even within each category (e.g. shock-resistant aneroid) vary in terms of quality and properties and there is correspondingly a large price range. In addition the way sphygmomanometers are used (and misused) varies greatly among different users (e.g. the level of maintenance and frequency of calibration ranges from none at all to precisely following the producer's recommendations). Thus, it is difficult to estimate how well the assumptions made when assessing the economic feasibility (including compliance costs in Annex 3b) of "representative" devices reflects the reality.

Two technically feasible devices based on auscultatory method, i.e. shock-resistant aneroid and (non-automated) electronic sphygmomanometers, are assessed against their economic feasibility. They can replace the mercury sphygmomanometer in all clinical conditions. The main results concerning economic feasibility are given in table A3a-2. It should be noted that the annualised costs of devices are highly sensitive to assumptions regarding the average lifetime and calibration frequencies. A detailed analysis including input data is available in Annex 3b.

Table A3a-2: Average prices of representative sphygmomanometers (ex factory, without VAT)

	Sphygmomanometer			
	Auscultatory			Oscillometric
	Mercury containing	Shock-resistant aneroid	Electronic	Semi-automatic
Investment cost (price of the device)	€40	€40	€110	€40
Average lifetime	10 years	5 years	10 years	not available
Annualised recurrent cost (including e.g. calibration and waste treatment costs)	€9	€16	€9	not available
Annualised cost per device (including investment and recurrent costs)	€14	€25	€22	not available

Source: Lassen et al. (2010), for oscillometric device Lassen et al. (2008)

Semi-automatic oscillometric devices are also reported to replace mercury sphygmomanometers. According to Lassen et al. (2008) they are available at approximately the same price as that of a mercury or shock-resistant aneroid sphygmomanometer. While these devices seem to be economically feasible they have not been analysed further neither in Annex 3b nor in section E. This is justified as the results of the analysis would not differ much from compliance cost calculations of shock resistant aneroid sphygmomanometers, which are analysed in detail.

The annualised cost of alternatives is estimated to be around €10 higher than the annualised cost of mercury sphygmomanometer. However, as the labour cost of using sphygmomanometer is much higher than the price of the equipment the overall impact on health care costs is insignificant[53]. Thus the alternatives are considered to be economically feasible for the users.

[53] Assuming that EU average cost of a 20 minute visit to a health care provider is (with overhead) €50 one can estimate that the cost of a blood pressure measurement (of 2 minutes) is about €5 in labour cost while the additional equipment cost is about €0.025 per measurement (€10 euros per annum divided by an assumed average blood pressure measurements of 400 per year). Comparing with the labour cost of measuring blood pressure, the additional cost is about 0,5%.

4. Justification why the proposed restriction is the most appropriate Community-wide measure (Part E)

4.1 Identification and description of potential risk management options

4.1.1 Risk to be addressed – the baseline

As described in section B.2, the total estimated amount of mercury placed on the market in measuring devices containing mercury is used to describe the maximum potential for mercury emissions to the environment that might ultimately occur. The amount of mercury in sphygmomanometers placed on the market in the EU is estimated to be around 4 tonnes in the EU in 2010 (see section 2). Based on information from producers of sphygmomanometers (Lassen et al., 2010) it is estimated that without additional legislative action the European market of mercury sphygmomanometers will decline by about 5% annually, i.e. from 45,000 in 2010 to about 28,000 in 2020.

The pool of mercury in sphygmomanometers in use in the EU is estimated to be around 40 tonnes in 2010 as described in the Chapter 2. The above mentioned declining trend in the placing on the market the mercury sphygmomanometers has an effect on the pool in the future.

Lassen et al. (2008) estimated that only 20% of the mercury in measuring devices, including sphygmomanometers, is collected as hazardous waste. It is difficult to estimate the future trend of collection and the share of proper waste management. However, there is no indication that the collection rate would improve without new targeted action in the future.

Although not the primary concern, it is worth mentioning that direct exposure of workers can occur during production, professional use of the sphygmomanometers and during waste management operations.

4.1.2 Options for restrictions

Based on the tentative screening of possible restriction options, two options to reduce the risk from mercury containing sphygmomanometers in the EU have been assessed more in detail. They are 1) Restriction on the placing on the market and 2) Restriction on the use of mercury sphygmomanometers. The option 2 should be regarded as a possible additional element to option 1 and its impacts are not assessed independently. Both options include derogations for specific applications of mercury sphygmomanometers based on the opinion of SCENIHR (2009). In addition, both options have a derogation to allow the placing on the market of historically and culturally valuable sphygmomanometers (see Part E of the main document for details).

1) Restriction on the placing on the market with limited derogations:

Restriction of placing on the market mercury containing sphygmomanometers after 18 months of entry into force with derogations for

a. on-going (at the time of entry into force) epidemiological studies
b. validation of new mercury-free devices

2) Restriction of use of mercury containing sphygmomanometers in addition to option 1:

Restriction of use of mercury containing sphygmomanometers after 6.5 (i.e. 5 years after ban on placing on the market) years of entry into force with derogations for

a. on-going (in the time of entry into force) epidemiological studies
b. validation of new mercury-free devices

In addition to these two restriction options which are further assessed in this report, the following additional aspects were considered, but for reasons explained below not retained for further assessment:

Conditions to prevent non-compliance were considered in conjunction with restriction options 1 and 2. Since the use of mercury containing sphygmomanometers for validation purposes and for epidemiological studies would not be restricted, mercury-containing devices would still be available on the market, and might be bought and used (illegally) for restricted uses. To prevent this kind of non-compliance, suppliers of mercury sphygmomanometers could be required to keep a list of their customers and their uses. Such a list could be used by enforcement authorities when checking the compliance with the restriction. Another possibility to prevent non-compliance, would be to require suppliers to inform the end-user about the allowed uses. These conditions were not considered further. The reason was that the administrative burden was considered rather high and not to be proportionate to the relatively small risk of some professional end-users buying mercury containing sphygmomanometers for a restricted use.

4.2 Assessment of risk management options (sphygmomanometers)

4.2.1 Option 1: Restricting the placing on the market of mercury sphygmomanometers

4.2.1.1 Effectiveness

Risk reduction capacity

The risk reduction achieved by introducing the restriction is described as an annual reduction of metallic mercury used in the EU. That is 3.8 tonnes in 2010 and declining 5 % annually. E.g. in 2015 risk reduction capacity is 3.0 tonnes and in 2024 1.9 tonnes of avoided mercury. This volume is a measure for reduction of the maximum potential for mercury emissions to the environment that might ultimately occur. In addition, it can be mentioned that the volume also reduces direct exposure of workers in production, use and waste phase -with the exception of exposure related to remaining production for exports.

Emissions related to the use and waste phase of devices already on the market will not be affected.

The number of new devices required for epidemiological studies and for validation of new mercury-free alternatives is expected to be very low, probably much less than 100 sphygmomanometers per year. Consequently, these derogations would result in very low volumes of ‘new’ mercury.

The risk associated with the alternative aneroid and electronic devices is considered to be insignificant in comparison with the potential emission and exposure associated with the amount of mercury in mercury-containing sphygmomanometers (see section C.1.2).

Proportionality

The proposed restriction is targeted to reduce the mercury pool in the society by gradually substituting mercury-containing sphygmomanometers with technically and economically feasible mercury-free alternatives. The proposed derogations for epidemiological studies and for validation of new mercury-free alternatives have been designed to ensure that the proposed restriction is proportionate.

<u>Technical feasibility</u>

The technical feasibility of alternatives is discussed more in detail in Chapter C.1.3.1. The SCENIHR (2009) opinion established that technically feasible alternatives are already available on the market and have a considerable market share. Two technically feasible alternatives have been identified. The alternatives are based on the auscultatory technique: i) shock resistant aneroid sphygmomanometer and ii) electronic sphygmomanometer. In addition, some oscillometric semi-automatic or automatic devices can replace mercury devices in most of the applications.

SCENIHR (2009) identified two applications where the use of mercury-containing sphygmomanometers would still be necessary because they considered that in these applications technically feasible alternatives do not exist. Based on the evidence given by SCENIHR, it is proposed that derogations apply for the following two applications:

> (1) use of mercury containing sphygmomanometers as a reference standard for clinical validation studies of existing and future non-mercury-containing sphygmomanometers ; and
> (2) use of mercury containing sphygmomanometers for on-going, epidemiological studies currently using mercury sphygmomanometers.

Economic feasibility (including the costs)

In section C.1.3.1 the economic feasibility of alternatives was described. In this section the compliance and administrative costs are summarised. More detailed information on compliance costs including the values used in calculations can be found in Annex 3b. Two alternatives using auscultatory technique are assessed against their economic feasibility. These are i) shock-resistant aneroid and ii) electronic sphygmomanometer with manual reading.

A third alternative – based on oscillometric technique – has also been analysed to some extent in Chapter C, as it is according to SCENIHR (2009) replacing mercury-containing sphygmomanometer by some users. In this compliance costs analysis the oscillometric devices are not separately addressed. The reason is that even if some proportion of mercury containing devices were replaced by sphygmomanometers based on oscillometric method the related costs would be quite similar to the costs of shock-resistant aneroid devices.

The overall costs for an end-user of a sphygmomanometer consist of the investment (price of the device) and recurrent costs. Recurrent costs related to sphygmomanometers are caused for instance by calibrating, waste handling, batteries, spill response and training. As the available estimates for spill response and training have more uncertainty than other parameters, they are not considered in the "central" case. The central case can be regarded as the best estimate. Nevertheless, the effect of spill response is taken into account in the sensitivity analysis. Compliance cost calculations for sphygmomanometers are highly sensitive to the cost and frequency of calibration.

The table A3a-3 presents the main outcomes of the compliance cost analysis. Taking into account the uncertainties, the additional annualised cost per device is estimated to be between €25 and -€23, negative value representing cost savings. This means that substituting the mercury sphygmomanometer with mercury-free alternative would either decrease or increase the annualised cost of the user. In the central case estimate the additional annualised cost would be around €11 per device.

Table A3a-3: Summary of compliance costs of avoiding mercury in sphygmomanometers and cost effectiveness

	Central case	Sensitivity analysis Scenario 1 "high costs"	 Scenario 2 "low costs"
Annualised cost of mercury sphygmomanometer per device	€14	€9	€35
Annualised cost of alternative[54] per device	€25	€34	€12
Additional annualised cost of alternative[1] per device	€11	€25	-€23
Compliance costs (present value 2015-2034 in the EU)	€29 million	€120 million	-€44 million
Compliance costs (in 2024 in the EU)	€3.2 million	€12 million	-€4.2 million
Cost per kg of mercury avoided	€1300	€3000	-€2400

Source: Annex 3b

Based on the results on additional costs per device, it is estimated that the annual cost for reducing 1 kg of mercury in the production of sphygmomanometers is around €1300 per kg of mercury avoided. For sensitivity, two other estimates have been calculated. In the "high cost" scenario the cost per kg of mercury avoided would be €3000. However, the "low cost" scenario actually results €2400 savings for each kg of mercury avoided. This saving is due to lower recurrent costs for operating electronic sphygmomanometers than for mercury containing devices.

To better understand the compliance costs in relation to other actions and policies to reduce mercury, one can compare the cost effectiveness of the proposed restriction (€1,313/kg Hg) with the policy options reviewed in Appendix 2.

Administrative costs

The restriction of placing on the market of sphygmomanometers has not been analysed with regard to administrative costs. The reasons are explained in sections E.2.1.2 (practicality) and E.2.1.3 (monitorability). In summary, the administrative costs are assumed to be so low that no specific analysis was carried out.

[54] A representative device which takes into account the replacement ratio between aneroid and electric sphygmomanometers, i.e. in base case 80 % replaces the hg sphygmomanometer with aneroid and 20 % with electronic device, in Scenario 1 0/100% and in Scenario 2 95/5%.

4.2.1.2 Practicality

Implementability and manageability

According to the SCENIHR (2009) opinion and as discussed in Section C, technically feasible alternatives for mercury containing sphygmomanometers are already readily available in the EU. In Section 3.4 above and Annex 3b it is demonstrated that these alternatives are also economically feasible. As the production of mercury containing sphygmomanometers may continue for export, and the import of the devices is also allowed for derogated uses, the availability of mercury sphygmomanometers for derogated uses is covered. In summary, the necessary technology and economically feasible alternatives are already available on the market and the transitional period of 18 months would allow the retailers to handle the existing stock within the timeframe set in the restriction.

The proposed restriction and derogations are simple and therefore easy to understand for the actors. As the number of devices needed for derogated uses is marginal, the mercury containing sphygmomanometers should not to be advertised in the EU markets anymore. This will contribute to a better awareness on the restriction among the users of sphygmomanometers.

Enforceability

The compliance with the restriction on placing on the market of mercury containing sphygmomanometers can be verified by following the fairly limited number of producers, importers and distributors of these equipments.

As a result of the restriction, the number of mercury containing sphygmomanometers will decrease dramatically over time. The restriction on the placing on the market of mercury containing devices may also raise, at least temporarily, the awareness of the users of the devices on the need for special care during the use and disposal of the devices. Therefore, the restriction may help in the implementation and enforcement of waste legislation.

4.2.1.4 Overall assessment of restriction option 1

The amount of mercury introduced to the European market is estimated to reduce by 3.0-1.2 tonnes per annum between 2015 and 2034. The range is due to the declining trend in the number of mercury sphygmomanometers sold annually. The continued use of existing devices until the end of their service-life, taking into account the uncertainties related to their proper disposal, will continue to cause some emissions and exposure. The technical feasibility of alternatives is demonstrated by SCENIHR (2009) and the specific derogations for epidemiological studies and validation purposes were suggested. The cost of reducing the use of mercury in sphygmomanometers is estimated to be between -€2400 (i.e. saving) and €3000 with a central estimate of €1300 per kg of mercury. These costs are considered to be proportionate to the risk reduction capacity. To better understand the estimated compliance costs in relation to other actions and policies to reduce mercury, one can compare the cost effectiveness of the proposed restriction (€1300/kg Hg) with the policy options reviewed in Appendix 2.

4.2.2 Option 2: Restricting the use of sphygmomanometers

Restricting the use of existing sphygmomanometers is an additional element to restricting the placing on the market of the new devices. A transitional period of five years for a use ban after entry into force of restriction on placing on the market (Option 1) is proposed, i.e. the ban on the use would become effective 6.5 years after entry into force. This will allow the use of newly purchased equipment for a reasonable time and would give sufficient time to users to replace their devices. When assessing the effectiveness and practicality of this additional element, all results reported above for restriction on the placing on the market would apply as well.

4.2.2.1 Effectiveness

Risk reduction capacity

A use ban is a chance for implementing more effective national collection campaigns, and a possibility to bring the message of proper collection of the mercury containing devices across. In this way a higher proportion of the devices in use could be collected in compliance with waste legislation. Thus, mercury emissions will be reduced (but not avoided) from the waste phase. The risk reduction capacity would be limited in comparison with a restriction on the placing on the market of new devices, since the volume concerns mercury in devices that are already on the market, no emissions can be avoided during the production and only very little emissions would be avoided in the use phase as a result of the earlier retirement of the devices. The risk reduction that can be associated to a use ban is a potential for a higher separate collection rate of the existing devices, and associated reduced (but not avoided) emissions in the waste phase. The impacts of a use ban and potential accompanying efforts for improving separate collection are difficult to assess and depend on the efforts taken by Member States to raise awareness on the use ban and to promote proper waste collection. In addition restricting the use of mercury containing sphygmomanometers could reduce the emission and exposure during the use and maintenance of the devices already on the market.

In addition, if the use of the devices is not restricted the awareness of proper waste handling of mercury sphygmomanometers among the few users still left after 10 or 20 years, will probably get worse. This may lead to more emissions to environment from the waste phase.

It can be estimated that the use ban after 6.5 years of the entry into force would affect approximately 200,000 mercury sphygmomanometers[55], i.e. 17 tonnes of mercury. The affected sphygmomanometers would be collected on average 2.5 years before the end of the service-life. Hence, the risk reduction capacity is dependent on the proposed transitional period.

[55] It can be assumed that banning the use after 5 years of the ban on placing on the market would have an effect on 200 000 mercury sphygmomanometers, as devices bought during five last years before the ban on placing on the market (between 2011-2015) would need to be replaced before end of their service-life.

Proportionality

Technical feasibility

Technical feasibility and availability of mercury-free sphygmomanometers is the same as for restriction option 1.

Achieving the risk reductions requires that Member States raise awareness on the use restriction and on proper disposal of sphygmomanometers. This can be achieved by different means, for instance by using the routine information channels and campaigns on proper collection and handling of hazardous waste. More targeted information campaigns could include the use of associations of medical professionals (websites, special magazines, events etc) or sending information letters to hospitals and private practitioners.

It might be sufficient to use and promote the use of existing hazardous waste collection points and treatment facilities. There can of course be national or local voluntary action to appoint temporary additional collection points. The suppliers of sphygmomanometers could also agree to voluntarily take back mercury-containing devices when new devices are bought.

Economic feasibility (including the costs)

Compliance costs
If the use of mercury containing sphygmomanometers were banned 5 years after the restriction for placing on the market becomes effective, it would truncate the service-life of around 200,000 existing devices. This will cause two kinds of additional costs for users. Before the use ban would become effective, it increases the annualised cost by reducing the life-time of the device (i.e. introducing a loss of residual value of the capital). After that it increases the annualised costs of the users as alternative devices are assessed to be more expensive in the central case. The additional present value compliance cost (for 2011-2024) is estimated to be around €8 million, i.e. approximately 26 % of the compliance costs of banning the placing on the market (present value for 2015-2034). To simplify the analysis, these calculations are based on the assumption that all the mercury sphygmomanometers are replaced by aneroid devices. The compliance costs are highly dependent on the proposed transitional period, just like the risk reduction capacity. For details, see Annex 3b.

Administrative costs
As the existing waste collection system can be used to collect sphygmomanometers no significant costs arising from the collection are foreseen. In fact the collection of existing devices can introduce cost savings related to enforcement of waste legislation and to keeping up the awareness and systems for collection of mercury sphygmomanometers.

Costs related to possible information campaign depends on the efforts taken by Member States. As an example, the cost of contacting all the doctors in the EU by sending letters is roughly estimated to be between €300,000-600,000[56]. The high awareness on the use restriction does not automatically translate to a high compliance. More intensive enforcement with additional inspections can be a way to promote the compliance, but will also introduce additional costs.

Total costs

The compliance costs of replacing 200 000 mercury sphygmomanometer before the end of their service-life are estimated to be around €8,000,000 (present value 2011-2024) and possible administrative costs between €300,000-600,000. Based on this, it is estimated that the cost of bringing forward the collection would be around €500 per kg of mercury. This cost is related to existing mercury sphygmomanometers and to bringing forward the disposal. This cost-effectiveness figure cannot be compared with cost-effectiveness as calculated in Restriction option 1.

4.2.2.2 Practicality

Implementability and manageability

Technically feasible alternatives available and the slightly increased costs for users due to earlier replacement of devices do not significantly affect the users.

As the mercury sphygmomanometers are widely used by general practitioners, achieving high awareness on requirements demands information campaigns. Without these campaigns the desired compliance and reduction in risk is not likely to be achieved. Due to high number of users, the efforts needed from Member States to raise the awareness to an adequate level can become significant. Member States may also use professional organisations to reach the practitioners. In addition, manufacturers and sellers of sphygmomanometers will promote the awareness on the legal requirements quite effectively, as they gain from the early replacement of mercury devices.

Enforceability

Mercury containing sphygmomanometers are widely used by general practitioners. Additional efforts needed to ensure high compliance may be significant, even if awareness is regarded to be at adequate level. In practice the enforcement of users may be limited due to dispersive use of sphygmomanometers.

4.2.2.4 Overall assessment of restriction option 2

[56] According to Eurostat, there is approximately 1.5 million doctors in the EU. Hospitals can be contacted with one letter, and it is assumed that 60-80% of doctors would be reached through hospitals. In addition, the staff time to prepare the letters is estimated to be 4-8 hours per Member State, i.e. 108-216 hours. Assuming an hourly expense of €30, the preparation of the letters would cost between €3240-6480 in total. Sending a letter can be estimated to cost €1 per letter.

Restricting the use of existing mercury containing sphygmomanometer is not suggested due to practical difficulties mainly in enforceability. After adequate awareness among users is achieved, the authorities would need to ensure high compliance. This could be done through enforcement. The risk reduction capacity is difficult to assess, but if a real improvement in waste handling is achieved, it could reduce the emissions from the waste phase significantly. The cost of bringing forward the collection of some mercury sphygmomanometers is estimated to be around €500 per kg of mercury. However, separate collection of devices entering the waste stage could also contribute to minimizing emissions of mercury and could therefore be considered as a complementary measure.

4.3 The proposed restriction(s) and summary of the justifications

Proposal:

The placing on the market of mercury containing sphygmomanometers after 18 months of entry into force of the amendment of Annex XVII with derogations to devices that are used (i) in epidemiological studies which are on-going on entry into force; (ii) as reference standards in clinical validation studies of mercury-free sphygmomanometers.

Summary of justification:

The main purpose of the proposed restrictions is to reduce the mercury pool in the society, thus avoiding negative impacts on human health and environment. Technically feasible alternatives to mercury containing sphygmomanometers are available with very limited exemptions as justified in the opinion of SCENIHR. Based on the assessment of compliance costs (in Annex 3b), the alternatives are also regarded as economically feasible. The cost-effectiveness (around €1300/kg) to avoid mercury is regarded as proportionate.

Annex 3b: Compliance cost calculations for Sphygmomanometers

Content

1. Introduction

This BD presents the compliance costs calculations of substituting mercury-containing sphygmomanometers with mercury-free alternatives after their service-life (restriction option 1 in the Annex XV restriction report). In addition, the additional cost impacts arising from the possible replacement of the existing stock of mercury containing sphygmomanometers (restriction option 2) is covered with limited efforts in Chapter 5. Two alternative devices (shock-resistant aneroid and electronic) are covered in the analysis due to their technical properties, which are quite similar to mercury-containing sphygmomanometer (e.g. manual reading as for mercury-containing sphygmomanometer). The technical feasibility of these alternatives has been assessed and verified by the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR 2009) and is not further discussed in this paper. Compliance costs are also calculated for this scenario, where both alternatives will gain a specific proportion of the markets.

2. Defining the temporal scope and choosing a representative year

The temporal scope of the analysis is established from the time when restriction is assumed to become effective in 2015 to 2034[57]. Taking into account the uncertainties related to available data and the assumed declining trend in the number of mercury sphygmomanometers 20 years scope is regarded sufficient. As the average lifetime of a mercury containing sphygmomanometer is estimated to be 10 years, the restriction would have its full effect in 2024, when all the existing mercury containing devices would be replaced.

The costs are reported in two ways:

1. In the cumulative approach the present values of costs are calculated for 2015-2034.
2. In the representative year approach the annualised costs, using the year 2024 as a representative year, are calculated.

3. Input data

The main sources of data used in the analysis are Lassen et al. (2008)[58], Concorde (2009)[59] and Lassen et al. (2010)[60]. The Table 1 below presents the input data used in

[57] This temporal scope is chosen for illustrative purposes. In reality the time when the restriction becomes effective (2015 in this analysis) depends on the speed of the decision making process and the transitional periods after entry into force.

[58] Options for reducing mercury use in products and applications, and the fate of mercury already circulating in society published by DG Environment. Available at http://ec.europa.eu/environment/chemicals/mercury/pdf/study_report2008.pdf

the analysis. The prices of devices (investment costs) are factory gate prices excluding VAT, but for other costs (recurrent costs) it is not known if the VAT is included or not.

In addition to data used for central case, the Table A3b-1 presents the values for parameters used in sensitivity analysis (scenarios 1 and 2). The sensitivity analysis with results is presented in Chapter 7.

4. Changes in the characteristics of the good

The value related to changes in characteristics of the good is not assessed in this analysis due to lack of data on end-users needs and perceptions. The technical feasibility of alternatives has been assessed and verified by Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR). The fact that end-users have not replaced the mercury sphygmomanometers with possibly more economical alternatives (resulting in cost savings calculated in Scenario 2), may indicate that certain characteristics of mercury devices are more valuable than perceived in this analysis. This might also be due to asymmetric (incorrect) information among practitioners on quality of alternative devices.

[59] Turning up the Pressure: Phasing out Mercury Sphygmomanometers for Professional Use published by European Environmental Bureau. Available at http://www.eeb.org/publication/2009/SphygReport_EEB_Final-A5_11Jun2009.pdf

[60] Appendix 3 of the restriction report

Table A3b-1: Input data used in the analysis

Parameter	Device	Central case	Scenario 1: High costs	Scenario 2: Low costs
Discount rate		4%	4%	4%
Mercury devices sold per year 2010		45000	45000	45000
Annual decrease in number of devices sold		5%	0%	10%
Mercury per device (kg)		0.085	0.085	0.085
Average lifetime (years)	Mercury	10	10	**9**
	Shock-resistant aneroid	5	**4**	**6**
	Electronic	10	**6**	**15**
Investment cost (price of device)	Mercury	€ 40	€ 40	€ 40
	Shock-resistant aneroid	€ 40	€ 40	€ 40
	Electronic	€ 110	€ 110	**€ 90**[61]
Calibration costs (per calibration)	Mercury	€ 15	**€ 30**	**€ 30**
	Shock-resistant aneroid	€ 20	**€ 30**	**€ 30**
	Electronic	€ 20	**€ 40**	**€ 40**
Calibration frequency (once in *x* years)	Mercury	2	**5**	2
	Shock-resistant aneroid	1	1	**5**
	Electronic	3	3	**4**
Batteries (per year)	Mercury	€ 0	€ 0	€ 0
	Shock-resistant aneroid	€ 0	€ 0	€ 0
	Electronic	€ 3	**€ 4**	**€ 2**
Waste treatment (per device) [62]	Mercury	€ 30	**€ 10**	**€ 40**
	Shock-resistant aneroid	€ 1	**€ 2**	€ 1
	Electronic	€ 2	**€ 4**	**€ 1**
Spill response (per year)	Mercury	€ 0	€ 0	**€ 12**
	Shock-resistant aneroid	€ 0	€ 0	€ 0
	Electronic	€ 0	€ 0	€ 0
Replacement ratio[63]		75/25	**100/0**	**95/5**

[61] To cover the possible trend of the price of the electronic sphygmomanometer, it is simply assumed in Scenario 2 that the price would be 90 € throughout the analysis (2015-2034). This has approximately the same effect on compliance costs as 2 % annual decrease in the price.

[62] It is not known if the estimate considers that not all the users dispose of the mercury sphygmomanometers in accordance of the hazardous waste legislation.

[63] The ratio of replacement of the mercury containing sphygmomanometers by aneroid or electronic alternatives.

5. Cost calculations

The calculations have been carried out in Excel sheets using NPV (for present value) and PMT (for annualised cost) worksheet functions. All values used in this analysis refer to year 2010 price level, i.e. the prices are "real" as the effect of inflation has not been included in the analysis. Throughout the analysis a 4% discount rate is used and the expenditures are assumed to occur in the beginning of each year, i.e. 1 of January.

Calculating investment costs

In the central case it is assumed that prices of mercury-containing and alternative devices do not change between 2015 and 2034. In reality, there could be change in the prices in favour of electronic sphygmomanometers due to relatively new technology used in the device. This assumption is included in the Scenario 2 presented in Chapter 7. Table A3b-2 presents the calculation of investment costs of mercury-containing sphygmomanometer and two alternative devices.

Table A3b-2: Annualised investment costs per device (in 2010 price level)

	Investment costs (€) per device		
Year	Baseline: Mercury sphygmomanometer	Alternative 1: Shock resistant aneroid sphygmomanometer	Alternative 2: Electronic sphygmomanometer
1	40	40	110
2	0	0	0
3	0	0	0
4	0	0	0
5	0	0	0
6	0		0
7	0		0
8	0		0
9	0		0
10	0		0
Annualised	**5**	**9**	**14**
Additional annualised		**4**	**9**

The prices of the mercury and shock-resistant aneroid devices are estimated to be €40, and electric device €110. Due to shorter lifetime of the Alternative 1 compared to mercury-containing device, the additional annualised investment cost is estimated to be €4 per device. For Alternative 2 additional annualised investment cost is estimated to be €9 per device.

Calculating recurrent costs

The recurrent costs of sphygmomanometers consist mainly of calibrating costs. In addition there are costs related to batteries for electronic device, waste handling, spill response and training but some of these costs are not considered in the central case analysis for the reason explained below. The devices are bought calibrated, i.e. the first calibration takes place at the earliest one year after the investment. The table A3b-3 presents the calculations of recurrent costs for different devices.

Table A3b-3: Annualised recurrent costs per device (in 2010 price level)

Year	Recurrent costs (€) per device		
	Baseline: Mercury sphygmomanometer	Alternative 1: Shock resistant aneroid sphygmomanometer	Alternative 2: Electronic sphygmomanometer
1	0	0	0
2	0	20	3
3	15	20	3
4	0	20	23
5	15	20	3
6	0	1	3
7	15	0	23
8	0	0	3
9	15	0	3
10	0	0	23
11	30	0	2
Annualised	**9**	**16**	**9**
Additional annualised		**8**[64]	**0**

The values of different parameters of recurrent costs are listed in table A3b-1 in Chapter 3. The additional annualised recurrent cost per device is estimated to be €8 for alternative 1 and €0 for alternative 2 compared to the baseline.

According to Concorde (2009) the annualised spill response cost per device is estimated to be €12 for the mercury containing sphygmomanometer and zero for alternatives (as there is no fear of mercury spill). The cost includes estimates on cost of spill kit, person-hours, spill area closure and cost of downtime, waste disposal etc. In addition it is assumed that there is a spill from 3 % of the mercury containing sphygmomanometers annually. The annualised training costs per device are estimated to be €5 for mercury containing, €2 for aneroid and €3 for electronic device. These parameters (spill response and training) are not considered in the base case analysis due to limited information on the assumptions behind the estimates. It is also difficult to assess if these actions take a place in the reality. Nevertheless, the spill response estimate is included in the Scenario 2 in sensitivity analysis. Taking into account these estimates changes the total recurrent costs in favour for alternatives.

Total costs and compliance costs

The following calculations (central case) are made assuming 5% annual decrease in the number of mercury-containing sphygmomanometers sold per year in the next 20 years, i.e. approximately 30 000 devices in 2020 compared to 45 000 in 2010. This

[64] The result may not seem to be correct (as 16-9=7) because of the rounding is used

reduction in using mercury-containing devices is at least partly due to increase in awareness of harmful properties of mercury. Table A3b-4 presents the calculations of total costs of mercury-containing sphygmomanometer and the two alternative devices.

Table A3b-4: Annualised total costs per device (in 2010 price level)

Year	Total costs (€) per device		
	Baseline: Mercury sphygmomanometer	Alternative 1: Shock resistant aneroid sphygmomanometer	Alternative 2: Electronic sphygmomanometer
1	40	40	110
2	0	20	3
3	15	20	3
4	0	20	23
5	15	20	3
6	0	1	3
7	15	0	23
8	0	0	3
9	15	0	3
10	0	0	23
11	30	0	2
Annualised	**14**	**25**	**22**
Additional annualised[65]		**12**	**9**

The additional annualised cost per device is estimated to be €12 for alternative 1 and €9 for alternative 2 compared to the mercury-containing device. These results can be derived from Tables 1 and 2 as sums of additional investment and recurrent costs.

In reality some of the users would replace the mercury sphygmomanometer with shock-resistant aneroid, some with electronic devices and some with alternatives not covered in this analysis due to their technical properties. According to SCENIHR (2009), in addition to sphygmomanometers covered in this analysis, also validated oscillometric devices are currently replacing mercury containing sphygmomanometers. Nevertheless, as the price of oscillometric device is approximately the same as aneroid shock-resistant sphygmomanometer, and there are no reasons to assume significant difference in recurrent costs, there is no need to assess them separately. Based on information from industry (Lassen et al., 2010) we assume in the central case that 75% of the mercury devices would be replaced with the shock-resistant aneroid sphygmomanometer and 25% with electronic one.

Table A3b-5 presents the compliance costs from replacing the mercury sphygmomanometer with shock-resistant or electronic alternative or with combination (75/25) of those as described above.

[65] The result may not seem to be correct (as 16-9=7) because of the rounding is used

Table A3b-5: Annualised and present value compliance costs for alternatives 1, 2 and the combination of alternatives (in 2010 price level)

	Compliance costs (€)		
	Alternative 1: Shock resistant aneroid sphygmomanometer	Alternative 2: Electronic sphygmomanometer	Alternatives 1+2
2015	421102	310914	393555
2016	822152	607023	768370
2017	1204104	889032	1125336
2018	1567869	1157612	1465304
2019	1914311	1413402	1789083
2020	2244255	1657011	2097444
2021	2558488	1889021	2391121
2022	2857758	2109982	2670814
2023	3142777	2320421	2937188
2024	3414223	2520839	3190877
2025	3251641	2400799	3038930
2026	3096801	2286475	2894219
2027	2949334	2177596	2756399
2028	2808890	2073901	2625142
2029	2675133	1975143	2500136
2030	2547746	1881089	2381081
2031	2426424	1791513	2267697
2032	2310880	1706203	2159711
2033	2200839	1624955	2056868
2034	2096037	1547577	1958922
Replacement ratio	**75%**	**25%**	
Compliance cost (present value 2015-2034)	**31,348,553**	**23,145,723**	**29,297,845**
Annualised compliance cost (2024)	**3,414,223**	**2,520,839**	**3,190,877**

The present value compliance costs for 2015-2034 are estimated to be between €23 million and €31 million and annualised compliance costs (2024) between €2.5 million and €3.4 million depending on the replacement ratio.

Costs related to banning the use of mercury containing sphygmomanometers

The compliance costs of banning the use of existing mercury containing sphygmomanometers are sensitive on the length of the possible transitional period between entry into force of the restriction and time when it becomes effective. The following compliance costs in Table A3b-6 are calculated based on assumption that no new mercury containing devices would be purchased after 2015, as there would be a ban on placing on the market, and that the use ban would become effective in 2020. For simplicity, it is assumed that all the mercury sphygmomanometers would be replaced by the aneroid alternative. As the annualised cost per devise for the mercury sphygmomanometers with only 5 years lifetime is lower than for alternatives (with central case assumptions), it is assumed that the use ban would not effect the demand of mercury devices before 2015.

Table A3b-6: Compliance costs of banning the use of mercury containing sphygmomanometers after 5 five year transitional period (in 2010 price level)

Year	Type of effect	Compliance cost (€)
2011	Higher annualised cost per sphygmomanometer due to reduced lifetime of mercury sphygmomanometer (loss of residual value of capital)	57,373
2012		114,027
2013		244,279
2014		381,662
2015		627,956
2016		627,956
2017		627,956
2018		627,956
2019		627,956
2020	Additional costs due to higher annualised costs of aneroid sphygmomanometer compared to mercury device	2,326,856
2021		1,815,004
2022		1,327,525
2023		863,260
2024		421,102
Compliance cost (present value 2011-2024)		**7,732,792**
Cost effectiveness (€ per kg)		**467**

The use ban results in two kinds of effects for the users. Before 2020, when the use ban would be effective, it increases the annualised cost by reducing the life-time of the device i.e. introducing a loss of residual value of the capital. As the lifetime of a mercury containing sphygmomanometer is assumed to be 10 years, the use ban would cut down the service-life of devices bought between 2011 and 2015. Between 2015 and 2019, the annual cost would remain the same, as the number of users (devices) that would be affected in each year (with higher annualised cost) remains the same. This is because no new mercury measuring devices would be allowed to be placed on the market anymore. After 2020 the use ban introduces an increase in the annualised costs of the users, as alternative devices are calculated to be more expensive (central case). This cost impact is similar to cost impacts in restriction option 1 in the restriction report (ban on placing on the market). As the last mercury devices are assumed to be purchased in the beginning on 2015, the last compliance costs take place in 2024, i.e. after the 10 years lifetime.

Introducing the use ban (in 2020) in addition to a ban for placing on the market (in 2015) for mercury sphygmomanometers would introduce an additional compliance cost of around €8 million which means approximately 26 % increase in compliance costs. Assuming 8 years transitional period instead of 5 would introduce compliance costs of around €1.5 million, but at the same time reduce the risk reduction capacity from 17 tonnes of mercury to 6 tonnes.

6. Cost effectiveness

Table A3b-7 presents the costs of reducing the consumption of mercury by one kg when banning the placing on the market of mercury sphygmomanometers. The calculation is based on the annualised compliance costs and on assumption that one mercury sphygmomanometer contains 85 g of mercury. The cost effectiveness is calculated using the following formula:

$$C - E = \Delta C_i \times y \times \frac{1}{m}, \qquad (1)$$

where

C - E = cost effectiveness (€/kg),

ΔC_i = additional annualised cost per device (€/year),

i = the device (Alternative 1 or Alternative 2)

y = lifetime of mercury-containing sphygmomanometer (years) and

m = mercury content per device (kg).

Table A3b-7: Cost effectiveness of replacing the mercury sphygmomanometers (in 2010 price level

	Central case	Scenario 1: High costs	Scenario 2: Low costs
Cost of reducing 1 kg of mercury consumption (€/kg)	**1,313**	3,014	-2,379

In the central case the cost of reducing 1 kg consumption of mercury in production of sphygmomanometer is estimated to be €1300. With parameters used for sensitivity analysis the cost is estimated to be between €3000 and – €2400 (cost savings) per kg.

One of the assumptions, the number of mercury-containing devices sold per year, does not have effect on cost-efficiency of action as both benefits (reduction in mercury consumption) and costs (compliance costs) will be affected by the same ratio. This is partly due to limited scope of our analysis (taking only into account the costs faced by end-users) which is not including e.g. regulatory costs. Nevertheless, the effect of annual number of mercury devices sold on cost-efficiency is assumed to be insignificant.

7. Assumptions and sensitivity analysis

One main assumption used in the analysis is the number of mercury-containing sphygmomanometers sold per year, which is assumed to decrease approximately 5 % annually 2015 and 2034 (45 000 devices sold in 2010) without regulation in central case. The other main assumption is that prices of devices are assumed to be stable between 2015 and 2034.

The assumptions, as well as the input data presented in Chapter 3, include more or less uncertainty especially as a quite long time horizon is adopted and the uncertainty tends to increase over a time.

To address the issue of uncertainty two scenarios are considered: a "high costs" with assumptions increasing the compliance costs (Scenario 1) and "low costs" in favour of banning mercury-containing devices (Scenario 2). Table A3b-8 gives the present value (2015-2034) and annualised (2024) compliance costs for the two scenarios. The values used in sensitivity analysis can be found in the Table A3b-1 in Chapter 3. The values in bold differ from the central case calculations and are chosen for sensitivity analysis as they are estimated to include significant uncertainty or possible trends before 2034.

Table A3b-8: Results of sensitivity analysis presented as annualised and present value compliance costs for the combination of alternatives (in 2010 price level)

	Central case	Scenario 1: High costs	Scenario 2: Low costs
Compliance cost (present value 2015-2034) (€)	72,295,288	116,054,281	-43,600,611
Annualised compliance cost (2024) (€)	6,903,029	11,529,562	-4,234,129

The annualised and present value compliance costs of Scenarios 1 and 2 can be regarded as lower and upper limit estimates with reasonable values for key parameters. Thus, the present value compliance costs are estimated to be between €116 million cost and €44 million savings.

8. Summary

The compliance costs of banning the placing on the market of mercury sphygmomanometers with mercury-free alternatives are estimated to be around €70 million (present value 2015-2034) or around €7 million (annualised in 2024). However, due to uncertainties in the data, high and low cost scenarios are analysed and they suggest present value compliance costs between €116 million and €44 million savings. This results in cost-effectiveness estimate between €3000 and –€2400 (cost savings) per kg of mercury avoided.

In addition, compliance costs for banning the use of mercury sphygmomanometers currently in use in 2020 (present value 2011-2024) is estimated to be around €8 million.

Annex 4: Strain gauges (used with plethysmographs)

Content

1. Technical description of strain gauges

Strain gauges are used for blood pressure and for pure blood flow measurements in body parts using a technique called strain gauge plethysmography[66] (measuring how limbs change in size at different pressures). They consist of a fine rubber tube filled with mercury which is placed around the body part in which the blood pressure or blood flow is measured. The method is used for instance for diagnosing certain kinds of arteriosclerosis. According to the Northeast Waste Management Officials' Association a standard mercury strain gauge contains approximately 1.25 grams of elemental mercury (NEWMOA 2010). The service-life of the mercury tube itself is around 1 year (Kemi 2005).

2. Description of release and exposure

Based on the approach described in Part B of the main document, the estimations on i) the total amount of mercury accumulated in devices in the EU and ii) the amount of mercury placed on the market annually in the EU are used to describe the potential release and exposure during the waste phase of the devices (see Table A4-1). Furthermore, to get a more comprehensive picture, the annual amounts iii) used in the production of devices, iv) imported into the EU and v) exported from the EU are given to illustrate the potential for direct exposure of workers during the production and service-life of the devices. However, it is stressed that this report does not further assess the potential concerns related to workers as explained in Part B. If quantitative estimates are not available, a qualitative description is given.

Table A4-1: Amounts of mercury accumulated, used in production, placed on the market, imported and exported in strain gauges in 2010

Mercury	Estimated amounts
Pool accumulated in strain gauges in the EU	~14 kg Hg
Placed on the market in strain gauges in the EU	~14 kg Hg/y
Used in production of strain gauges in the EU	0.015 kg in Sweden (Kemi, 2007)
Imported into the EU in strain gauges	<14 kg Hg/y
Exported from the EU in strain gauges	0 kg (One identified producer in Sweden producing less than 150 mercury strain gauges annually for Swedish markets)

[66] Mercury strain gauges are always used with a separate device, namely plethysmograph. No measurements with strain gauges are possible without the device.

Box 1: General qualitative description of potential release and exposure

Production, use and waste phase of mercury strain gauges

Kemi (2005) estimates that in Sweden no more than 200 mercury strain gauges are needed annually. When extrapolated to the whole EU27 (based on the population of Sweden which is approximately 1.8% of the population of EU27), it would suggest that only around 14 kg of mercury is used in mercury strain gauges sold annually in the EU27 (in around 11,000 strain gauges). This is also more or less the stock of mercury in strain gauges in the EU as the average service-life of a gauge is estimated to be 1 year (Kemi 2005). In Sweden the placing on the market of mercury strain gauges has been prohibited for many years, with only limited exemptions (KemI, 2007). Therefore, the estimate of 14 kg for the whole EU may be a significant underestimate. Nevertheless, there is no data available from the other Member States.

Some emissions to the environment and exposure of workers may occur in the production phase of mercury strain gauges. However, there is only one identified producer in the EU using only around 20 g of mercury annually.

The average lifetime of a mercury strain gauge is around 1 year (Kemi 2005). The relatively short service-life might be caused by the aging of the silicon tube (Kemi 2007). In addition the aging of the strain gauge causes the copper to dissolve in the mercury and thus the pressure in the gauge will go down and it cannot be used anymore (NEWMOA 2010). According to information received via public consultation, a producer of mercury strain gauges encourages the user to return the mercury strain gauges to the producer for collection and recycling (D.E. Hokanson, Inc., 2011).

As the rubber tubes are quite strong, the strain gauges are not susceptible to brake and emissions occurring during the service-life are estimated to be low. As the strain gauges are mainly used by hospitals, the level of proper waste handling may be similar to the situation with sphygmomanometers at hospitals. As described in Annex 3a (Sphygmomanometers), there are reported problems related to waste handling of sphygmomanometers used in hospitals.

3. Available information on alternatives (Part C)

3.1 Identification of potential alternatives

Several kinds of mercury-free alternatives exist for mercury strain gauges. Some of the alternatives can be used with the same plethysmographs as mercury strain gauges, but some of them are based on a different method. The mercury-free alternatives include:

- Strain gauges with indium-gallium
- Photo cell
- Laser-Doppler techniques
- Ultrasound-Doppler
- Ultrasound
- Filtrass

The strain gauges with indium-gallium are marketed for the same purposes as mercury strain gauges and they function based on the same technique. For these reasons indium gallium strain gauges are considered the main alternatives for mercury gauges, and technical and economic aspects of other alternatives are considered only when the technical and economic feasibility of indium gallium strain gauge is questionable.

The photo-cell technique registers changes in tissue colour at different pressures and can be used with the same plethysmographs.

The laser-Doppler technique measures the velocity of red blood cells to determine the blood flow in different pressures and is meant for big vessels. The Ultrasound-Doppler is based on the same technique but meant for small measurement volumes. Both photo cell and Doppler techniques are typically used for measurements in fingers and toes. (Kemi 2005)

Filtrass is a type of plehtysmographic method, but it does not use strain gauges.

3.2 Human health and environmental risks related to alternatives

The following paragraphs report some available information on indium and gallium. Indium-gallium strain gauges are considered the most direct alternative for mercury strain gauges as they rely on the same principles and use the same method, and they can be used with the existing plethysmographs for the same applications as the mercury strain gauges. Consequently, risks related to other identified alternatives than indium-gallium strain gauges are not further discussed here, although as described in section C.2.1 of the main report, the risks related to electronic alternatives are several orders of magnitude lower than the use of mercury containing devices.

Classification and labelling

Gallium and indium have no harmonised classification under Regulation (EC) No 1272/2008. A screening of C&L notifications received by ECHA revealed that most of the C&L notifications indicate for both gallium and indium skin and eye irritation hazard category 2. Some of the notifications also indicate aquatic chronic hazard category 4, STOT Single exposure hazard category 3, and in addition for indium STOT Repeated Exposure hazard category 1 and Flammable Solid hazard category 2. In US gallium is classified and labelled as corrosive (U.S.DOT-hazard level 8) (Repetto, G. and Paso, A.d. 2001).

Gallium

No registrations on Gallium were received by ECHA by 3 January 2011.

According to a company, properties of gallium have not been fully investigated, but it is reported to cause skin, eye and respiratory tract irritation, and may cause bone marrow abnormalities with damage to blood forming tissues (ACI Alloys, 2010). Administration of gallium to humans has caused metallic taste, skin rashes, and bone marrow depression. Ingestion (which is an irrelevant exposure route) may cause gastrointestinal irritation with nausea, vomiting and diarrhea (ACI Alloys, 2010). However, since gallium has a very low vapour pressure (1 Pa at 1037°C, in comparison to mercury which reaches 1 Pa at 42°C, Wikipedia 2010a, Wikipedia 2011), inhalation is not considered a relevant route of exposure, at least not in comparison to mercury. No information has been readily available concerning ecotoxicological properties of mercury.

Some information is available on mutagenic properties of the gallium nitrate and gallium arsenide (the latter is used in the semi-conductor industry). Gallium nitrate is undergoing research as a possible mutagen for its capacity of altering several cellular defence mechanisms involved in carcinogenesis. If bound to plasma transferrin concentrates at sites of accelerated cellular proliferation. (IARC Monographs, 2006, Repetto, G. and Paso, A.d. 2001). Gallium nitrate and chlorate have proven anticancer activity (Collery et al., 2002). However, as indicated above, oral and inhalation routes are not considered relevant routes of exposure when compared to mercury exposure from the same type of applications, and no information is available on the possible absorption rates of metallic gallium, and the subsequent oxidation rates from gallium to ionic gallium.

Indium

No registrations on Indium were received by ECHA by 3 January 2011.

There is less information available on the toxicological properties of indium than gallium. It seems that it has not been tested for its ability to cause cancer in animals. The probable carcinogenic properties of indium are linked to alterations in the synthesis and maintenance of enzyme systems that metabolize organic carcinogens (Repetto, G. and Paso, A.d. 2001).

Indium-gallium alloy

A comparative study performed by Chandler et al in 1994 revealed that indium-gallium alloy may be suitable substitute for mercury in dentistry amalgam, as their ion revealed not significant toxicity (Chandler et al, 1994). No further information on hazardous properties or risk related to indium-gallium alloy is available.

In addition, some information is available on galinstan, which is an alloy consisting of indium, gallium and tin. Compared with the high vapour pressure of mercury at room temperature (16.3×10^{-6} Pa (at 20°C)), galinstan has a significantly lower vapour pressure ($<10^{-6}$ Pa (at 500°C)) (Surmann, 2005). Therefore, the occurrence of galinstan vapours from accidental spills, waste (landfills) and its emission in the air is unlikely. Consequently, the direct exposure of workers is likely to be low.

Conclusion

As presented above, mercury has a more severe classification than gallium or indium. In addition, based on the information on gallium and on Galinstan (alloy of gallium, indium, and tin), the indium-gallium alloy seems to have significantly lower vapour pressure than mercury. This leads to lower emissions and exposure by lower evaporation rate. Furthermore, there is no information on fate or ecotoxicological properties. Thus, considering the clear evidence on the hazardous properties and risk of mercury, and acknowledging the scarce data on gallium and indium, the risk potential of the indium-gallium strain gauges can be considered to be lower, potentially by several orders of magnitude. Consequently, the transfer from mercury strain gauges to indium-gallium strain gauges is considered to reduce the overall risk to the environment and human health.

3.3 Technical feasibility of alternatives

According to Kemi (2005) the mercury-free alternatives are replacing mercury containing strain-gauges. The reasons why mercury containing strain gauges were still used in 2005 are both technical and economic.

Different alternatives can be used for different measurements and applications (Kemi 2007). As the indium gallium strain gauges function based on the same method as mercury strain gauges they are considered the main alternatives.

According to the information received in the public consultation, it seems that indium-gallium strain gauges are not suitable for measurements when the length of the tube is below 6cm. This is related to much lower resistance of the indium gallium compared to the mercury. However, according to Kemi (2005) there is no need for mercury plethysmographs for toe and finger examinations as they can use laser-Doppler or ultrasound equipments.

According to Kemi (2005) the mercury strain gauges were still needed in 2005 in research of absolute blood flow in arms and legs due to the huge amount or reference material available. It was also reported that mercury equipment is still in use for the diagnosis and monitoring of critical limb ischemia and monitoring certain kinds of

4
arteriosclerosis. However, Kemi (2005) estimated that within 4 to 5 years (i.e. by 2010) mercury-free plethysmographic equipment will be validated for all areas where mercury strain gauges are used.

As described in Section B.5 the current Swedish ban from 2007 has time limited exemptions (that can be prolonged) for strain gauges that reads:

> "*The applicant may manufacture and sell up to 150 mercury containing strain gauges each year and these must be used in already existing equipment*
>
> > *- to measure blood flow in a muscle within clinical routine activities up to 2010-12-31*
> > *- for other uses within clinical routine activities up to 2009-12-31*
> > *- for research and development up to 2012-12-31 given that the project started prior to 2007-12-31. If the research concerns blood flow in a muscle the project may start not later than 2010-12-31.*
> > *- to validate mercury free alternatives up to 2010-12-31.*
>
> *The applicant has the duty to keep records on the uses*."

Only the exemption for ongoing scientific research and development projects is still valid in the beginning of 2011. However, according to the information received in the public consultation, only two years would be needed to validate the mercury-free alternatives for all application areas, i.e. until end of 2012. The proposed restriction with the additional time needed for the decision making and the 18 months transitional period will not apply before that.

3.4 Economic feasibility of the alternatives

According to a website of a supplier of strain gauges, a mercury strain gauge costs around €70 without VAT[67]. The most direct alternative indium gallium strain gauge costs around €82 without VAT[68], i.e. the additional annualised cost is €12 assuming average service life of 1 year for both mercury and indium gallium tube. (PMS instruments, 2011)

In other words, the indium gallium strain gauges are around 17% more expensive than mercury strain gauges. A producer of the strain gauges (Hokanson, 2011) estimated the price difference to be around 30%.

The tube functions with complex electronic equipment (plethysmograph) that cost more than €20,000. As the service-life for the electronic equipment is 10-15 years, the hospitals hesitate to invest in new equipment unless the old one breaks down (Kemi, 2005). However, according to the information received in the public consultation, indium-gallium strain gauges can be used also with existing plethysmographs and consequently, there is no need to replace existing devices.

Considering the additional annualised cost of around €12 and considering the relatively high investment cost of more than €20,000 of the plethysmographs (dominating the cost per measurement), the indium gallium strain gauges are considered economically feasible alternatives for the users.

[67] £595.2 per set of 8 mercury gauges including VAT at 20%
[68] £691.2 per set of 8 indium gallium gauges including VAT at 20%

There is no data available to estimate the compliance costs related to using laser-Doppler and photocell techniques for measurements where short strain gauges are needed. However, considering that the photocells can be used with the same existing plethysmographs as mercury strain gauges (Kemi 2007), and considering the fact that this is only one specific application area, this impact is considered small.

4. Justification why the proposed restriction is the most appropriate Community-wide measure (PART E)

4.1 Identification and description of potential risk management options

4.1.1 Risk to be addressed – the baseline

As described in section B.2, the total estimated amount of mercury placed on the market in measuring devices containing mercury is used to describe the maximum potential for mercury emissions to the environment that might ultimately occur. For strain gauges this is roughly estimated to be 14 kg/y (in around 10,000 gauges). This is also the amount of mercury included in the strain gauges sold annually in the EU, as the lifetime is estimated to be 1 year. There are no data available to assess the trend of using mercury strain gauges but given the overall tendency to reduce mercury, it would seem appropriate to assume that the trend is declining.

Although not the primary concern, it is worth mentioning that some direct exposure of workers can occur during production, professional use of the strain gauges and during waste management operations.

4.1.2 Options for restrictions

Only one option to reduce the risks related to use of mercury in strain gauges is assessed further in the BD:

1. Ban on placing on the market of mercury strain gauges for plethysmographs after 18 months of the entry into force.

In the original Annex XV restriction report two additional restriction options were considered. These options were considered as it was not possible to conclude that indium gallium strain gauges could be used with existing plethysmographs. During the public consultation it became evident that also existing plethysmographs can use the indium gallium strain gauges. Thus, these additional options are not presented in this BD.

4.2 Assessment of risk management options

Restricting the placing on the market of mercury strain gauges to be used with plethysmographs after 18 months of the entry into force

The risk reduction capacity of the proposed restriction is around 14 kg per year. This is the maximum potential for mercury emissions to the environment that might ultimately occur. For 2014-2025, this is around 280 kg. In addition, it can be mentioned that the volume also reduces direct exposure of workers in use and waste phase.

Technically feasible alternatives exist for all the applications. The proposed restriction is estimated to introduce additional cost of €12 per strain gauge to the users of these devices. However considering the high investment cost of the plethysmographs itself (<€20,000), the additional cost introduced by indium-gallium strain gauges to the overall cost of the measurement is small and the alternatives are consider economically feasible.

Assuming no trend in the number of devices placed on the market annually (i.e. 11,000), gives a compliance cost of €132,000 per year. Between 2015-2024, this is around €2.6 million.

Based on the additional cost of €12 per device and assuming 1.25 g of mercury per strain gauge, it can be estimated that the proposed restriction would cost around €9,600 per kg of mercury not placed on the market. This estimate does not consider e.g. the possible differences in the waste handling fees of the devices.

With this restriction, it will be possible to reduce a relatively small amount of mercury (14 kg per year) from the market. It would not be worth the effort to regulate strain gauges alone as the administrative costs related to setting up a restriction would be relatively high. Given that a restriction needs to be set on many other devices, there is no significant additional administrative cost related to restricting the mercury strain gauges.

4.3 The proposed restriction(s) and summary of the justification

As described above, mercury strain gauges are used in plethysmographs.

<u>Proposal:</u>
Restriction on the placing on the market of mercury strain gauges to be used with plethysmogrpahs after 18 months of entry into force of the amendment of Annex XVII.

<u>Summary of justification:</u>
The main purpose of <u>the proposed restrictions is to reduce the mercury pool in the society, thus avoiding negative impacts on human health and environment</u>. Technically and economically feasible alternatives to mercury strain gauges are available for all applications.

Annex 5a: Thermometers[69]

Contents

[69] Including psychrometers (hygrometers) and other applications of mercury as a thermometric liquid.

1. Technical description of mercury thermometers

Mercury thermometers can be used for manual reading of all temperature measurements in the interval from the freezing point of mercury, -39°C, up to about 800°C, with an accuracy up to 0.01°C for high-precision laboratory thermometers (Lassen et al., 2008). Mercury-thallium thermometers can be used down to -58°C. Amongst the advantages of mercury as a thermometric liquid are cited that it does not age, does not cause wetting of the glass surface[70], and has a good expansion linearity over a wide temperature range (Ludwig Schneider, 2010).

Five types of mercury thermometers are identified and assessed in this restriction report:

- Mercury-in-glass thermometers
- Six's thermometer (maximum minimum thermometer)
- Maximum thermometers
- Mercury dial thermometers
- Mercury psychrometer (hygrometer)

In addition, mercury heat indicators, mercury triple point cells and possible other non-electrical thermometric applications are assessed. Hydrometers are sometimes specifically mentioned to have a mercury thermometer inside. They are not assessed separately since they are only one of the many applications of thermometers.

Mercury tilt switches in thermostats and mercury thermoregulators (also designated contact thermometer or accustat) are not in the scope of this restriction report, since they are dependent on electric currents in order to work properly, and therefore fall under the definition of 'electrical and electronic equipment' in the RoHS Directive (see section B.2 and Appendix 4).

Psychrometers (hygrometers) are based on thermometers and, therefore, they are covered in this mercury thermometer section of the restriction report.

Mercury-in-glass thermometers

Mercury-in-glass thermometers consist of mercury encased in a thin glass tube that rises and falls (expands and contracts) with temperature.

The amount of mercury in thermometers can vary significantly according to the application and design. Lassen et al. (2008) reported the mercury content of thermometers used for laboratories and in industry settings to range from 1 to 20 g, with an average content of 3-4 g. This is consistent with a producer, who reported a typical content of 3.5 g/piece (Lassen et al., 2010).

[70] Non-wetting of glass is a colloquial term pointing to the very low adhesive properties of mercury to glass compared to the strong cohesive forces in liquid mercury, causing very low capillary action and a convex meniscus of mercury in a glass tube (water in a glass tube for example has a concave meniscus and high capillary action).

Thermometers used in laboratories contain typically around 14 g of mercury (Lassen and Maag, 2006). In Lassen et al. (2010), producers reported a typical mercury content of 3, 4 and 11 g per laboratory thermometer.

In laboratories precision is often of importance. Precision laboratory thermometers typically have reading scales varying from 1 to 0.1°C. High-precision laboratory thermometers are used for determining ice point and boiling point, for calorimetry, and for other purposes, and have reading scales down to 0.01°C. In industrial settings a resolution of 0.1°C is generally not necessary (Lassen et al., 2010). This is confirmed by information in a catalogue of engine thermometers from two producers. Both usually have a reading scale less precise than 1°C, and only a few models have a 0.5°C scale (Ludwig Schneider, 2010 and Palmer Wahl, 2010).

Six's thermometers (maximum minimum thermometer)

Six's thermometer is a mercury-in-glass thermometer with a U-shaped tube that can be used to indicate minimum and maximum temperature during a given period of time. It is a less expensive, but generally less accurate, way to measure minimum and maximum temperature, compared to the standard combination of a separate mercury containing maximum thermometer and a spirit filled minimum thermometer (Finklin and Fischer, 1990). Alcohol is used as thermometric liquid, while the mercury serves merely as an indicator. This type of thermometer is still used to measure the extremes of temperature at a certain location, where great precision is not essential (Finklin and Fischer, 1990), for instance for professional gardening.

Maximum thermometers

Maximum thermometers are used for reading maximum temperatures in meteorology (daily temperatures), and industrial processes (Lassen et al., 2010), such as sterilisation (Amarell, 2010). A capillary constriction prevents the mercury column to flow back after cooling. The column has to be shaken back after every measurement. Maximum thermometers are provided by several producers, with a resolution down to 0.1°C (Lassen et al., 2010).

Mercury dial thermometers

Mercury dial thermometers consist of a mercury filled metal bulb connected to a dial (a bourdon coil and a needle for reading the temperature). They are applied mostly in the process industry and for marine applications. This group of thermometers has only a very limited remaining market.

For remote measurement, to e.g. control of large engines or combustion processes, thermometers consisting of a sensor and a mercury filled capillary connecting the sensor to the dial are used. Lassen et al. (2008) reported that these capillaries might be up to 40 m, and according to a consulted product catalogue even up to 76 m long (Palmer Wahl 2010).

The mercury content of mercury dial thermometers ranges from about 5 to 200 g (Lassen et al., 2008).

Mercury psychrometer (hygrometer)

A mercury psychrometer is a type of hygrometer used in the measurement of relative humidity and consists of two mercury thermometers, one with a dry bulb and one with a wet bulb. Evaporation from the wet bulb lowers the temperature. The temperature difference between the wet and the dry bulb provides the basis for calculating the relative humidity. Unless mentioned otherwise, mercury psychrometers are considered to be comprised in the word “thermometer” for the sake of simplicity.

Other non-electrical thermometric applications

Producer AGA Rangemaster Limited informed ECHA that it uses ‘*mercury heat indicators*’ in its AGA cookers. The heat indicator provides a guide to the user that the cooker has sufficient heat stored by means of an indicator band. The device does not give an actual temperature reading. The visual indication of the stored heat allows adjustment of a separate thermostat that regulates the desired amount of stored heat. Once set, the ovens then operate at fixed temperatures. The heat indicators carry approximately 1.8 g of mercury and the EU annual market is around 2500 cookers containing such a device. This results in approximately 4.5 kg of mercury used for these high temperature applications, which is negligible in comparison with the use of mercury for thermometers. The producer believes the device is not used in other similar equipment or products. Nevertheless other non-electrical thermometric applications of mercury might exist. (AGA Rangemaster, pers. comm., 2010)

Equipment for the calibration of platinum resistance thermometers using the *triple point of mercury* is prescribed in the 1990 International Temperature Scale (ITS-90). ITS–90 uses numerous defined points, all of which are based on various thermodynamic equilibrium states of fourteen pure chemical elements and one compound (water) (Wikipedia, 2010e). One of those elements is mercury (mercury triple point cell). Three types of mercury triple point cells described by Strouse and Lippiatt (2001) contain 2,6 to 3,4 kg of mercury. However there are thought to be only a very limited amount in certain dedicated calibration laboratories. According to Lassen et al. (2008), the use of mercury for these applications is estimated to be negligible. As far as is known, at least the Nederlands Meetinstituut (Nmi - Dutch Measuring Institute) would have such a device (see also Peruzzi et al., 2007). Mercury triple point cells would amongst others be produced by the National Physical Laboratory in the UK (Lassen et al., 2010).

2. Description of release and exposure

In addition to the general restriction to place mercury measuring devices on the market for sale to the general public (including thermometers), specifically, the placing on the market of mercury-in-glass thermometers as a fever thermometer is restricted for all uses (i.e. including professional use) by Entry 18a of Annex XVII as of 3 April 2009. To date, mercury-in-glass thermometers can still be placed on the market for the industrial and professional uses including as ambient temperature thermometers, laboratory thermometers and as thermometers for combustion and industrial processes. Thus the description of release concentrates on these types of thermometers.

Based on the approach described in the section B of the main document, the estimations of i) total amount of mercury accumulated in devices in EU and ii) the amount of mercury placed on the market annually in the EU are used to describe the potential release and exposure during the waste phase of the devices. (Table A5a-1). Furthermore, to get a more comprehensive picture, the annual amounts iii) used in the production of devices, iv) imported into EU and v) exported from EU are given to illustrate the potential for direct exposure of workers during the production and service-life of the devices. However, it is stressed that this report does not further assess the potential concerns related to workers as explained in Part B. If quantitative estimates are not available, a qualitative description is given.

Table A5a-1: Amounts of mercury accumulated, used in production, placed on the market, imported and exported in thermometers in the EU in 2010

Mercury	Estimated amounts
Pool accumulated in thermometers	90 tonnes *
Placed on the market in thermometers	0.7-1.6 tonnes per year **
Used in the production of thermometers	1.0-1.5 tonnes per year **
Imported in thermometers	0.2-0.8 *
Exported in thermometers	0.5-0.8 *

Sources: * calculated from Lassen et al. (2008), see Box 1. **Lassen et al. (2008).

Box 1: General qualitative description of potential release and exposure

Production phase

It is estimated that the EU use of mercury for thermometer production is somewhere in the order of 1.0-1.5 t/y, of which around 50% is destined for the EU market (Lassen et al., 2008). The volume also includes mercury included in thermometers that are present in hydrometers. About 1000-1500 employees are involved in the EU production of mercury thermometers (Lassen et al., 2008).
In addition to releases from the waste phase of thermometers, some emission to the environment and exposure of workers may occur in the production phase of thermometers.

Service life

Mercury thermometers have a vast application area. Such areas include chemical and other process industries; laboratories in industry; research and education; machines and engines; climate and refrigeration equipment; storehouses; museums; food sector (conservation and preparation); meteorology. Mercury is present in thermometers in small amounts and the use of thermometers can be characterised as being geographically very dispersed.

Roughly around half of the mercury used in thermometers for the EU market is for laboratory use, the other half for industrial and marine applications (Lassen et al., 2008). Lassen et al. (2008) estimated that around 0.6-1.2t/y is used in mercury-in-glass thermometers for the EU market, 0.1-0.3 t/y in mercury dial thermometers, and 0.01-0.1 t/y in psychrometers, which gives a total use of mercury in thermometers for the EU market of around 0.7-1.6t/y. The remaining (professional) uses of mercury room thermometers and other meteorological applications might not be included in this estimate, but are thought to be relatively small. It has not been possible to obtain information on the volumes for these applications during the preparations and consultations carried out for this report.

The following gives a general qualitative description of potential release and exposure from the pool of thermometers that were brought on the market in the past and are currently still in use.

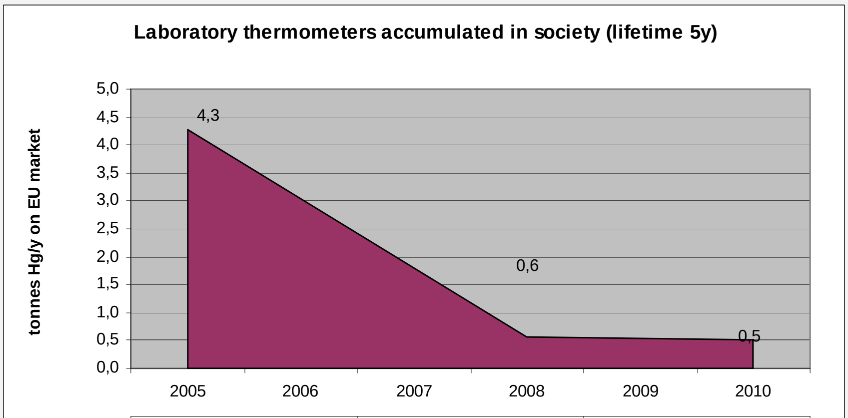
Based on estimates reported by Lassen et al. (2008), the volume of mercury that is included in non-fever thermometers[71] for the EU market in 1995 was estimated to be 28t/y (out of 55 t/y in measuring devices).

In 2002, the amount of mercury placed on the market in mercury containing measuring devices was estimated to be 33 t/y (EU 15+3). If the same proportions are applied to this figure as for the 1995 estimate, around 17t/y would have been placed on the market in non-fever thermometers. From 2008 onwards, the mean estimate of 0.7-1.6t/y is used for non-fever thermometers based on the estimations made by Lassen et al. (2008). Based on these figures, and assuming linearity between the above data points, the volume of mercury accumulated in industry thermometers is estimated to be 78 tonnes (lifetime of 13y[72]), in laboratory thermometers roughly 8 tonnes (lifetime of 5y), totalling to around **90 tonnes** in 2010 of mercury accumulated in non-fever thermometers. This is considerably more than the estimated volume of 40-100 tonnes for all measuring devices by Lassen et al. (2008). Lassen et al. (2008) used in the calculations a lifetime of thermometers of 5 years for all thermometers. If similarly a lifetime of 5 years would be used for industry thermometers in the above calculations, the estimated pool of mercury circulating in society would be 34 tonnes in 2010.

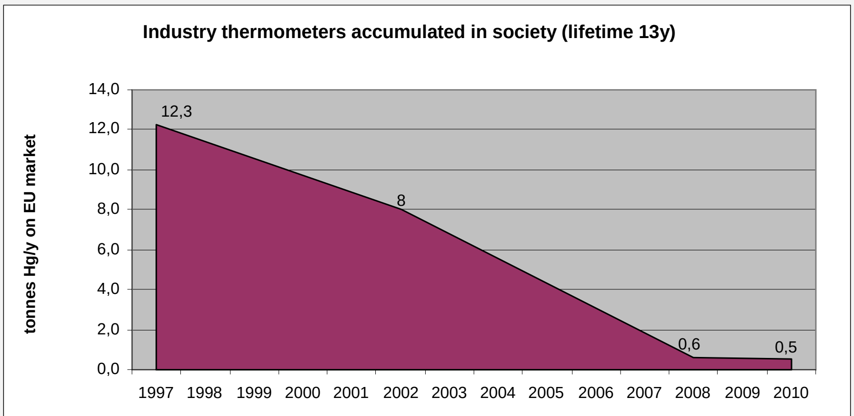
In addition to emissions from the waste phase (see below), mercury in glass thermometers for laboratory and industrial use easily break which results in emissions to the environment as well as direct human exposure (Lassen and Maag, 2006).

[71] Lassen et al. use the term ‘medical thermometers’ in stead of ‘fever thermometers’. It is assumed that they are interchangeable in this context, since the authors write for example that ‘mercury use in medical thermometers is now banned in the EU’.

[72] See assumptions for lifetimes in Annex 5b (Compliance cost calculations for thermometers).



	2005	2008	2010
volume	4,3	0,6	0,5



	1997	2002	2008	2010
volume	12,3	8	0,6	0,5

<u>Waste stage</u>

As described in section B.4 of the main document, the waste phase is crucial for the potential releases of mercury to the environment (whether the mercury thermometers are collected separately from other waste streams and whether the separately collected devices are handled in accordance with hazardous waste legislation).

Partly the thermometer waste ends-up with unsorted municipal waste, another part is collected as hazardous waste. Lassen et al. (2008) estimated that only 20% of mercury containing measuring devices would be collected as hazardous waste. There does not seem to be evidence showing that this estimate would not be valid for thermometers, but it has to be noted that the figure is entailed with high uncertainty.

3. Available information on alternatives (Part C)

3.1 Identification of potential alternative substances and techniques

Alternatives are available for all applications of mercury-containing thermometers (Lassen and Maag, 2006). The following alternatives are described in this section:

- Mercury-free liquid-in-glass thermometers
- Gas or liquid dial thermometers
- Bi-metal dial thermometers
- Electronic thermometers
- Infrared thermometers

Mercury-free liquid-in-glass thermometers

The mercury-free liquid-in-glass thermometer is the most common replacement of the mercury thermometer at temperatures up to 250°C (Lassen et al., 2008). These thermometers are similar to mercury-in-glass thermometers, but use a different thermometric liquid.

The liquids typically used in mercury-free liquid-in-glass thermometers are organic liquids such as ethanol (ethyl alcohol), methanol, pentane, pentanol, toluene (toluol), kerosene, creosote, petroleum, i-amyl benzoate (isoamyl benzoate or isopentyl benzoate), and ‘citrus-extract-based solvents’ are reported to be used (Lassen et al., 2008) (Ludwig Schneider, 2010) (Amarell, 2005). To make the liquid more visible usually a red or blue dye is added. Product catalogues also refer to a blue-colored, organic, spirit fill (Trerice, 2010), or “eco-friendly, green filling, thermometer liquid and colour biodegradable”, “red/blue special liquid” (Amarell, 2005), “non-toxic, mercury-free Blue Liquid” (Palmer Wahl, 2010).

The market share of these alternatives is unknown, and this information is not readily available. From a product catalogue it appears that the choice of liquid depends amongst others on the range of temperature measurement the liquid allows (Ludwig Schneider, 2010), and thus the market share is thought to be in part steered by the needs of measurement. Liquids are at least from the point of view of measurement range, to a certain extent interchangeable, for instance creosote and i-amyl benzoate[73] seem to have nearly the same measurement range (-40°C untill +210°C and -40°C untill +220°C respectively) (Ludwig Schneider, 2010).

Apart from organic liquids, also gallium or gallium alloys are used. Gallium has a very high liquid range, and compared to mercury has a low vapour pressure at high temperatures. Gallium alloy thermometers can be used in temperature ranges from 0 to 1200°C (Ludwig Schneider, 2010). Unlike mercury, liquid gallium metal is wetting. Wetting action of gallium-alloys can be overcome by covering the glass with a layer of gallium(III) oxide (Wikipedia, 2010a). Gallium is also used in Galinstan, an alloy of gallium, indium and tin, that is used in medical thermometers (Geratherm,

[73] CAS nr. 94-46-2, the substance has no harmonised classification.

2010). One company markets a maximum-thermometer for laboratory appliances with gallium filling for measurements up to 750°C (Amarell, 2010).

It is important to note that gallium thermometers are marketed for temperature measurements higher than 800°C, and/or for their exceptionally large measurement range (0-1200°C) (Appendix 3; Ludwig Schneider, 2010; Amarell, 2010). For these reasons, other technical reasons (precision and wetting of glass), and economic reasons (see Appendix 3), gallium is not considered to be a direct alternative to mercury in thermometers. In conclusion, gallium thermometers are normally used where mercury or other liquids would not be used.

Liquid-in-glass lab thermometers with a resolution up to 0.1°C and psychrometers with alcohol filling with a reading scale of 0.2°C exist in the market (Ludwig Schneider, 2010). A liquid-in-glass lab thermometer with organic filling, PerformaTherm™, has a resolution of 0.1°C and satisfies ASTM[74] standards (Lassen et al. 2008, and Lassen et al. 2010). Industry thermometers with "red/blue/green special liquid" fillings up to 360°C and a scale of 2°C exist on in the EU market (Amarell, 2005).

Liquid-in-glass thermometers are not only an alternative to mercury thermometers. They also complement mercury thermometers outside their measurement range (-58°C to +800°C). For low temperature, for example ethanol can be used, which has a melting point of -114°C (EC JRC, 2000a). For high temperature measurements, gallium fillings can be used. In addition, minimum thermometers are normally liquid-in-glass thermometers with organic filling (WMO, 2008). A producer markets meteorological precision minimum thermometers with alcohol filling, having a scale of 0.2 or 0.5°C depending on the needs (Ludwig Schneider, 2010).

Gas or liquid dial thermometers

Gas or liquid dial thermometers are similar to the mercury dial thermometers, but are filled with gas or liquid instead of mercury. Examples of such liquids are 'inert gas (non-toxic)', xylol (xylene), silicon oil, 'non-toxic, odorless, organic, and non-flammable liquid' (Trerice, 2010) (WIKA, 2010) (Palmer Wahl, 2010).

A producer offers capillary lengths up to 5 m for liquid filled remote systems, with liquid fillings both in "remote" and "rigid" (i.e. not remote) systems that can be used up to 500°F (260°C) (Palmer Wahl, 2010). The models in this catalogue have the same resolution whether they are actuated with mercury or with another liquid. According to Lassen and Maag (2006), such thermometers are available for measurements up to +600°C, which is confirmed by a product catalogue of WIKA, that offers "Gas Actuated Thermometers" within the ranges of -60°C to +600°C, scale spacing from 1 to 10°C according to the model, and capillary lengths according to user specifications.

Gas or liquid dial thermometers are direct replacements of mercury dial thermometers for temperature measurements from the lowest range up to +600°C. The resolution

[74] ASTM International (American Society for Testing and Materials) is one of the largest voluntary standards development organizations.

seems not to be affected (see above), but is anyhow not an important characteristic for the industrial applications where dial thermometers are used (Lassen et al., 2010).

Bi-metal dial thermometers

A bi-metal dial thermometer uses a bimetallic strip wrapped into the form of a coil. One end of the coil is fixed to the housing of the device and the other drives an indicating needle. The bimetallic strip converts a temperature change into mechanical displacement. The strip consists of two layers of different metals which expand at different rates as they are heated. The different expansions force the flat strip to bend if heated. (Wikipedia, 2010c)

Bi-metal thermometers are available for measuring temperatures in the range from about -70°C to 600°C (Lassen et al., 2008). Bi-metal thermometers have reading scales varying according to the model from 1 to 5 °C according to consulted product catalogues (WIKA, 2010) (Ludwig Schneider, 2010).

The dial thermometers have typically replaced mercury-in-glass thermometers for the temperature range above 250°C, e.g. for measuring the temperature of exhaust gases of diesel engines (Lassen et al., 2008), and are considered as replacements of mercury dial thermometers (Lassen et al., 2010). It is assumed that the authors refer to gas or liquid dial thermometers, as well as bi-metal dial thermometers.

Electronic thermometers

Electronic thermometers are also designated 'digital thermometers'. The working of this group of alternatives is based on the thermoelectric effect, which is the conversion of temperature differences to electric voltage. The three main types – thermocouples; platinum resistance thermometers and thermistors – are described below. Electronic thermometers can be connected to a data logger via an analogue-to-digital converter.

Electronic thermometers are generally more accurate than mercury-containing thermometers, if properly calibrated (Lassen et al., 2008). Ripple and Strouse (2005) mention as advantages of electronic thermometers (platinum resistance thermometers, thermistors and thermocouples) possibly smaller measurement uncertainties, the ease of automation, the independence of the reading from the visual judgement of the user, and the absence of mercury. As disadvantages the need for a power source and somewhat higher initial costs are mentioned. Also higher calibration frequency, and thus higher recurrent costs could be mentioned as a disadvantage (see section 3.4 and Annex 5b). In addition mercury-in-glass and liquid-in-glass thermometers used below 150°C can be calibrated using the ice-point only, whereas platinum resistance thermometers (PRTs) and thermistors usually require a minimum of three calibration points.

Electrical thermometers with a digital display and/or automatic data logging make up an increasing part of the thermometer market. They are used throughout industry for automatic temperature measurements, and use in laboratories is reported to represent an increasing part of the market in Denmark[75] (Lassen et al., 2008).

According to the World Meteorological Organisation electrical thermometers are in widespread use in meteorology. Their main virtue there is said to lie in remote indication, recording, storage, or transmission of temperature data. For soil temperature measurement, mercury thermometers are even regarded as unsuitable in comparison with electrical thermometers. (WMO, 2008)

Electronic thermometers approved by international insurance companies are marketed for refrigerated containers (Lassen and Maag, 2006).

1) Thermocouples
A thermocouple is made of two dissimilar metals joined so that a potential difference generated between the points of contact is a measure of the temperature. Thermocouples have a wide range from -270°C to 1800°C (MicroDAQ, 2010) and fast response time (under a second in some cases according to Burns Engineering, 2010).

Certain combinations of alloys have different sensitivities, and resulted in industry standard types such as K, S, R, E, J, and N thermocouples. Type K (chromel–alumel) is the most common general purpose thermocouple. Selection of the thermocouple type is driven by cost, availability, convenience, melting point, chemical properties, stability, and output (Wikipedia, 2010b).

2) Platinum resistance thermometers (PRTs)
An platinum resistance thermometer is a resistance temperature detector (RTD) that uses platinum for its element. Their function is based on the principle that electrical resistance of the metal changes in a predictable way depending on the rise or fall in temperature. The temperature range is -260 to 850°C (MicroDAQ, 2010).

The Pt100 sensor has a resistance of 100 ohms at 0°C and is by far the most common type of RTD sensor. The Pt500 sensor has a resistance of 500 ohms at 0°C and the Pt1000 has 1000 ohms resistance at 0°C (Omega, 2010). These thermometers are very accurate, and are used by laboratories accredited for calibration (Lassen et al., 2008). They are for example widely used for monitoring the temperature of foodstuffs during transport (Lassen et al., 2008). A very high precision system has a resolution of 0.001°C and a temperature range of -200 to +400°C. This device is marketed for process monitoring and production control in the chemical, pharmaceutical and food industries, as well as for research and development (Ludwig Schneider, 2010). On the internet the device is indicated to cost €980 (without VAT)

[75] Note that laboratory use is exempted from the Danish restriction of mercury thermometers, see section B.5

(Labnewsletter.com, 2010). The temperature sensor is available separately, and is provided with a DKD calibration certificate[76].

ASTM E1137 (Standard Specification for Industrial Platinum Resistance Thermometers) is a standard establishing physical, performance, and testing requirements, as well as resistance-temperature relationship and tolerances for metal-sheathed industrial platinum resistance thermometers (PRT) suitable for direct immersion temperature measurement (ASTM, 2010)

3) Thermistors
Thermistors also rely on the known variation of electrical resistance with temperature of a specially constructed resistor to convert temperature into a measurable electrical property, but unlike the above described PRTs the material used in a thermistor is generally a ceramic or polymer, in stead of metals (Wikipedia, 2010d). Thermistors have stabilities approaching a few thousandths of a degree Celsius per year, and are highly sensitive (approximately 4% change in resistance per degree Celsius). The typical temperature range is -80 to 150°C (MicroDAQ, 2010). However, the usable temperature range is limited to not more than 100°C for a single thermistor, and the maximum temperature of use is 110°C (Ripple and Strouse, 2005).

Infrared thermometers

Apart from the previously described electronic thermometers, infrared thermometers can be used to measure temperature in applications where conventional sensors cannot be employed. Infrared thermometers appear to have replaced mercury pyrometers (Lassen et al., 2008). An infrared thermometer is a non-contact temperature measurement device. The most basic design consists of a lens to focus the infrared (IR) energy on to a detector (thermocouple), which converts the energy to an electrical signal that can be displayed in units of temperature (Omega, 2010).

3.2 Human health and environment risks related to alternatives

In this section the human health and environment risks related to alternatives are described.

Mercury-free liquid-in-glass thermometers

For reasons explained in general part C, the risks as a result of organic liquids (such as alcohol, pentane, pentanol, toluene, kerosene, creosote, petroleum, i-amyl benzoate, and citrus-extract-based solvents) used in liquid-in-glass thermometers are

[76] The DKD Calibration Certificate documents officially the traceability of measuring results to national and international standards as required by the standards DIN EN ISO 9001 and ISO/IEC 17 025 for the monitoring of measuring instruments

in general considered to be low or insignificant, especially compared to the risks of mercury.

Gallium is also used in some thermometers, but as explained in section 3.1, these thermometers are not to be seen as direct replacements of mercury thermometers. However for the sake of completeness some considerations are given here shortly. Since gallium has a very low vapour pressure, exposure through inhalation is not considered relevant for thermometer users, and minimal during the production phase. Some cases of skin irritation might occur, but overall there are no indications that there would be considerable risks associated with gallium filled thermometers. See also Annex 4 for a description of the intrinsic properties of gallium.

Gas or liquid dial thermometers

Substances used in gas or liquid dial thermometers such as 'inert gas (non-toxic)', xylol (xylene), silicon oil, 'non-toxic, odourless, organic, and non-flammable liquid' are not considered to pose any considerable risks in comparison with mercury actuated systems.

Electronic thermometers

As described in general part C, the human health and environmental risks related to the use of electronic alternatives are insignificant in comparison with the potential emission and exposure associated with the amount of mercury in thermometers.

Bi-metal dial thermometers

Materials used for these articles are amongst others plastic, stainless steel, aluminium, anodized aluminium, galvanized steel, brass, nickeled metal, coatings, glass, silicone (Ludwig Schneider, 2010; Omega, 2010; Trerice, 2010). There are no indications of risks to human health or the environment related to the use of bi-metal dial thermometers (see also description on mechanical alternatives in general part C).

3.3 Technical feasibility of alternatives

An overview of the technical feasible alternatives to mercury thermometers is given in Table A5a-2. Alternatives exist for all applications of mercury-containing thermometers (Lassen and Maag, 2006). It is generally accepted that alternatives exist to all uses of mercury dial thermometers and mercury-in-glass thermometers at measuring resolution of 1°C and below 200°C (Lassen et al., 2008). Indeed, none of the producers of the thermometers consulted in the course of preparing this restriction report have indicated that mercury thermometers for measuring temperatures below 200°C at a resolution > 0.5 °C would be an essential use (Lassen et al., 2010).

Liquid-in-glass thermometers are in general fully suitable -and are the most common- replacement for all uses that do not require an accuracy better than 0.1°C, as long as the temperature measurements are below the 250°C range (Lassen et al., 2008) (Lassen et al., 2010). The maximum temperature of 105°C, response time, and separation of the liquid, have been mentioned as obstacles for the wide-spread use of the liquid-in-glass thermometer PerformaTherm™ (Lassen et al., 2008) (Lassen et al., 2010). Consulted companies have not given explicit technical reasons why gallium thermometers would not be technically feasible alternatives (Lassen et al., 2010).

Mercury dial thermometers used in the industry and marine applications can be replaced by gas or liquid dial thermometers or by bi-metal coil thermometers for all purposes. The producer Brannan (UK) claimed that mercury dial thermometers do not need to use mercury as an actuating medium, since alternatives exist (Lassen et al., 2008).

For laboratory thermometers that require measurements at 0.1°C or better, the alternatives are electronic thermometers (Lassen et al., 2008). For laboratory measurements that need high temperature measurements gallium or electronic thermometers can be used.

Room temperature thermometers, including Six's thermometers, can be replaced directly by liquid-in-glass alternatives (Lassen et al., 2008). This would also apply for the thermometers that are inside hydrometers. For meteorological applications that would require higher precision than 0.1°C, the situation is similar to laboratory thermometers.

Maximum thermometers were mentioned by one producer to be an essential use in the consultation ECHA carried out for preparing this restriction report (Lassen et al., 2010). However there is no known reason to treat them differently from other mercury thermometers that require high precision (Lassen et al., 2010), and are therefore not treated separately in the report.

According to a producer, electronic alternatives to psychrometers (hygrometers) could in '*some cases not be used because of the structure of their temperature and chemical resistant sensor housing*' (Lassen et al., 2010). According to Lassen et al. (2010), this seems not to be justified: psychrometers have been banned for many years in Denmark, and consulted calibrating laboratories were not able to identify any applications where it has been difficult to replace mercury psychrometers. Klif confirmed that placing on the market of psychrometers is prohibited in Norway. It seems that psychrometers have successfully been replaced in Denmark, Sweden and Norway without any reported problems (see section B.5).

In industrial settings a resolution of 0.1°C is generally not necessary (Lassen et al., 2010). For temperature measurements above 200°C at a resolution of 1°C, dial thermometers with coiled bimetal or a liquid or air filled metal cylinder with a dial for manual reading are available (Lassen et al., 2008).

According to the Commission's review (Appendix 5), a company would have defended the use of mercury in a limited number of highly specialised professional uses, such as retort[77] thermometers in the canning industry (Appendix 5). However, several producers offer electronic alternatives for retort thermometers, such as "Palmer Wahl DST600" (Palmer Wahl, 2010), and "Digital Temperature Gauge for Retort Applications" (Anderson, 2010). In addition bi-metal thermometers can be used in the canning industry (Omega, 2010).

Mercury heat indicators and other non-electrical thermometric applications

Producer AGA Rangemaster Limited informed ECHA that it has alternative solutions in place for its mercury heat indicator in their *electric* ovens. The producer says there are no known alternatives for the heat indicator for ovens that operate *without electricity*, and function on gas or oil. It is also said that the area where the heat indicator is located would be 'far too hot for an electronic solution'. In addition, supply of replacement parts for existing devices are mentioned as an obstacle. The producer indicated that to date suppliers have been unable to provide a high temperature infill which lasts more than 4 months, although they would have samples on trial. Producer AGA Rangemaster Limited estimates a need of 12 months for substitution of the mercury heat indicator with alternatives in new devices. (AGA Rangemaster, pers. comm., 2010)
On the basis of this information it is understood that there will be feasible technical alternatives available before the potential entry into force of a restriction.

There are no known technical feasible alternatives to mercury triple point cells for calibration of platinum resistance thermometers. As described in section 1 it is one of the elements *defining* the 1990 International Temperature Scale (ITS-90). The Dutch mercury restriction has a derogation for "*equipment for the calibration of platinum resistance thermometers using the triple point of mercury*" for these reasons.

Based on the available information it is concluded that there are technically feasible alternatives available for the minor use of mercury in mercury heat indicators, and possible other non-electrical thermometric applications. It would not be technically feasible to restrict the use of equipment for the calibration of platinum resistance thermometers using the triple point of mercury.

[77] Retort: A retort is a machine similar to a domestic pressure cooker, where batches of cans are heat processed under pressure. The retort has temperature and pressure gauges and should also have temperature / time recording charts. (http://www.cip.ukcentre.com/keywords.htm#R)

Table A5a-2 Overview of the technical feasible alternatives to mercury thermometers

Application area & product type	Alternatives	Applicability	remarks
Mercury-in-glass thermometers *(T range -58°C to +800°C and accuracy up to 0.01°C for high precision thermometers)*			
For laboratory use, including industry labs for material testing (precision and high precision thermometers). Reading scale Hg thermometer up to 0,01°C	Liquid-in glass thermometers	T range <250°C, accuracy 1°C, and up to 0,1°C	Typically replace mercury-in-glass thermometers for T-range < 200°C, where accuracy >0,1°C is not required
	Gallium thermometers	T-range 0-1200°C, accuracy 5°C or 2°C (possibly more accurate as well)	Seems to be a niche market for economical and it appears also technical reasons. Seems to be used as a very wide range thermometer
	Electronic thermometers	More accurate than Hg in glass, very large T range (-200 to 1800°C), resolution 0.1°C (or better)	Advantages are data recording and remote reading. Might replace many mercury thermometers.
	High precision electronic thermometers	Resolution up to 0.001°C, T range -200 to +400°C	Higher resolution than high precision Hg-in-glass thermometers. Might replace many mercury thermometers.
For industrial use. Reading scale Hg thermometer usually 1-5°C, sometimes 0,5°C	Liquid-in glass thermometers	T range <250°C, accuracy 1°C	Typically replace for T-range < 200°C
	Dial thermometers	T range -70°C to +600°C, accuracy 1°C	Replacement for T-range > 200°C, also used as a mechanical back-up for electronic thermometers
	Electronic thermometers	More accurate than Hg in glass, very large T range (-200 to 1800°C), resolution 0.1°C or better	Accuracy higher than 1°C is normally not an issue for industry thermometers. Reasons to choose electronic thermometers might be: data logger, possibilities for remote reading, real-time monitoring & feedback mechanisms, alarm systems,…
Meteorological measurements and room temperature measurement. Reading scale of Hg meteorological thermometers usually not smaller than 0,2°C.	Liquid-in glass thermometers	Accuracy 1°C, and up to 0,2°C	All room temperature thermometers and Six's thermometers, and most if not all other meteorological applications such as psychrometry, can be directly replaced by LiG thermometers.
	Electronic thermometers	Resolution 0.1°C (or better)	Data recording and remote reading. Widespread use in meteorology. For soil temperature much better than mercury thermometers.
Mercury dial thermometers (5-200g Hg/piece)	Dial thermometers	T range -70°C to +600°C, accuracy 1°C	Replacement for T-range > 200°C, also used as a mechanical back-up for electronic thermometers
	Electronic thermometers	More accurate than Hg in glass, very large T range (-200 to 1800°C), resolution 0.1°C or better	Data logger, possibilities for remote reading, real-time monitoring & feedback mechanisms, alarm systems,…
Mercury heat indicators (approximately 1.8g Hg/piece)	other liquids or other systems		Producer AGA Rangemaster Limited estimates a need of 12 months for substitution of the mercury heat indicator with alternatives in new devices
Mercury triple point cells used for calibration of platinum resistance thermometers	none		Application is prescribed in the 1990 International Temperature Scale (ITS-90)

Standards prescribing the use of a mercury thermometer

Analysis standards often list equipment and techniques to be used, and step-by-step instructions how to use the equipment. Such analysis standards might specifically refer to the use of mercury thermometers, and might therefore constitute a practical obstacle for using alternatives to the mercury thermometers in laboratories.

These references to mercury thermometers in *analysis standards (test methods)* can be made in the form of references to a certain specific *technical standard (technical specification)* of a mercury thermometer. Technical standards are defining technical specifications including accuracy and dimensions. They play an important role for production and choice of industrial as well laboratory thermometers. An example of such a technical standard is ASTM E1 - 07 Standard Specification for ASTM Liquid-in-Glass Thermometers[78].

According to Ripple and Strouse (2005), many hundreds of ASTM test methods would rely on mercury-in-glass (ASTM E1) or liquid-in-glass thermometers (ASTM E1 for low accuracy and E 2251 for high accuracy[79]).
In addition, according to information from one producer, 60 to 80 %, and in some sectors nearly a 100% of thermometers used in laboratories would be used for measurements where procedures prescribe standard thermometers (Lassen et al., 2010). The latter does not imply that these standard thermometers are mercury thermometers.

Although traditionally many standards have prescribed mercury thermometers in analysis, many standards now allow for the use of alternatives (Lassen et al., 2010)[80]. Standards for testing in the petrochemical sector in general allow for electronic devices to be used, and automatic equipment is available for most tests (Lassen et al., 2010). An example of this is flash-point determination where standards often have been cited to prescribe mercury thermometers. In fact, currently the standards fully allow for the use of electronic alternatives (at least all ISO and ASTM standards), and in fact it seems that at least in Germany the use of automatic apparatus for flash point determination is common practise (Lassen et al., 2010).

Three cases of analysis standards that still would prescribe the use of mercury thermometers were identified in the course of the information gathering and consultations by Lassen et al. (2010):

[78] ASTM International is a major standardisation organisation.
[79] ASTM E1 is a technical standard for mercury thermometers, and low-precision liquids. ASTM standard E2251 - Specification for Liquid-in-Glass ASTM Thermometers with Low-Hazard Precision Liquids, has a list of thermometers with alternative liquids that can replace some of the mercury thermometers specified in ASTM standard E1, Specification for ASTM Liquid-in-Glass Thermometers.
[80] Relevant standards for materials' testing are developed by ISO, CEN, ASTM, DIN and IP/BS (Lassen et al., 2010). The focus here is on ASTM because most of the available information describes ASTM standards (Lassen et al., 2010 and ASTM International (2010)). ISO and CEN appear to develop standards together, at least in the area of flash point determination (Lassen et al., 2010).

- method A1 "Melting/freezing temperature", in the Test Method Regulation (Regulation (EC) No 440/2008) would specify technical standards for thermometers that require mercury;
- Regulation (EC) No 1031/2008 requires testing according to the Abel-Pensky method which is specifically defined as DIN 51755, a national standard for flash point; and
- a drop point apparatus with a mercury thermometer is described in the European Pharmacopoeia 5.0 from 2005.

Concerning Regulation (EC) No 1031/2008, it seems sufficient that the standard DIN 51755 (from March 1974) would be amended (if that has not yet happened). Note that this Regulation is amending Council Regulation (EEC) No 2658/87 on the tariff and statistical nomenclature and on the Common Customs Tariff. Amendment of the relevant annex to this Regulation (Annex I) occurs several times a year.

Regarding the CLP Regulation (Regulation (EC) No 1272/2008), it seems sufficient that the standards that are mentioned for flash point testing (Table 2.6.3 of the CLP Regulation) would be updated where required, without the need to amend the Regulation itself.

According to ASTM, there would still be many standards referring to the use of a thermometer according to ASTM standard E1 or call out the usage of a mercury thermometer (ASTM, pers. comm., 2 June 2010). However this does not necessarily mean that the standard does not allow for alternatives to be used. As examples of standards that call out for the usage of a mercury thermometer, ASTM mentioned D97, D566, D938, D972 and D2595 (ASTM, pers. comm., 14 June 2010).

ASTM standards have to be reviewed every 5 years, but can be updated at any time. Since the start of the mercury initiative of ASTM in 2006, ASTM International is working to identify industrial standards and test methods that require the use of mercury thermometers in order to determine whether the use of alternatives is feasible (ASTM 2010). This action is supported by the US EPA initiative to phase-out mercury thermometers used in industrial and laboratory settings (US EPA 2010).
Where removal of the reference or requirement from an ASTM standard was relatively straightforward, changes have been completed (ASTM, pers. comm., 2 June 2010). Reasons for cases where this has not yet happened can be because of a lack of industry support for the change; lack of testing for a suitable replacement; and needs for new interlaboratory studies (costs and time associated with it and lab participation) (ASTM, pers. comm., 2 June 2010).

As ASTM points out, although electronic alternatives might be preferable because of their higher accuracy, there might be issues of bias between temperature readings from electronic thermometers in comparison with mercury thermometers: "*Most electronic thermometers considered as alternatives are minimally or not at all affected by emergent stem temperature. Therefore, in this type of test method, as in many ASTM test methods, the use of an alternative temperature measurement device may provide more accurate temperature measurements but may not reproduce the previously accepted values of the test method.*"(ASTM, 2009). Because of these reasons, there is a need for research comparing data obtained with an alternate device of well-defined geometry and construction and the specified mercury-in-glass thermometers with samples of the same test material. The ASTM subcommittee E20.05 will determine effects on charts, data, and precision & bias statements (ASTM, 2009).

Information that ECHA has received from Denmark, the Netherlands and Norway in early 2010 shows that current national restrictions on mercury thermometers foresee exemptions for mercury thermometers where analysis standards prescribe a mercury thermometer (see section B.5). This information is to a certain extent supportive to the evidence that standards would constitute a technical obstacle.

Sweden seems to be an exception. With regard to CEN and ISO standards, Sweden has not implemented standards that prescribe the use of mercury measuring devices since 1998 (KemI, 2004). According to information received from the Swedish Chemicals Agency (KemI), the only remaining exemption on mercury thermometers is issued for flash point determination according to Directive 67/548/EEC, which was granted in 2007 and will expire on the 30th of June 2011.

Conclusions on technical feasibility of alternatives

For all known applications, there are technically feasible alternatives that can replace all mercury thermometers and other non-electrical thermometric devices using mercury, with the exception of

- **thermometers used for testing according to analysis standards (test methods) that prescribe mercury thermometers, and**
- **mercury triple point cells that are used for the calibration of platinum resistance thermometers.**

For AGA heat indicators, technically feasible alternatives are estimated to be available well before the entry into force of the proposed restriction.

This conclusion is supported by the conclusion of the US National Institute of Standards and Technology (NIST) that there are no fundamental barriers to the replacement of mercury thermometers. NIST and US EPA are collaborating to resolve difficulties in using alternative thermometers in certain elevated temperature applications, such as autoclave operations and asphalt processing. However, some Federal and State Regulations contain requirements to use mercury thermometers either directly or through citations of standards and methods from organizations such as ASTM International and the American Petroleum Institute (API). The US EPA is taking steps to revise its regulations to allow non-mercury alternative thermometers. In addition, US EPA is working with ASTM International and the API to revise their standards to include flexibility allowing non-mercury alternatives. (US EPA, 2011)

3.4 Economic feasibility

The analysis of economic feasibility builds on the technical feasibility of alternatives, and on the compliance cost calculations for thermometers that are presented in Annex 5b.

Both mercury thermometers and their alternatives have variable properties – even within each market segment. The best endeavour is made to compare mercury containing devices with alternatives that have similar technical properties for each of the main market segments. Factors that seem to influence the price of mercury thermometers and their alternatives are accuracy, temperature range and level, compliance with standards, calibration certification, and suitability to measure temperature in adverse environmental conditions. For electronic alternatives also additional features and optional interfaces can be added to this complexity of elements influencing the price of a particular thermometer. The combinations of all factors results in a substantial price diversity of thermometers. Therefore, the analysis of economic feasibility (including compliance costs calculations in Annex 5b) is based on what is considered by producers to be a "typical mercury containing thermometer" and a "typical alternative thermometer" taking into account all available information, in particular from Lassen et al. (2008) and Lassen et al. (2010).

The price of liquid-in-glass thermometers is roughly the same as for mercury thermometers. For this reason, and because of the many common technical properties, liquid-in-glass thermometers are the most common replacement for mercury thermometers up to 200°C and with resolution not better than 0.1°C (Lassen et al., 2008 and Lassen et al., 2010). They can directly replace mercury room temperature thermometers (Lassen et al., 2008). Gallium thermometers are reported to have a low market share, which seems to be related to their (higher) price (Lassen et al., 2010). They are not further considered in the assessment.

Prices of the electronic alternatives are higher than mercury thermometers. However, the electronic devices have additional features such as automated temperature recording, alarm systems, real-time process monitoring and feedback systems[81]. Thus, the prices cannot be compared directly. In fact, the advantage of electronic reading for example is one of the drivers for replacing mercury thermometers with electronic devices. Due to the additional features customers are willing to pay a higher price for the electronic devices (Lassen et al., 2010). No information is available to quantify the value of these additional features and to deduct it from the investment costs of the

[81] Amongst additional features are higher precision and automation offered by electronic thermometers. These advantages can result in additional savings in industrial applications, e.g. lower operational costs due to the use of less energy to, for example, heat large industrial volumes to a certain temperature. Automatic reading and data storage are likely to reduce the need for labour due to less time spent to collect temperature readings manually and additional savings associated with reducing human reading errors. Automated temperature feedback mechanisms might result in higher efficiency of reactions, or to a better quality of the end-product. Temperature alarm systems (and to a certain extent automated temperature feedback mechanisms) might substantially reduce the risks of damage. All these benefits may have substantial value, however, whether these additional functions are of importance depends on the application (see also Annex 5b).

electronic alternatives. Therefore, the costs associated with the transitioning from a mercury thermometer to an electronic alternative are likely to be overestimated.

The users of analysis standards that prescribe mercury thermometers might have to pay an additional cost for a standard update originating from a restriction (a restriction would require standards to be amended in order to allow for the use of non-mercury alternatives, see also section 3.3). It seems that the cases where an update would be a direct result from a restriction would be limited. It is not considered possible to estimate the compliance costs related to the purchase of standards, but it is thought that the additional cost for the lab thermometer market segment would not be substantial[82].

A problem that has been mentioned is the need for modification of existing equipment, also called retrofitting (Lassen et al., 2010)[83]. On the basis of the available information, it was concluded that usually the effect on the investment costs would be negligible. See Annex 5b for a more detailed discussion.

The economic feasibility of the following main market segments are discussed in this section: laboratory thermometers, industrial thermometers, and thermometers for meteorological measurements.

Laboratory thermometers

Mercury-free liquid-in-glass lab thermometers are one of the most common replacements for mercury-in-glass thermometers used to measure temperature below 200°C in applications where high precision is not needed. Their price is roughly the same as for mercury thermometers or about 10% lower (Lassen et al., 2010). In the main scenario used for laboratory thermometers in this segment, investment costs are assumed to be the same. However, the operating costs for the liquid-in-glass thermometers would be lower due to their assumed lower waste treatment costs in comparison to their mercury-containing counterparts. Table A5a-3 shows that the lower operating costs would result in savings of €2.6 per year for each liquid-in-glass thermometer compared to a mercury-in-glass lab thermometer in this market segment. Therefore, liquid-in-glass thermometers are an **economically feasible alternative** to the mercury-containing devices when measuring temperature **below 200°C** in applications where **high precision is not needed**.

[82] It is unknown how many standards would actually prescribe mercury thermometers to be used, and therefore it is not known how many standards would have to be changed as result of a restriction. Considering the difficulty in identifying standards that would *prescribe* mercury thermometers during the information gathering and consultations carried out in the course of preparing this dossier, it is thought that the amount would be limited. When a new version of a standard is published, customers need to purchase the entire standard again, but note that one analysis standard is likely to cover several thermometers in one lab (ASTM standards vary in price from $34 to $120 USD each (ASTM, 2010, pers. comm.)). However, in so far a standard is updated during the normal update process it is thought there would be no additional cost that can be attributed to a restriction. In the case of ASTM standards that are already in the process of being modified under the mercury initiative, it would be difficult to argue if, and to what extent, an update would result from a restriction in the EU.

[83] This is considered to be an economical issue rather than a technical feasibility issue since it seems that these modifications can always be carried out (at a certain cost).

Table A5a-3 also shows the costs for mercury-in-glass thermometers used in laboratories where an **accuracy of 0.1°C or better** is needed **or** for temperature measurements **above 200°C**. The purchase price of an electronic system is higher than their mercury counterparts. However, as it is assumed that mercury thermometers can be replaced by 60% fewer electronic alternatives, the analysis concludes that laboratories would pay €3 (i.e., 4%) more per year to replace each mercury containing device. Calibration frequency of mercury thermometers is considered to be once every two years – twice more frequent that industrial thermometers due to the higher precision needed, while the electronic alternatives are assumed to be calibrated annually similar to the assumptions made in the industrial segment. The life-times are considered to be similar. In sum, electronic thermometers are an **economically feasible alternative** to the mercury-containing devices in this market segment.

Table A5a-3: Costs of mercury containing thermometers and their alternatives in laboratory applications[84]

	Lab (res >0.1°C and T<200°C)		Lab (res 0<.1°C or T>200°C)	
Device Costs (€)	**Mercury-in-glass**	**Liquid-in-glass**	**Mercury-in-glass**	**Electronic**
Investment cost	40.0	40.0	80.0	180.0*
Lifetime of device (years)	5	5	5	5 (10)**
Annualised investment cost	9.0	9.0	18.0	31.9
Recurrent costs	27.0	24.4	52.9	41.9
Annualised total cost	**35.9**	**33.7**	**70.9**	**73.8**
Additional annualised total cost	0.0	-2.6	0.0	2.9

Source: Tables 1-4 and 7-10 in Annex 5b

Notes: * The investment cost for electronic thermometers is much lower than the purchase price of a full measurement set because of the assumption that 60% fewer electronic alternatives can replace mercury-in-glass thermometers.

**5 years for the probe and 10 years for the data reader.

Industrial thermometers

In the market segment of industrial mercury-in-glass thermometers measuring temperatures **below 200°C**[85], mercury-free liquid-in-glass industrial thermometers cost somewhat less than mercury-containing devices. Table A5a-4 shows that the transition to liquid-in-glass thermometers will result in annual savings to users (assuming that the waste treatment costs of the alternatives are lower than the mercury-containing devices). Thus, in this market segment there **are economically feasible alternatives**.

Mercury-in-glass thermometers used in industry to measure temperature **above 200°C**, can be replaced by electronic or mercury-free dial thermometers. When

[84] The costs in the analysis represent factory gate prices excluding VAT for investment costs, but for other costs (recurrent costs) it is not known if the VAT is included or not. All values used in this analysis refer to year 2010 price levels.

[85] Precision is not a critical characteristic for industrial thermometers, see section 3.3.

excluding the labour time savings, the additional annualised costs for users of the alternative are about €98 per device[86]. Since the electronic alternatives offer the advantage of automation, thereby reducing the need for an individual to visually verify the temperature, the cost calculations were refined to reflect labour time savings. The additional annualised costs per device are €13 ±€42[87] per annum per device, including labour time savings (Table A5a-4).

The calibration costs and calibration frequency of the alternative devices have a major impact on the costs. These factors are uncertain and it is thought that there are differences between the recommended calibration frequency and the real frequency in practice. The analysis in Annex 5b assumes that alternatives have a four times higher calibration frequency. In the extreme case, when calibration costs are ignored and labour time savings are taken into account, the annualised *savings* per electronic device are €61. When both calibration costs and labour time savings are ignored, the additional annualised costs would be lower, i.e. €23.3 and €40.2 per device per annum for respectively the electronic and mercury-free dial thermometers[88].

In addition, the economic impact of the transition to alternatives on users of industrial mercury thermometers measuring temperature above 200°C will be relatively small because:

- the additional annualised costs associated with the transition to the alternatives are estimated to be a small percentage of the users' total costs for purchases of goods and services;[89]
- the measurement costs overall do not represent a substantial portion of the total production costs; therefore, the additional annualised costs due to the transition to the alternative are expected to contribute only marginally to the final product cost and thus, are not expected to lead to (sizeable) price increases to consumers downstream;
- the alternatives have additional benefits over the mercury-containing devices which were not fully taken into account in the cost calculations:
    - cost savings due to lower spill cleanup costs[90];

[86] There are a number of reasons why the transition to alternatives in the high resolution/T>200°C lab segment is more cost-effective than the industry segment over 200°C. The main factors include: the lower long-term investment cost of the alternative due to the assumption that mercury lab thermometers can be replaced by fewer electronic alternatives; and the shorter lifetime (5 years in lab instead of 13 years in industry) that is equal for both mercury and alternative lab thermometers (see Annex 5b).
[87] Labour time savings of 4 hours with an uncertainty margin of ±2 hours per year are assumed.
[88] The mercury-free dial thermometers are in this case more expensive due to their short life-time
[89] As an illustrative example, the additional annualized total cost of €13 per thermometer can be compared to the total purchases of goods and services (TPGS) for high volume users of industrial thermometers measuring temperature over 200°C, e.g., manufacturing companies. In the EU-27, the average TPGS for a manufacturing company was €2.3 million (TPGS and number of enterprises, Eurostat, 2007). Assuming that a manufacturing company in the EU-27 purchases between 1 and 100 non-mercury thermometers every five years (the lifetime of the cheaper alternative), the additional total costs associated with the use of the alternatives (€13 – €1,300) are estimated to be between 0.0006% and 0.06% of the average TPGS per manufacturing company. Two other sectors were also analysed – the mining & quarrying and electricity, gas & water supply industries – which are also estimated to be high volume users of thermometers measuring temperature over 200°C. The share of the additional annualised total cost of €13 (or €98 if labour cost savings are taken into account) per thermometer represents even smaller percent of the TPGS per enterprise in these sectors.

  - o cost savings due to avoidance of contamination of batch with mercury upon breakage;
  - o other potential benefits in addition to reduced labour time savings, e.g., increased accuracy of process control;
- alternatives have already taken over the market for industrial thermometers (Lassen et al., 2008) and the majority of users are no longer heavy users of mercury-containing devices.

It can be concluded that the alternatives to industrial mercury-in-glass thermometers measuring temperature over 200°C can also be considered economically feasible. This is due to the fact that the possible additional annual costs associated with the transition to the alternatives are estimated to be a small outlay in comparison to other expenditures on goods and services of users of these thermometers. Consequently, these additional expenditures will not lead to significant price increases of the final goods or services produced by the users of these thermometers.

Table A5a-4: Costs of mercury-in-glass thermometers and their alternatives in industrial applications[91]

	Industry (T<200°C)		**Industry (T>200°C & Dial)**		
Device Costs (€)	**Mercury-in-glass**	**Liquid-in-glass**	**Mercury-in-glass**	**Mercury-free Dial**	**Electronic**
Investment Costs	22.5	22.5	45.0	125.0	134.2
Lifetime of device (years)	13	13	13	3	5
Annualised Investment Costs	2.3	2.3	4.5	45.0	26.0
Recurrent Costs					
- excluding labour time savings	28.6	27.8	28.6	85.6	104.7
- including labour time savings	28.6	27.8	28.6	85.6	20.4
Annualised Total Costs					
- excluding labour time savings	**30.9**	**30.0**	**33.1**	**130.6**	**130.7**
- including labour time savings	**30.9**	**30.0**	**33.1**	**130.6**	**46.4**
Additional Annualised Total Costs					
- excluding labour time savings		-0.8		97.5	97.6
- including labour time savings		-0.8		97.5	13.2

Source: Annex 5b

[90] Although specific estimates for spill cleanup costs for thermometers have not been obtained, the following estimates for sphygmomanometers can assist the reader to put the costs in perspective: €400 clean up cost per spill (cost of spill kit, person-hours, spill area closure and cost of downtime, waste disposal, etc.), and €30 per sphygmomanometer for staff training on spill response. (Concorde East/West 2009)

[91] The costs in the analysis represent factory gate prices excluding VAT for investment costs, but for other costs (recurrent costs) it is not known if the VAT is included or not. All values used in this analysis refer to year 2010 price levels.

Mercury dial thermometers used in industry can be replaced by electronic or mercury-free dial thermometers. In the absence of information, the costs of mercury dial thermometers and their alternatives are assumed to be the same as the mercury-in-glass industrial thermometers for measuring temperatures above 200°C (Table A5a-4). The reported figures do not include labour time savings resulting from the use of electronic alternatives, but since the figures are the same as for mercury-in-glass thermometers, the additional annualised cost including labour time savings would also drop from €98 to €13 (in the 2010 price level). Mercury dial thermometers are confirmed by producers to hold only a very limited residual market because alternatives have taken over (Lassen et al., 2008), and no consulted producers have mentioned that alternatives to dial thermometers would not be economically feasible (Lassen et al., 2010). The economic importance of mercury dial thermometers is thought to be marginal[92].

For these reasons it can be concluded that the alternatives to mercury dial thermometers can be considered economically feasible.

Thermometers for measuring ambient temperature and other meteorological measurements (including Six's thermometers and psychrometers)

The transition from mercury-containing to mercury-free ambient thermometers, psychrometers (hygrometers), and most other thermometers for meteorological applications, is expected to result in additional annualised savings, similar to mercury-in-glass lab and industrial thermometers for measuring temperature below 200°C and with a resolution not better than 0.1°C. This is likely to take place due to the following reasons:

- the price of the liquid-in-glass alternatives in ambient temperature is similar to the mercury-containing thermometers (no resolution <0.1°C needed);
- Six's thermometers with organic liquids are available at similar or lower prices than the mercury filled counterparts (Lassen et al., 2010);
- electronic or spirit-filled psychrometers are available for most applications at approximately the same price as mercury psychrometers (Lassen et al., 2010);
- it costs less to dispose of a mercury-free device at the end of its useful life;
- the calibration frequency and costs of the mercury and liquid-in-glass devices are similar; and
- the lifetime of the mercury and liquid-in-glass devices is similar.

[92] In addition, because the market of these thermometers was known to be marginal, minimal effort has been given to better estimate costs and life-times of these devices. Therefore the data from mercury-in-glass thermometers was used. It has to be emphasised that the cost estimate is conservative in several ways. The assessment used a conservative estimate of a lifetime of 13 years for mercury dial thermometers vs. three years for gas or liquid actuated dial alternatives, and a yearly calibration of the alternatives vs. once every 4 years for the mercury dial thermometer. It seems however that the technology of the mercury dial thermometers gas or liquid actuated dial alternatives is not very different, and in reality the lifetimes and calibration frequencies might be equal or similar (analogue to the situation of mercury-in-glass and liquid-in-glass alternatives). Assuming that the mercury dial thermometers have the same lifetime and calibration frequency as their gas-actuated alternative systems (and ignoring labour time savings), the additional annualised total cost would be €24.30 (for mercury-free dial) and €24.40 (electronic) instead of €97.5/ device and €97.6/ device respectively.

Therefore, it can be concluded that alternatives to mercury thermometers for measuring ambient temperature and other meteorological measurements (including Six's thermometers and psychrometers) are economically feasible.

Conclusions on economic feasibility of alternatives

It is concluded that the alternatives for all laboratory thermometers, mercury dial thermometers, industrial mercury-in-glass thermometers for measuring temperature below 200°C, and thermometers for measuring ambient temperature and other meteorological measurements are economically feasible.

The analysis of the market segment of industry mercury-in-glass thermometers measuring temperature over 200°C showed that the transition to non-mercury containing alternatives will induce approximately €97.5 additional annualised total cost per device, or when the assessment is refined by including the labour time savings, approximately €13±42[93] per annum per device. Possible additional annual costs associated with the transition to the alternatives are estimated to be a small outlay in comparison to other expenditures on goods and services of users of these thermometers. Therefore, it can be concluded, although with less certainty than the other market segments, that **the alternatives for industry mercury-in-glass thermometers measuring temperature over 200°C are economically feasible.**

4. Justification why the proposed restriction is the most appropriate Community-wide measure (PART E)

4.1 Identification and description of potential risk management options

4.1.1 Risk to be addressed – the baseline

As described in section B.2, the total estimated amount of mercury placed on the market in measuring devices containing mercury is used to describe the maximum potential for mercury emissions to the environment that might ultimately occur.

In 2007, between 0.7-1.6 tonnes of mercury was placed on the market in the EU in new thermometers (Lassen et al., 2008). Based on the declining trend in the thermometer market, as described in Box 1 in section 2 of this annex, it is assumed that without additional legislative action the European market of mercury thermometers will decline by about 5% annually. Thus, in 2010 this would result in a volume brought on the market of 0.6-1.5 tonnes. For the purposes of the analysis of the baseline of thermometers, it is assumed that the mid-point, i.e. 1 tonne, will be placed on the market in 2010 and that this amount will decline by 5% annually. Table A5a-5 and Figure 5a-1 give the baseline for thermometers. In addition, the

93 Labour time savings of 4 hours with an uncertainty margin of ±2 hours per year are assumed.

accumulated amount in the years 2015-2034 is presented in Table A5a-5 for use in section 4.2.

Although not the primary concern, it is worth mentioning that direct exposure of workers can occur during production, professional/industrial use of thermometers and during waste management operations.

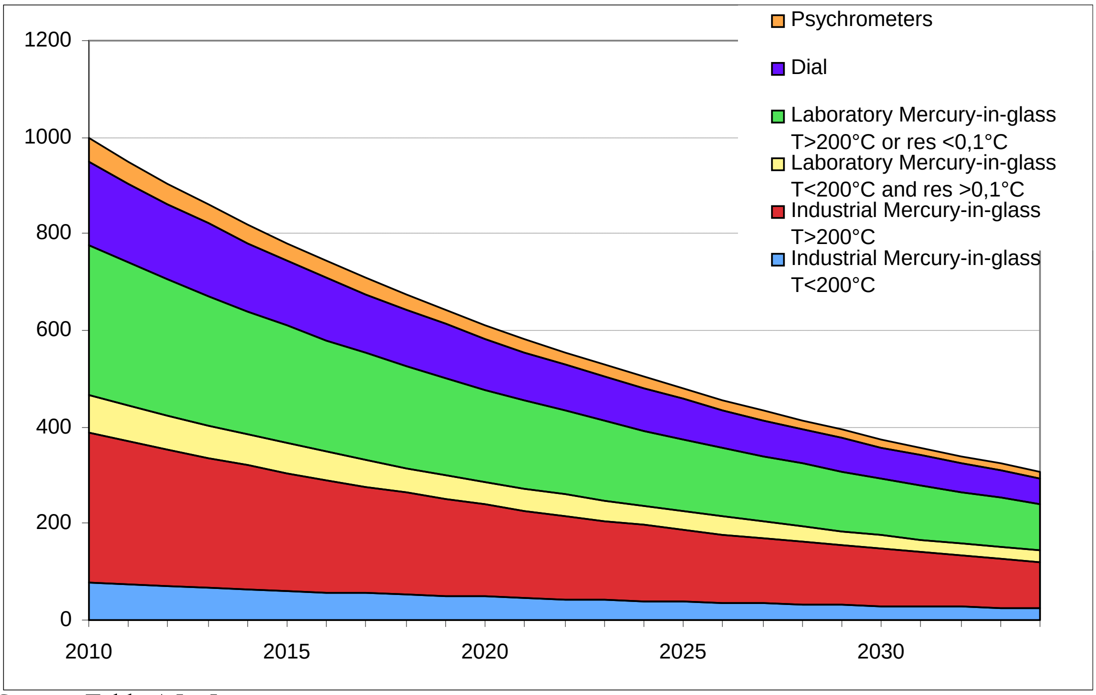
Table A5a-5: Estimates of the amount of mercury placed on the market each year in mercury containing thermometers for 2010-2034 - Baseline assumptions (kg per year)

Year	**Thermometer type**						**Total**
	Industrial			***Laboratory***		***Psychro-meters***	
	Mercury-in-glass		*Dial*	*Mercury-in-glass*			
	T<200° C	*T>200° C*		*T<200°C and res >0,1°C*	*T>200°C or res <0,1°C*		
2010	78	311	173	78	311	48	998
2011	74	296	165	74	296	45	950
2012	71	282	157	71	282	43	905
2013	67	269	149	67	269	41	862
2014	64	256	142	64	256	39	820
2015	61	244	135	61	244	37	781
2016	58	232	129	58	232	35	744
2017	55	221	123	55	221	33	708
2018	53	210	117	53	210	32	675
2019	50	200	111	50	200	30	642
2020	48	191	106	48	191	28	612
2021	45	182	101	45	182	27	583
2022	43	173	96	43	173	26	555
2023	41	165	92	41	165	24	528
2024	**39**	**157**	**87**	**39**	**157**	**23**	**503**
2025	37	150	83	37	150	22	479
2026	36	142	79	36	142	21	456
2027	34	136	75	34	136	20	434
2028	32	129	72	32	129	19	414
2029	31	123	68	31	123	18	394
2030	29	117	65	29	117	17	375
2031	28	112	62	28	112	16	357
2032	27	106	59	27	106	15	340
2033	25	101	56	25	101	15	324
2034	24	96	54	24	96	14	309
Σ 2015-2034	**800**	**3,190**	**1,770**	**800**	**3,190**	**470**	**10,210**

Source: Estimate based on figures from Lassen et al. (2008).

Note: No estimates were available for other meteorological applications than psychrometers, but the volumes are thought to be very small.

Figure 5a-1: Estimates of the amount of mercury placed on the market each year in mercury containing thermometers for 2010-2034 - Baseline (kg per year)



Source: Table A5a-5

As described in the Chapter 2 of this annex, the pool of mercury in lab and industry thermometers currently used in society is estimated to be roughly 90 tonnes in 2010.

As described in section B.4 of the BD collection efficiencies of mercury in measuring devices, including mercury thermometers, in accordance with requirements set out in the hazardous waste legislation are estimated to be low. It is difficult to estimate the future trend of collection and share of proper waste management, however, there is no indication that the collection rate would improve without new targeted action and considerable efforts by the Member States in the future. Even with improved collection compared to the current situation, it seems unlikely that high enough collection rates would be achieved[94].

4.1.2 Options for restrictions

A tentative identification of possible restriction options was carried out based on the conclusions from the technical and economic feasibility in sections 3.3 and 3.4 of this Annex. The main results are presented in Table A5a-6. Based on those conclusions, two main issues need to be assessed further. These relate to analysis standards that refer to mercury thermometers for certain laboratory applications (including laboratories in industry), and to temperature measurements above 200°C in industry. Since these issues impact a separate market segment, it is considered more practical to

[94] Collection efficiencies above 50% should in general not be expected (Lassen et al., 2008Lassen et al., 2008).

assess the restriction options of industry and laboratories separately[95]. For the sake of that approach, the meteorological applications were included in the laboratory assessment.

Table A5a-6: Information to help determine options to reduce mercury placed on the market in thermometers

Market segment	Technically feasible?	Economically feasible?	Volume Hg in thermometers in 2015-2034 (kg)	Cost-effectiveness to reduce mercury (€/kg)
Laboratory thermometers				
Lab res>0.1°C and T<200°C	Yes, **but** standards	Yes	800	-3,700
Lab res<0.1°C or T>200°C	Yes, **but** standards	Yes	3,190	4,185
Industrial thermometers				
Industry T<200°C	Yes	Yes	800	-3,100
Industry T>200°C	Yes	**Yes**	3,190	
- excluding labour time savings				362,200
- including labour time savings				49,200
Dial thermometers	Yes	Most likely	1,770	12,400
Meteorological thermometers				
Psychrometers	Yes	Yes	470	*
Others	Yes	Yes	**	*

Source: Sections 3.3 and 3.4, and Table A5a-5 of this Annex, and Annex 5b.
Notes: Negative value means saving
*Cost calculations for psychrometers and other meteorological thermometers are not available but due to the reasons described in section 3.4 and Annex 5b, their cost-effectiveness is expected to be high (even resulting in negative values), similar to mercury-in-glass lab and industrial thermometers for measuring temperature below 200°C and with a resolution not better than 0.1°C.
**No data is available about the size of this market segment.

Based on the tentative identification of possible restriction options, 5 options to reduce the risk from mercury contained in thermometers in the EU have been assessed

[95] The described options are considered to be independent from one another. In real life, a restriction in one of the market segments might have an influence on other market segments. As an example, a reduced overall market after restriction of a segment can influence prices in another segment, and there may be some issues in relation to enforceability or implementability. However, such effects are thought to be minor.

in greater detail ('options for analysis'). It was concluded to repeat two limited derogations, namely:

1) a derogation for mercury triple point cells that are used for the calibration of platinum resistance thermometers in the options for the laboratory market segment (on the basis of technical feasibility, see section 3.3); and
2) a derogation to allow the placing on the market of thermometers with historic or cultural value in all options (See Part E of main document for details).

The impact of these two derogations on risk reduction capacity and economic feasibility of the restriction options is considered negligible. See Part E of the main document for the derogation on thermometers with historic or cultural value. The mercury placed on the market in mercury triple point cells that are used for the calibration of platinum resistance thermometers is estimated to be negligible (Lassen et al., 2008).

Options for analysis

Laboratory (& meteorology)

- Option 1a: Restriction on the placing on the market of all mercury laboratory thermometers and thermometers for meteorological applications from 2015[96] onwards with the two recurring derogations.

- Option 1b: A restriction as in option 1a, and in addition a *time-limited* derogation of 5 years[97] for mercury laboratory thermometers exclusively intended to perform tests according to standards that require the use of mercury thermometers.

Industry

- Option 2a: Restriction on the placing on the market of all industrial mercury thermometers from 2015 onwards with the derogation on thermometers with historic or cultural value.

- Option 2b: A restriction as in option 2a, and in addition a derogation for mercury-in-glass thermometers used in industrial applications for temperature measurements above 200°C as demonstrated by the reading scale.

- Option 2c: A restriction as in option 2b, and in addition a derogation for dial thermometers.

[96] Assuming that a restriction would apply 18 months after the entry into force, it is estimated for the purpose of this assessment that the restriction comes into effect in the year 2015.

[97] Based on the available information (see section 3.3) it seems that not many standards would prescribe mercury thermometers to be used anymore, and at least ASTM is already in the process of phasing out mercury thermometers from its standards from 2006. Since ASTM standards would have to be reviewed every 5 years, it seems reasonable to assume that all remaining ASTM and other standards still prescribing mercury can be amended by approximately 2018.

Options not retained for further assessment

In addition to the restriction options described above and that were assessed in detail, the following additional aspects have been considered, but for reasons explained not retained for further assessment:

- A derogation for mercury-in-glass thermometers in laboratories > 200°C or with a resolution <0.1°C.

  Similarly to the derogation in restriction Option 2b for the market segment of mercury-in-glass thermometers in industry for measurements above 200°C, a derogation on the restriction for lab thermometers for all applications that need a resolution better than 0.1°C or used for measurements >200°C could be envisaged. However, unlike for the industry segment, the estimated additional annualised cost per thermometer is only marginally higher[98] and the measure is cost-effective (€2600€/kg of mercury not placed on the market, see Annex 5b). A derogation was not deemed warranted and this option was not analysed further.

- Restriction on the placing on the market of mercury thermometers with a derogation for all industry mercury-in-glass thermometers

  This restriction would be similar to Option 2b with the difference that in addition thermometers measuring temperature below 200°C would be derogated. This would imply that during 2015-34 some 4 tonnes of mercury would still be placed on the market in thermometers for measuring temperature below 200°C. Derogating all industrial mercury-in-glass thermometers might be legally somewhat clearer and easier to enforce, but since the transition to alternatives would be cost neutral or even imply savings, enforceability and legal clarity were not deemed to be sufficient reasons for such a derogation (Table A5a-6).

- A system might be installed by which users or suppliers could apply for an exemption on the general restriction (as in the Swedish and Norwegian restriction, see section B.5 in the main report).

  Administrative efforts to implement such a system were deemed to be disproportionately high, and the risk reduction capacity is unlikely to improve substantially in comparison with derogations in the options. Also the enforceability of such a system might be slightly reduced. For these reasons, this option was not considered further.

[98] There are a number of reasons why the transition to alternatives in the high resolution/T>200°C lab segment is more cost-effective than the industry segment over 200°C. The main factors include: the lower long-term investment cost of the alternative due to the assumption that four mercury lab thermometers can be replaced by one electronic alternative; the calibration neutrality of the cost calculations for lab thermometers as the calibration frequency and cost of both mercury and alternative thermometers is assumed to be the same, and the shorter lifetime (5 years in lab instead of 13 years in industry) that is equal for both mercury and alternative lab thermometers (see Annex 5b).

- A restriction on the professional use of mercury fever thermometers.

  It was considered whether a use ban of existing fever thermometers in the medical sector, might be combined with a possible use ban of sphygmomanometers. The total volume of the mercury included in fever thermometers still in society is estimated to be 12 tonnes in 2010, but is steeply declining to an estimated volume of 0 already in 2014 (the restriction of placing on the market fever thermometers entered into force in April 2009). At the time the use restriction would come into effect, due to the short estimated useful lifetime of fever thermometers, there could only be some amount of fever thermometers recuperated that are 'lingering on' in store rooms in hospitals and with general practitioners. Because of the low volumes, and because a use ban on sphygmomanometers was not considered to be proportionate (see Annex 3a), this option was not analysed further.

- A derogation for long-term studies for laboratory mercury thermometers.

  There might be a bias between temperature readings from alternatives to mercury thermometers. Lowe (2009) suggests that readings of mercury thermometers, Galinstan thermometers and electronic thermometers do not differ significantly. This study was limited to fever thermometers, however.

  Conversely, according to ASTM (2009) there is a need for research comparing data obtained with alternate devices and the mercury-in-glass thermometers. All ASTM test methods (see section 3.3) are required to have a Precision and Bias statement, and based on information received from ASTM (2010) it seems that such issues would have to be resolved before a standard can be published in its updated form (i.e. allowing the use of alternatives). Because of this, the issue is directly linked to a possible derogation for analysis standards. A separate derogation for laboratory thermometers is therefore not considered further.

4.2 Assessment of risk management options

4.2.1 Option 1a: Restriction on all laboratory thermometers

Restriction to place mercury on the market in non-electrical equipment used to measure or indicate temperature in laboratories and for meteorological applications, after 18 months of entry into force with derogations for:

- mercury triple point cells that are used for the calibration of platinum resistance thermometers; and
- placing on the market thermometers with historic or cultural value (see details in Part E of the main document).

4.2.1.1 Effectiveness

Risk reduction capacity

The risk reduction capacity that can be achieved by introducing restriction Option 1a is described as an annual reduction of mercury placed on the market in the EU (see section B.2 of the main report). Assuming an annual declining trend of 5%, restriction Option 1a would avoid placing on the market a volume of around 220 kg of mercury in 2024[99], or a cumulatively amount of about 4.5 tonnes of mercury would not be placed on the market in the period 2015-34 (Table A5a-5). Note that the amounts for other meteorological applications other than psychrometers are not estimated and thus, not included in this number. This volume is a measure for reduction of the maximum potential for mercury emissions to the environment that might ultimately occur. In addition, it can be mentioned that the volume also reduces direct exposure of workers in production, use and waste phase -with the exception of exposure related to remaining production for exports.

Emissions related to the service-life and waste phase of mercury thermometers already in use will not be affected by restriction Option 1a.

The risk associated with placing on the market of alternatives to mercury thermometers is not considered to be significant in comparison to the risk associated with mercury thermometers (see Section 3.2).

Proportionality

Technical feasibility

In section 3.3 it was concluded that – apart from the issue relating to standards and the two recurring derogations – there are no known technical obstacles to replace all mercury thermometers for all applications.

Until standard organisations have updated their analysis standards referring to mercury thermometers in order to support the use of alternatives, it will in practice not be possible to replace mercury thermometers in certain laboratory applications.

As a conclusion it is not considered technically feasible to restrict placing on the market of mercury thermometers with the limited derogations as proposed in Option 1a.

Economic feasibility (including the costs)

Section 3.4 of this Annex described the economic feasibility of alternatives. This section summarises the compliance and administrative costs associated with the proposed restriction Option 1b from the compliance cost analysis in Annex 5b. Table A5a-7 presents the main outcomes.

[99] The year 2024 is a chosen as a representative year for compliance cost calculations, see section E of the main document for the justification.

As a result of the implementation of Restriction Option 1a, the replacement of 220 kg[100] of mercury in 2024[101] (or cumulatively 4.5 tonnes for the period 2015-34). This is estimated to cost €0.6 million in 2024 (or €6.9 million cumulatively in 2015-34).[102]

Table A5a-7: Restriction Option 1a: Amount of mercury not placed on the market in thermometers, compliance costs and cost effectiveness for laboratory thermometers

	Amount of mercury not placed on the market in thermometers		Additional annualised costs for alternative	Total compliance cost		Cost effective -ness
	in 2024	cumulative 2015-34		in 2024	cumulativ e 2015-34	
	(kg)	(kg)	(€ /device /annum)	(€ million)	(€ million)	(€/kg)
Lab res>0.1°C and T<200°C	39	797	-2.6	-0.2	-2.0	-3,692.5
Lab res<0.1°C or T>200°C	157	3,188	2.9	0.7	8.9	4,185.2
Psychrometers	23	470	*	*	*	*
Total	**220**	**4,455**		**0.6**	**6.9**	**2,609.7**

Notes:
Negative values represent cost savings.
*Cost calculations for psychrometers are not available but due to the reasons described in section 3.4 and Annex 5b, their additional annualised and total compliance costs are expected to be low and even negative, similar to mercury-in-glass lab and industrial thermometers for measuring temperature below 200°C and with a resolution not better than 0.1°C. Similarly, the cost effectiveness of psychrometers is expected to be high (even resulting in negative values).
Source: Annex 5b

Although the socio-economic benefits of reducing mercury use have not been estimated, the cost-effectiveness of the alternatives (Table A5a-7) in comparison to other measuring devices and other implemented policies (Appendix 2) suggests that Option 1a is economically feasible.

Administrative costs resulting from the restriction of placing on the market of mercury laboratory thermometers is considered to be small, or might even result in savings (see section 4.2.1.2 Practicality).

[100] The mid-point of the estimated mercury use in the EU in 2010: 780-1,040 kg.
[101] The year 2024 is a chosen as a representative year for compliance cost calculations, see section E of the main document for the justification.
[102] No cost estimates are available for psychrometers.

4.2.1.2 Practicality

Implementability and manageability

As the cost difference of electronic alternatives is small, and as laboratories are already using such equipment for the advantages they have, no major problems are foreseen in terms of implementability or manageability of this market segment, with the exception of thermometers for measurements according to analysis standards prescribing mercury thermometers.

No problems concerning implementability have been reported by Denmark, The Netherlands, Norway and Sweden with regard to implementation of their national restrictions (see also section B.5 of the main report). However, Denmark, the Netherlands and Norway have an exemption for thermometers used for analysis standards or laboratory use in general.

Because of the simplicity of a restriction with only two limited derogations, the legal clarity of restriction Option 1a would be high for all actors, including enforcers.

The administrative burden for laboratory operators of restriction Option 1a would be negligible. In fact there may be savings since many of the thermometers would be replaced by electronic thermometers that have significant advantages concerning keeping temperature records, and inserting data in computer models etc.

As mentioned before, for mercury laboratory thermometers that are used for measurements according to analysis standards, the restriction Option 1a is not considered to be technically feasible, and thus not implementable.

Enforceability

The compliance with restriction Option 1a can be assessed by inspecting producers (at least 11 in the EU according to Lassen et al., 2008), and by verifying if importers and distributors still supply mercury thermometers. Amongst importers can be users (labs or meteorological institutes) that buy thermometers from outside the EU. This last group would be more difficult to inspect. The clarity of the legal obligations would be high.

It would often be sufficient to visually inspect the thermometers to ensure that they do not use mercury as a thermometric liquid. In some circumstances gallium fillings might initially be confused with mercury, because gallium has a similar silvery liquid metal appearance. However, the capillary would have a concave instead of convex meniscus observed with mercury in a glass capillary.

4.2.1.3 Overall assessment of restriction Option 1a

The advantage of the restriction option is the legal clarity and the highest achievable risk reduction capacity for the laboratory segment. Restriction Option 1a would avoid placing on the market a volume of around 220 kg mercury (including in psychrometers) in 2024 (or cumulatively 4.5 tonnes between 2015 and 2034). This is estimated to cost €0.6 million in 2024 (or €6.9 million cumulatively for the period 2015-34).[103] The restriction would be cost-effective.

However, this option has as a major shortcoming originating from the fact that it does not address the issue of analysis standards. This issue is addressed in option 1b.

4.2.2 Option 1b Restriction on laboratory thermometers with a time-limited derogation for use according to analysis standards.

Restriction to place mercury on the market in non-electrical equipment used to measure or indicate temperature in laboratories and for meteorological applications, after 18 months of entry into force with derogations for:

- mercury triple point cells that are used for the calibration of platinum resistance thermometers;
- placing on the market thermometers with historic or cultural value (see details in Part E of the main document); and
- *a time-limited derogation of 5 years for mercury laboratory thermometers exclusively intended to perform tests according to standards that require the use of mercury thermometers.*

4.2.2.1 Effectiveness

Risk reduction capacity

The avoided volume of mercury placed on the market in the EU would be slightly lower than in Option 1a during the 5 year period the derogation on analysis standards would apply (it has not been possible to estimate the derogated volume).

In the years after the derogated period, the risk reduction capacity would be similar to Option 1a (from approximately the year 2018 onwards).

Proportionality

<u>Technical feasibility</u>

The only problem concerning technical feasibility that was identified and discussed in Option 1a, would be lifted with the derogation for laboratory thermometers exclusively intended to perform specific analytical tests according to established standards. Based on the available information (see section 3.3) it seems that not many standards would prescribe mercury thermometers to be used anymore, and at least ASTM is already in the process of phasing out mercury thermometers from its standards from 2006. Since ASTM standards would have to be reviewed every 5

[103] No cost estimates are available for psychrometers.

years, it seems reasonable to assume that all remaining ASTM and other standards still prescribing mercury can be amended by approximately 2018.

Economic feasibility (including costs)

The compliance cost of implementation of the Restriction Option 1b is estimated to be similar to Option 1a, but with the following differences:

- The total compliance cost would be somewhat lower as the total number of thermometers that have to be replaced would be lower (5 year derogation);
- The cost-effectiveness of Option 1b would be the same (as the cost effectiveness is not affected by the number of thermometers on the market).

Overall, Option 1b is in all aspects similar to Option 1a in terms of economic feasibility.

4.2.2.2 Practicality

Implementability and manageability

Option 1a had a problem relating to technical feasibility due to the fact that it did not take into account the need to perform specific analytical tests according to established standards with mercury containing thermometers in laboratories. Option 1b remedies this problem with the time-limited derogation for laboratory thermometers exclusively intended to perform specific analytical tests according to established standards.

However, legal clarity would be reduced in comparison with Option 1a as a result of the derogation.

Enforceability

A temporarily decreased enforceability would be the main difference with Option 1a. In the 5 years the derogation would be applicable, enforcement would have to take place on the level of users (laboratories) in order to confirm that laboratory thermometers placed on the market are indeed used for measurements according to analysis standards. Enforcing the derogation might require a high level of technical knowledge from enforcement authorities, and additional resources would be required for enforcers to familiarise themselves with the analysis standards that are prescribing mercury thermometers. The need for resources would significantly increase (in terms of personnel, time, travelling costs, administrative costs, etc.) and would therefore represent an obstacle for the enforceability of a derogation as proposed in this Option.

4.2.2.3 Overall assessment of restriction Option 1b

The risk reduction capacity would be slightly lower in Option 1b than in Option 1a. However, implementability and technical feasibility would be optimised in comparison with Option 1a. However, effective enforcement of the time-limited derogation might be problematic.

4.2.3 Option 2a Restriction on all industrial mercury thermometers

Restriction to place mercury on the market in non-electrical equipment used to measure or indicate temperature in industrial applications, after 18 months of entry into force with derogations for:

- placing on the market thermometers with historic or cultural value (see details in Part E of the main document).

4.2.3.1 Effectiveness

Risk reduction capacity

The risk reduction capacity that can be achieved by introducing restriction Option 2a is described as an annual reduction of metallic mercury used in the EU (see section B.2 of the main report). Assuming an annual declining trend of 5%, restriction Option 2a would avoid placing on the market a volume of around 280 kg of mercury in 2024, or a cumulative amount of about 5.8 tonnes of mercury would not be placed on the market in the period 2015-34 (Table A5a-5). This volume is a measure for reduction of the maximum potential for mercury emissions to the environment that might ultimately occur. In addition, it can be mentioned that the volume also reduces direct exposure of workers in production, use and waste phase -with the exception of exposure related to remaining production for exports.

The risk associated with placing on the market alternatives to mercury thermometers is not considered to be significant in comparison with the risk associated with mercury thermometers (see section 3.2).

Emissions associated with the production of mercury thermometers will remain where production continues for export. Emissions related to the service-life and waste phase of mercury thermometers already in use in the industry will not be affected by restriction Option 2a.

Proportionality

<u>Technical feasibility</u>

The technical feasibility of Option 2a has been demonstrated in section 3.3 of this Annex. The current national restrictions on mercury thermometers in Denmark, The Netherlands, Norway, and Sweden have no exemptions on industrial thermometers. This would support the assessment that from a technical point of view there is no obstacle to replace mercury thermometers with alternatives for all industrial applications.

<u>Economic feasibility (including the costs)</u>

Table A5a-8 presents the main outcomes of the compliance cost analysis. As a result of the implementation of Restriction Option 2a the replacement of 280 kg of mercury in 2024 (or cumulatively 5.8 tonnes between 2015 and 2034) will take place. This is estimated to cost €8.4 (±24 million[104]) in 2024 including labour cost savings from the use of electronic alternatives (or €90 ±256 million[105] cumulatively for the period 2015-34). When labour cost savings are excluded, the figures become €56 million in 2024 and €602 million for the period 2015-2034.

In terms of cost effectiveness, this means €30,600 per kg of mercury for the restriction of the whole industrial segment (restriction option 2a), when labour time savings are taken into account. Assuming a range of 2 to 6 hours of labour time savings per annum, the cost effectiveness figures range between €117,400 (assuming 2 hours per annum) and savings of €56,100 (assuming 6 hours per annum) per kg of mercury. When labour cost savings are excluded, the figure becomes €204,000 per kg of mercury removed from the market.

In the segment of mercury industrial thermometers for measuring temperature above 200°C, the transition to alternatives will be associated with higher costs to society if no labour time savings are assumed (362,165 €/kg in Table A5a-8). As explained in Annex 5b, labour time savings are realised from the transition to electronic alternatives. Therefore, labour time savings of 4 hours with an uncertainty margin of ±2 hours per year are here assumed. The cost effectiveness is €49,200 (±€156,700) per kg of mercury. The "break-even" point of using an electronic thermometer would be if the employer would save 4.7 hours of work per year.

Table A5a-8: Restriction Option 2a: Amount of mercury not placed on the market in thermometers, compliance costs and cost effectiveness for industrial thermometers

Thermometer Market Segment	Amount of mercury not placed on the market in thermometers		Additional annualised costs for alternative	Total compliance cost		Cost effecti-veness
	in 2024	cumulative 2015-34		in 2024	cumulative 2015-34	
	(kg)	(kg)	(€ / device / annum)	(€ million)	(€ million)	(€/kg)
Industry T<200°C	39	797	-0.84	-0.12	-1.28	-3,127
Industry T>200°C	157	3,188				
- excluding labour time savings			97.5	55.1	591.6	362,165
- including labour time savings			13.2	7.5	80.4	49,201
Dial thermometers	87	1,771	97.5	1.1	11.3	12,367
Total (excluding labour time savings)	**284**	**5,757**		**56**	**601.6**	**203,956**
Total (including labour time savings)				8.4	90.4	30,622

Note: Negative values represent cost savings.
Source: Annex 5b

[104] Labour time savings of 4 hours with an uncertainty margin of ±2 hours per year are assumed.
[105] Labour time savings of 4 hours with an uncertainty margin of ±2 hours per year are assumed.

To better understand the compliance costs in relation to other actions and policies to reduce mercury, one can compare the cost effectiveness of the restriction Option 2a (€30,600/kg Hg) with the other policy options reviewed in Appendix 2. Furthermore, the fact that there are no reported problems related to the national restrictions in Denmark, The Netherlands, Norway and Sweden which have no derogations for industry thermometers (see also section B.5), provides indication that the costs are proportionate to the risks. Based on the information described above, it is concluded that the costs of restriction Option 2a are proportionate to the risk reduction capacity.

4.2.3.2 Practicality

Implementability and manageability

For most industrial applications electronic alternatives are replacing mercury thermometers due to the advantage of automation (Lassen et al., 2008). Mercury dial thermometers are confirmed by producers to hold only a very limited residual market because alternatives have taken over (Lassen et al., 2008). In fact, when the estimated volumes of mercury included in thermometers that are placed on the EU-market is considered, it is evident that there is in general a steep decline in thermometers used in all segments of the market.

No problems concerning implementability have been reported by Denmark, The Netherlands, Norway and Sweden with regard to implementation of their national restrictions (see also section B.5). None of the national restrictions foresees any derogations for industry thermometers. From this experience it appears that a restriction for all thermometers in industry would be implementable as well as technically feasible in those countries.

Because of the simplicity of a restriction with only two derogations, the legal clarity of restriction Option 2a would be high for all actors, including enforcers.

The administrative burden for industry of restriction Option 2a would be negligible. In fact, there may be administrative cost savings since many of the thermometers would be replaced by electronic thermometers that have significant advantages concerning keeping temperature records, and inserting data in computer models.

Enforceability

The compliance with restriction Option 1a can be assessed by inspecting the fairly limited number of producers (at least 11 in the EU according to Lassen et al., 2008), and by verifying if importers and distributors still supply mercury thermometers. The clarity of the legal obligations would be high.

It would often be sufficient to visually inspect the thermometers to ensure that they do not use mercury as a thermometric liquid. In some circumstances gallium fillings might initially be confused with mercury, because gallium has a similar silvery liquid metal appearance. However, the capillary would have a concave in stead of convex meniscus observed with mercury in a glass capillary.

Mercury dial thermometers have a mercury filled metal bulb, and thus visual inspection would not be sufficient. For these devices mobile XRF analysers can be used to verify if mercury is used as the thermometric liquid (non destructive analytical method) (see also First Advice of the Forum on the enforceability of the proposed restriction on mercury measuring devices, adopted 19 November 2010).

4.2.3.3 Overall assessment of restriction Option 2a

The advantage of the restriction option is the legal clarity and the highest achievable risk reduction capacity for the industrial market segment. Restriction Option 2a would avoid placing on the market a volume of around 280 kg of mercury in 2024 (or cumulatively 5.8 tonnes in 2015-34). Although not as clear-cut as in the other thermometer segments, the alternatives for the mercury industrial thermometers for measuring temperature above 200°C are considered economically feasible, and the overall cost-effectiveness of industrial segment acceptable.

4.2.4 Option 2b Restriction on industrial mercury thermometers with a derogation for mercury-in-glass thermometers for temperature measurements above 200°C

Restriction to place mercury on the market in non-electrical equipment used to measure or indicate temperature in industrial applications, after 18 months of entry into force with derogations for:

- placing on the market thermometers with historic or cultural value (see details in Part E of the main document); and
- *industrial mercury-in-glass thermometers that have a reading scale indicating a maximum temperature that is higher than 200°C.*

4.2.4.1 Effectiveness

Risk reduction capacity

The risk reduction capacity that can be achieved by introducing restriction Option 2b is much lower than in Option 2a. The restriction would avoid placing on the market a cumulative volume of around 2.6 tonnes of mercury between 2015 to 2034 (Table A5a-9), which is close to 60% lower than Option 2a which has a risk reduction of approximately 5.8 tonnes over the same period.

Proportionality

<u>Technical feasibility</u>

The technical feasibility of Option 2b has been demonstrated.

Economic feasibility (including the costs)

As a result of the implementation of Restriction Option 2b, 130 kg of mercury will be replaced in 2024 (or cumulatively 2.6 tonnes for the period 2015-34). This is estimated to cost €0.9 million in 2024 (or €10 million cumulatively in 2015-34). See also Table A5a-9.

Table A5a-9: Restriction Option 2b: Amount of mercury not placed on the market in thermometers, compliance costs and cost effectiveness for industrial thermometers. Derogation for industrial thermometers for temperature measurements above 200°C.

Thermometer Market Segment	Amount of mercury not placed on the market in thermometers		Additional annualised costs for alternative	Total compliance cost		Cost-effective-ness
	in 2024	cumulative 2015-34		in 2024	cumulative 2015-34	
	(kg)	(kg)	(€ / device / annum)	(€ million)	(€ million)	(€/kg)
Industry T<200°C	39	797	-0.84	-0.12	-1.28	-3,127
Dial thermometers	87	1,771	97.5	1.1	11.3	12,367
Total	**127**	**2,568**		**0.9**	**10.0**	**7,558**

Note: Negative values represent cost savings.
Source: Annex 5b

The cost-effectiveness is much higher than in Option 2a due to the derogation on industrial thermometers measuring temperatures above 200°C, and in addition, for reasons described in section 3.4 of this annex, the cost estimates for dial thermometers might be too conservative.

In sum, the cost-effectiveness of the alternatives (Table A5a-9) in comparison to other measuring devices and other implemented policies (Appendix 2) suggests that Option 2b is economically feasible.

4.2.4.2 Practicality

Implementability and manageability

Legal clarity of Option 2b would be slightly reduced in comparison with Option 2a as a result of the derogation.

Enforceability

Enforcing the derogation would be similar to Option 2a, although enforcers would have to check the maximum temperature level that an industrial mercury-in-glass thermometer can indicate on its reading scale. If the maximum is below 200°C a breach can be concluded. This can easily be verified by visual inspection. However, the difference between industrial mercury-in-glass thermometers sold as inserts for metal cases and laboratory thermometers is not considered to be straightforward (general purpose thermometers in laboratories do not require high precision). Thus, when inspecting producers, importers and distributors it might be difficult for enforcers to prove that a thermometer is not compliant or vice-versa for the actor to provide evidence of the contrary.

4.2.4.3 Overall assessment of restriction Option 2b

Restriction Option 2b would avoid placing on the market a cumulative volume of approximately 2.6 tonnes of mercury in thermometers between 2015 and 2034. The risk reduction capacity is close to 60% lower compared to Option 2a. In return, however, Option 2b increases economical feasibility due to the derogation for industrial mercury-in-glass thermometers measuring temperature above 200°C, which was the reason for the comparatively high compliance costs of Option 2a.

4.2.5 Option 2c Restriction on industrial mercury thermometers with a derogation for mercury-in-glass thermometers for temperature measurements above 200°C and a derogation for mercury dial thermometers.

Restriction to place mercury on the market in non-electrical equipment used to measure or indicate temperature in industrial applications, after 18 months of entry into force with derogations for:

- placing on the market thermometers with historic or cultural value (see details in Part E of the main document);
- *industrial mercury-in-glass thermometers that have a reading scale indicating a maximum temperature that is higher than 200°C; and*
- *mercury dial thermometers.*

4.2.5.1 Effectiveness

Risk reduction capacity

The risk reduction capacity that can be achieved by introducing restriction Option 2c is much lower than in Option 2a and Option 2b. A cumulative amount of mercury of about 0.8 tonnes would not be placed on the market between 2015 to 2034 (Table A5a-10), instead of 5.8 tonnes in Option 2a or 2.6 tonnes in Option 2b.

Proportionality

<u>Technical feasibility</u>

The technical feasibility of Option 2c has been demonstrated.

Economic feasibility (including the costs)

The implementation of Restriction Option 2c will result in the replacement of 39 kg of mercury in 2024 (or cumulatively 0.8 tonnes between 2015 and 2034) (Table A5a-10). The implementation of this restriction option can result in cost savings of approximately €120,000 in 2024 (or €1.3 million cumulatively for the period 2015-34), due to the assumed lower waste treatment costs of the alternative liquid-in-glass thermometers than their mercury counterparts. Clearly Option 2c is economically feasible.

Table A5a-10: Restriction Option 2c: Amount of mercury not placed on the market in thermometers, compliance costs and cost effectiveness for industrial thermometers. Derogation for dial as well as industry thermometers that have maximum temperature measurements above 200°C.

Thermometer Market Segment	Amount of mercury not placed on the market in thermometers		Additional annualised costs for alternative	Total compliance cost		Cost-effective-ness
	in 2024	cumulative 2015-34		in 2024	cumulative 2015-34	
	(kg)	(kg)	(€ / device / annum)	(€ million)	(€ million)	(€/kg)
Industry T<200°C	**39**	**797**	**-0.84**	**-0.12**	**-1.28**	**-3,127**

Source: Annex 5b
Note: Negative values represent cost savings.

4.2.5.2 Practicality

Implementability and manageability

The implementability and manageability of restriction Option 2c would be similar to Option 2b, however, legal clarity of Option 2c would be slightly reduced in comparison with Option 2b as a result of the introduction of an additional derogation.

Enforceability

Option 2c has the same enforcement issues in relation to the derogation of industrial mercury-in-glass thermometers measuring temperature above 200°C as Option 2b. Enforceability of Option 2c will be just slightly improved with regard to Option 2b as a result of the derogation on dial thermometers: enforcers would not need to check if dial thermometers would contain mercury or not.

4.2.5.3 Overall assessment of restriction Option 2c

The restriction would avoid placing on the market a cumulative amount of mercury of about 0.8 tonnes from 2015 to 2034 – much lower than in Option 2a and Option 2b. Option 2c would be cost neutral or even result in savings, but the risk reduction capacity is considered insufficient to address the risk. In sum, Option 2c seems not to be a proportionate response to the concern related to mercury.

4.3 Comparison of the risk management options

Table A5a-11 summarises the risk reduction capacities and costs associated with the implementation of different restriction options.

Table A5a-11: Summary of risk reduction capacities and costs associated with the implementation of different restriction options

Options	Amount of mercury not placed on the market in thermometers		Total compliance cost		Cost Effec-tiveness (weighted average)
	in 2024	cumulative 2015-34	in 2024	cumulative 2015-34	
	(kg)	(kg)	(€ mill)	(€ mill)	(€ million)
Option 1a	220	4,455	0.6	6.9	2,610
Option 1b	<220	<4,455	<0.6	<6.9	<2,610
Option 2a	284	5,757			
- excluding labour time savings			56	601.6	203,956
- including labour time savings			8.4	90.4	30,622
Option 2b	127	2,568	0.9	10	7,558
Option 2c	39	797	-0.1	-1.3	-3,127

Source: Annex 5b
* The risk reduction capacity and the costs related to Option 1b are estimated to be slightly lower than Option 1a.

Table A5a-12 gives a qualitative overview of the risk management options. The table can be seen as summary of the main elements of the assessment, and allows for a rough comparison of the options on the basis of technical feasibility, risk reduction capacity, economic feasibility, and practicality. Based on the assessment, a combination Options 1b and 2a is considered the most appropriate risk management measure.

Table A5a-12 Overview of the risk management options

Options	derogation	Technically feasible?	Risk reduction capacity	Economic feasibility	Remarks practicality
Lab					
Option 1a	none	yes, but standards	++++	+++	/
Option 1b	standards	yes	+++	++++	Enforceability issue (temporary)
Industry					
Option 2a	none	yes	++++	+	/
Option 2b	MiG* >200°C	yes	++	+++	Enforceability issue
Option 2c	MiG >200°C +dial	yes	+	++++	/

*MiG = mercury-in-glass thermometers
Note: The indication "/" means that no major additional concerns relating to practicality have been identified

4.4 The proposed restriction(s) and summary of the justifications

The restriction that is proposed for thermometers is a combination Options 1b and 2b:

Restriction to place mercury on the market in non-electrical equipment used to measure or indicate temperature after 18 months of entry into force with derogations for:

- mercury triple point cells that are used for the calibration of platinum resistance thermometers;
- placing on the market thermometers with historic or cultural value (see details in Part E of the main document); and
- a time-limited derogation of 5 years for mercury laboratory thermometers exclusively intended to perform tests according to standards that require the use of mercury thermometers.

<u>Justification</u>

Based on the assessment of risk management options and on the comparison of restriction options in section 4.3, a combination of Options 1b and 2a is the most appropriate risk management measure.

The main purpose of <u>the proposed restrictions is to reduce the mercury pool in the society, thus avoiding negative impacts on human health and the environment</u>. The proposed restriction would avoid placing on the market of around 500 kg of mercury in 2024. Cumulatively, the proposed restriction would avoid placing on the market an amount of mercury of about 10 tonnes in the period 2015-34. The costs of this reduction effort are estimated to be €9 ±24 million per annum or €97 ±256 million for the period 2015-34.[106] If labour time savings related to the use of electronic alternatives are excluded, the estimated cost impact is €56.6 million per annum or €609 million for the period 2015-34.

To better understand the relevance of the estimated compliance costs, a literature review estimating the compliance costs of other policies to reduce mercury and the human health benefits of reduced mercury emissions, as well as the restoration costs is presented in Appendix 2. As indicated in Table A5a-6, the cost-effectiveness of restricting different thermometer market segments varies considerably.

The transition to alternatives in the segment of mercury industrial thermometers for measuring temperature above 200°C will be associated with substantial costs to society if no labour time savings are assumed (362,165 €/kg Hg). As explained in Annex 5b, this assumption would not be true to the real-life situation. Therefore, labour time savings of 4 hours with an uncertainty margin of ±2 hours per year are here assumed, resulting in a cost effectiveness figure of 49,200 ±156,700 €/kg Hg.[107] Furthermore, some other additional benefits offered by electronic alternatives could not be taken into account in the cost effectiveness estimate. Considering the relatively small impact to users, and aspects related to enforceability of the proposed restriction, this cost-effectiveness estimate for this segment is considered acceptable.

In the case of dial thermometers, the cost effectiveness was estimated to be €12,000/kg Hg. and the proposed restriction for dial thermometers is deemed proportionate. In addition, they are known to hold only a very limited residual market,[108] and consequently the economic importance of mercury dial thermometers is thought to be marginal (see section 3.4[109]).

Certain analysis standards (test methods) currently require the use of mercury thermometers and are thus preventing the use of alternatives. A time-limited derogation of 5 years for mercury laboratory thermometers exclusively intended to perform tests according to such standards is therefore considered justified.

In conclusion, the proposed restriction is considered proportionate, implementable, manageable and enforceable.

[106] Labour time savings of 4 hours with an uncertainty margin of ±2 hours per year are assumed.
[107] Labour time savings of 4 hours with an uncertainty margin of ±2 hours per year are assumed.
[108] It is estimated that the mercury dial thermometers represent less than 1% of the estimated total industrial and lab thermometers in 2010.
[109] In addition the cost is likely overestimated

Annex 5b: Compliance cost calculations for thermometers

Contents

1. Introduction

This annex presents the compliance costs calculations of substituting mercury-containing thermometers with mercury-free alternatives in support of the development of restriction options for thermometers in the Annex XV restriction report (Annex 5a). From section 1 "Technical description of mercury thermometers" in Annex 5a it is apparent that the applications and types of mercury thermometers on the market are very diverse. Similarly to section 3.3 of annex 5a on the technical feasibility of alternatives, the thermometer market was split in three main groups for the purposes of calculating the costs of compliance with the proposed restriction:

- Mercury-in-glass laboratory thermometers
  - Thermometers measuring temperature typically from -58°C to up to 200°C and where an accuracy of 0.1°C or better is not needed, i.e. generic thermometers;
  - Thermometers measuring temperature above 200°C or where an accuracy of 0.1°C or better is needed. This includes certain meteorological measurements; and
  - Mercury thermometers measuring ambient temperature and for most other meteorological measurements (including Six's thermometers and psychrometers).[110]
- Mercury-in-glass industrial thermometers
  - Thermometers measuring temperature typically from -58°C to up to 200°C, i.e. generic thermometers; and
  - Thermometers measuring temperature above 200°C (e.g., with application in the processing industry, marine applications, engines, etc.).
- Mercury dial thermometers

2. Defining the temporal scope and choosing a representative year

The temporal scope of the analysis is from the time when the restriction is assumed to become effective in 2015 to 2034.[111] Taking into account the uncertainties related to available data and the assumed declining trend in the number of mercury thermometers, 20 years scope is regarded sufficient. This temporal scope was also selected for consistency purposes to present comparable results to the analysis of sphygmomanometers.

[110] No specific cost information on this market segment has been gathered, since it is considered to be a residual market. For the sake of simplicity they are combined with the laboratory market segment (see Section 5.1.3)

[111] This temporal scope is chosen for illustrative purposes. In reality the time when the restriction becomes effective (2015 in this analysis) depends on the speed of the decision-making process and the transitional periods after entry into force.

The costs are reported in two ways:

1. In the cumulative approach, the present values of costs are calculated for 2015-2034.
2. In the representative year approach, the annualised costs, using the year 2024 as a representative year, are calculated.

3. Data sources and approach

The main sources of data used in the analysis are Options for reducing mercury use in products and applications, and the fate of mercury already circulating in society published by DG Environment (Lassen et al. 2008)[112] and Appendix 3 of the restriction report (Lassen et al., 2010).

The calculations have been carried out in Excel using NPV (for net present value) and PMT (for annualised cost) worksheet functions.

4. Main assumptions

Mercury volume in thermometers for the EU-market

The mercury volume in mercury-in-glass thermometers for the EU-market is estimated at 0.6-1.2 tonnes for 2007. Based on information from producers, it is estimated that approximately half of the mercury is used in thermometers for laboratory use and the other half is used for industrial and marine applications (Lassen et al. 2008). For the purposes of this analysis, it is assumed that the number of mercury-containing thermometers sold per year in the next 20 years will decline annually by 5%. This reduction in using mercury-containing devices is partly due to increased awareness of the harmful properties of mercury and partly because of the advantages of some alternatives, particularly related to automation.

Therefore, it is estimated that in 2010 the use of mercury for placing on the EU market industrial and lab mercury-in-glass thermometers is approximately 390kg each.[113] As it is unclear what portion of that is for thermometers measuring temperature above 200°C, for the purpose of this analysis it is assumed that they represent 80% of the volume in the total lab and industry segment of the EU thermometer market. This number is supported by information from a German producer that estimated the market to be 100 kg of mercury per year for the industry thermometer segment (>200°C), and 100 kg for lab >200°C segment in Germany alone. If this is compared to the estimated EU volume of 300 – 600 kg mercury per year[114], the percentage has to be relatively high. The impact of this assumption is assessed in the sensitivity analysis.

The use of mercury for placing on the EU market mercury dial thermometers is estimated to be 0.1-0.3 tonnes for 2007 in the EU (Lassen et al., 2008). Based on the

[112] Available at http://ec.europa.eu/environment/chemicals/mercury/pdf/study_report2008.pdf
[113] Based on the 50% mid-point of the 2007 consumption level in the EU of 0.6-1.2 tonnes.
[114] Total of 0.6-1.2 tonnes per year, where the industry and lab market represent about half each.

assumption of 5% annual decline, for the purpose of this analysis it is estimated that the volume in the European Union is approximately 150kg in 2010.

Psychrometers represent a small marker segment of the mercury market. The mercury volume in psychrometers placed on the EU-market is estimated at 0.01-0.1 tonne in 2007 (Lassen et al., 2008). No data is available for thermometers used for other meteorological applications, but the residual market is thought to be limited (see Section 5.1.3).

Mercury content

The mercury content of thermometers used for laboratories and in industry range from 1 to 20 g per thermometer, with an average content of 3-4 g (Lassen et al. 2008). The analysis assumes that all mercury-in-glass thermometers contain on average 3.5g of mercury. This average was also supported by producers describing "typical" thermometers (Lassen et al., 2010). The sensitivity analysis assesses the influence of the mercury content on compliance costs taking into account that some high precision, broad temperature range thermometers can have higher mercury content.

The mercury content of dial thermometers tends to be very variable, ranging from about 5 to 200 g (Lassen et al., 2008). The "rigid" type has relatively low mercury content, whereas the "remote" type can have a much higher content, since they can have a mercury filled capillary up to 40 m or more. The mid-point of 102.5g mercury per device is assumed for this analysis.

Lifetime

<u>Mercury-in-glass industrial thermometers</u>
The average <u>technical</u> lifetime of mercury thermometers can exceed 25 years. As no data are available for the breakage rate and other influencing factors such as changing of production lines, etc., a shorter <u>useful life</u> estimate of 13 years is adopted, as per the response of a major producer of mercury thermometers that a realistic average lifetime of these thermometers in practice is between 10 and 15 years (Lassen et al., 2010).

<u>Mercury dial thermometers</u>
It is likely that the actual lifetime of the "rigid" type will be very different from the "remote" type, since it can be expected that the capillaries are especially vulnerable to breakage, wearing, and loss of accuracy. It is possible that the actual lifetime of dial thermometers is comparable to the alternative liquid- or gas-actuated systems. However, as there is no specific information for the lifetime of mercury dial thermometers, as a conservative assumption, the same average lifetime as other industrial thermometers is used for the analysis.

<u>Mercury-free dial thermometers</u>
The lifetime of bi-metal and liquid- or gas-actuated dial thermometers varies depending on the type of the dial thermometer and the conditions in which it is used. The average lifetime for the dial thermometer is indicated by the mercury thermometer manufacturer to be 1-2 years whereas the manufacturer of alternatives indicates 1-5 years for mechanical systems depending on the environment. A Danish manufacturer of mechanical thermometers estimates the typical lifetime of bimetallic

thermometers at 2-5 years and of gas-filled thermometers at 5-10 years (Lassen et al., 2010). A three-year lifetime for all mechanical systems is assumed for the purpose of this analysis.

Electronic thermometers

The lifetime of the electronic probes (sensors) is generally shorter than for the rest of the system (the data reader or indicator), as the probes are often placed in more harsh environments (vibration, temperature, humidity, corrosive gases, etc.) and are in general more delicate than the rest of the system. The lifetime of thermocouple probes can vary between one and five years and 1-10 years for the resistance thermometers. In very harsh environments with higher temperatures (e.g. waste incinerators) the lifetime of the probes is less than half a year. Based on the available data a typical lifetime for the electronic sensors is considered three to six years (Lassen et al., 2010). A five-year lifetime for all electronic probes is assumed for the purpose of this analysis. As there is no detailed information for the lifetime of the data reader, a 10 year lifetime is assumed for the purpose of this analysis.

Mercury-in-glass lab thermometers

The analysis assumes a lifetime of five years for this market segment, which is based on an estimate of the University of Minnesota, Floyd *et al.* (Lassen et al. 2008, Lassen et al., 2010). It is assumed that a high rate of breakage would be indeed more typical for the lab thermometers, since the thermometers are frequently handled manually, are often not fixed in a device, can have a long stem length of 30-70cm, and, compared to industry thermometers, are usually not protected by sturdy encasings. All these factors will result in a shorter lifetime than the lifetime of industrial thermometers.

Replacement ratio of mercury thermometers with alternatives

The analysis assumes that one mercury-containing device can be replaced by one mercury-free mechanical alternative. However, when it comes to electronic alternatives, in certain circumstances, one electronic system can replace a number of mercury thermometers. Therefore, different replacement ratios are assumed for mercury in glass thermometers in labs for measuring temperature above 200°C. The assumptions made are explained in greater detail in the respective sections for laboratory and industry thermometers.

Device prices

The price of mercury thermometers and their alternatives is assumed to be a function of factors such as accuracy, temperature range and level, compliance with standards, calibration certification, and suitability to measure temperature in adverse environmental conditions. Prices of the electronic alternatives are also driven by additional features such as automated temperature recording, alarm systems, real-time process monitoring and feedback systems, etc. The various combinations of these factors (based on customer requirements) results in a substantial price diversity of thermometers available on the market. Therefore, the analysis is based on prices of what is considered by producers to be a “typical thermometer” and a “typical alternative” taking into account information in the Lassen et al. (2008) and Lassen et al. (2010).

Due to the uncertainty associated with the device prices and as the alternative market is thought to have reached maturity, it is assumed that the prices of mercury-containing and alternative devices do not change between 2015 and 2034. In reality, there could be a change in prices in favour of the alternatives as the technology further matures.

The costs in the analysis represent factory gate prices excluding VAT for investment costs. Recurrent costs also likely exclude VAT. All values used in this analysis refer to year 2010 price levels, i.e. the prices are "real" as the effect of inflation has not been included in the analysis.

Alternatives considered

The analysis takes into account technically feasible alternatives identified in Section 3.3 of Annex 5a. Investment and recurrent costs of the mercury containing devices are specifically compared to alternatives identified as "typical" in Lassen et al. (2010). When several alternatives are shown to be technically feasible, the analysis assumes that customers will replace the mercury-containing thermometers with the cheaper alternatives.

Gallium thermometers are technically feasible alternatives to the mercury thermometers, in particular as a very wide range thermometer and for measuring temperature outside the range of mercury thermometers (above 750°C). These thermometers are difficult to manufacture as each thermometer has to be individually filled resulting in high prices for these thermometers (Lassen et al., 2010). Gallium thermometers are excluded from the cost calculations due to their limited application in practice because of their high costs and because their use is rather complementary to mercury thermometers (outside the temperature range of mercury thermometers).

Comparability of alternatives

As far as possible, alternative devices with technical properties similar to mercury-containing thermometers are considered in the analysis. Electronic alternatives have additional features that mercury thermometers do not possess. These include: automated temperature recording, alarm systems, real-time process monitoring and feedback systems, etc. These additional benefits may lead to energy savings, labour cost savings, minimisation of human reading errors, higher efficiency of reactions, a better quality of the end-product, reduced risks of damage, etc. These additional benefits present a challenge in the direct comparison of the alternatives to the mercury-containing thermometers (and impact the price of the alternatives). In fact, the advantage of electronic reading for example is one of the drivers for replacing mercury thermometers with electronic devices, which for many customers offsets the extra costs of the thermometers (Lassen et al., 2010). Insufficient information was available to estimate the value of these additional features and to deduct it from the investment costs of the electronic alternatives. However, since the real-life situation is that the market has moved (and is moving) to the use of electronic alternatives for the additional benefits they bring, the impact of the value of these benefits on the cost effectiveness has been estimated by taking into account assumptions for labour time savings[115] due to automatic reading and monitoring. This approach was taken only for the compliance cost calculations of industrial mercury-in-glass thermometers because the economic feasibility and cost effectiveness of restricting the market segment is clearly shown without taking into account the value of these additional benefits. On the basis of qualitative indication, labour cost savings due to replacement of a mercury industrial thermometer measuring temperature above 200°C with an electronic alternative were estimated to be on average 4 hours a year (or 40 seconds per day). Due to the substantial uncertainty on the true average labour cost savings in the whole market segment of the industrial thermometers measuring temperature over 200°C, the estimated average impact on the cost calculations is reported with an uncertainty margin of ±2 hours per annum. The "break-even" point is presented as well.

Calibration frequency

Calibration frequency is particularly difficult to estimate due to the diverse requirements for calibration and industry practices. For the purposes of this analysis it is assumed that all devices are bought calibrated.

Mercury-containing industrial thermometers
Mercury thermometer producers reported that industrial mercury-in-glass thermometers do not need frequent recalibration because its glass capillary keeps its accuracy for 30 years and more. The actual calibration frequencies, however, are dependent on the procedures set up by the users in their quality management system. Thermometers are thought to be checked regularly when used to measure temperature in industrial processes where temperature is of high importance (e.g., in the diary industry). Lassen et al. (2010) estimates that calibration once every three to five years would be typical (based on information from producers and a Danish reference lab). For the purpose of this analysis it is assumed that all industrial mercury thermometers (including dial) will be calibrated once every four years for all industrial (including dial) segments.

Mercury-free industrial thermometers
According to the information in Lassen et al., 2010, the calibration frequency of the alternative mechanical (dial) system is 6-12 months, while the frequency for the electronic systems is 6-24 months. According to a Danish producer it is typically necessary to recalibrate the probe after installation where the probe is "aged" by changing the temperature about 10 times. After the aging, the probe is often stable for some 5 years and does not drift more than 0.1°C. Many customers calibrate the thermometers every year because it is required by their quality management system. The analysis assumes that both dial and electronic alternatives are calibrated once a year for all thermometer segments.

Liquid-in-glass industrial thermometers
As no specific information was gathered for liquid-in-glass thermometers, and because of their similarities, it is assumed that they have the same calibration frequency as mercury-in-glass thermometers.

115 Other possible benefits are: energy savings; minimisation of human reading errors; higher efficiency of chemical reactions; a better quality of the end-product; reduced risks of damage (automated warning/alarm function); etc.

<u>Mercury-in-glass and mercury-free lab thermometers</u>
Similar to industrial mercury thermometers, it is difficult to determine the frequency of calibration of a typical mercury lab thermometer. For mercury and mercury-free liquid-in-glass devices that do not need a high accuracy and do not need to measure temperatures above 200°C, the calibration frequency is assumed to be the same (once every fourth year) as in the industry segment for measurements below 200°C, as high accuracy is not considered a critical factor in either of these segments.

For mercury and mercury-free devices with accuracy of 0.1°C or better or measuring temperature above 200°C, one manufacturer indicated that the mercury thermometers do not need calibration while another – a 15 year validity of calibration. According to a Danish manufacturer, certified test laboratory mercury thermometers are usually calibrated every 3-5 years (Lassen et al., 2010). However, it was noted that in many laboratories the frequency of calibration is one to two calibrations per year independent on thermometer type (Lassen et al., 2010). For the purpose of this analysis, it is assumed that mercury-free (electronic) laboratory thermometers will be calibrated annually, while mercury lab thermometers – once every two years which is twice more frequent than the industrial market segment and the low precision/low temperature lab segment due to the higher need for accuracy in this lab segment.

Calibration costs

The cost of a calibration depends among others on the number of calibration points used. Lassen et al, (2010) indicates a price of €100-€150 for the calibration of an electronic thermometer. For this study the cost of calibration, done by a certified laboratory in Denmark, is reported to be about €200-€300, where the calibration of high precision thermometers tends to be more expensive. A price of €200 has been reported by a major German producer of electronic thermometers. With a traceable certificate the cost of calibration from the producer is about €350 (Lassen et al., 2010). As all the estimates for calibration costs in Lassen et al. (2010) are for Western European users, this analysis assumes the mid-point of the lowest estimates (€125) for all thermometers, to take into account the lower labour costs in Eastern Europe. These calibration costs are assumed for all thermometers included in the compliance cost calculations.

The cost of calibration is higher than the cost of new electronic equipment, but used electronic equipment is more stable than new equipment (Lassen et al., 2010).

Other recurrent costs

In addition to calibration costs, the analysis also takes into account other recurrent costs such as costs for power or batteries for the electronic device and waste handling. It is assumed that the device is purchased with batteries.

Waste treatment expenditures are assumed to occur the year after the end of the useful life of the device. As no specific data was gathered for these recurrent costs for thermometers, the analysis is based on assumptions presented in the cost calculations for sphygmomanometers. It is not known whether this estimate for sphygmomanometers considers that not all users dispose of the mercury devices in accordance with hazardous waste legislation. The values presented for sphygmomanometers were reduced by half to reflect the lower mercury content and the smaller size of thermometers.

In the event of breakage of a mercury containing thermometer, there are costs associated with the cleaning of the spill. As no information was gathered regarding these costs they are not considered in the analysis.

One particular problem mentioned is the need for modified/additional installations in existing facilities if spare mercury thermometers are not available ("retrofitting") (Lassen et al., 2010). Mercury-free replacement thermometers (spare parts) fitting into the existing installations are sometimes claimed not to be readily available. A Danish producer of thermometers informed that the price of the adjusted alternatives is only slightly higher than the standard thermometer (Lassen et al., 2010). This is supported by product catalogues and on-line information assessed by ECHA. The alternatives encountered all use the same industry standards (such as DIN) for dimensions, fittings, etc. that are used for mercury thermometers. Usually producers mention that besides the standard versions, also custom dimensions, connection heads, transmitters, etc. can be supplied upon request.

As a specific case of retrofitting, finding solutions to accommodate certain older autoclaves with electronic alternatives has been reported as problematic. For these reasons, mercury-containing maximum thermometers to be placed inside older autoclaves are exempted from the restriction in Norway.[116] However, a report by the Swedish Chemicals Agency (KemI) indicates that mercury thermometers are being replaced with for example thermocouples in this equipment, and that this has advantages with respect to automated data collection and recording (Lassen et al., 2010).

It is concluded that on average there is no problem with retro-fitting, since in general the alternatives use the same industry dimensions, and that for the cases where customisation is needed, in most cases this has little effect on the investment costs. Therefore, for the purpose of the cost calculations, the installation/modification costs are considered immaterial and therefore, ignored in the analysis.

Discount factor

Throughout the analysis a 4% discount rate is used and the expenditures are assumed to occur in the beginning of each year, i.e. 1 of January.

[116] The Norwegian Climate and Pollution Agency (Klif) mentioned two possibilities for retrofitting of older autoclaves (where the thermometers are placed inside the autoclave) that both seem to be problematic. One is to place an electronic thermometer with data logger inside the autoclave, but the loggers are said not to withstand high temperatures. Another alternative is to place a thermocouple inside with connections to a meter outside. Some laboratories would have tried to lay thin conducting wires through the gasket, but it would have been difficult to avoid leakage caused by the high pressure. (Klif, 2010, pers. comm.)

5. Cost calculations

5.1. Mercury-in-glass lab thermometers

5.1.1. Mercury-in-glass lab thermometers (<200°C and resolution not better than 0.1°C)

5.1.1.1. Introduction

A number of mercury-in-glass thermometers are used to measure temperature below 200-250°C in applications where high precision and broader temperature range is not needed. Mercury-free liquid-in-glass thermometers are one of the most common replacements of these thermometers. Most mercury-free liquid-in-glass thermometers are not suitable for accurate measurements at 0.1°C resolution, but are fully suitable for less accurate measurements (Lassen et al., 2010). Their price is roughly the same as for mercury thermometers or about 10% lower (Lassen et al., 2010). It is assumed that the prices of these devices is approximately half the price of the mercury-in-glass lab thermometer for measuring temperature above 200°C, as it is assumed that high-precision, broad temperature range thermometers command higher prices.

Other thermometers that can replace mercury devices in this marker segment include electronic thermometers and gallium-indium thermometers. These thermometers command higher prices (up to 10-times the price of mercury-thermometers) due to their additional features such as data logger (for electronic thermometers) or broader temperature range (gallium thermometers). Therefore, for the purposes of estimating the cost effectiveness of substituting the mercury-in-glass thermometers measuring temperature below 200°C, only liquid-in-glass thermometers are considered.

Assuming 3.5g of mercury content for thermometers in this market segment, it is estimated that there are approximately 22,200 thermometers in the EU in 2010.

Table A5b-1 presents the input data used in the analysis.

Table A5b-1: Input data – Mercury-in-glass lab thermometers (<200°C)

Parameter	Device	Central case
Discount rate		4%
Mercury devices sold per year 2010		22,200
Annual decrease in number of devices sold		5%
Mercury per device (kg)		0.0035
Average lifetime (years)	Mercury Liquid-in-glass	5 5
Investment cost (price of device)	Mercury Liquid-in-glass	€ 40 € 40
Calibration costs (per calibration)	Mercury Liquid-in-glass	€ 125 € 125
Calibration frequency (once in *x* years)	Mercury Liquid-in-glass	4 4
Batteries (per year)	Mercury Liquid-in-glass	€ 0 € 0
Waste treatment (per device)	Mercury Liquid-in-glass	€ 16 € 2

5.1.1.2. Cost calculations

Investment costs

Table A5b-2 presents the investment costs of the mercury- and liquid-in-glass thermometers for measuring temperature below 200°C.

Table A5b-2: Annualised investment costs per device (in 2010 price level) – Mercury-in-glass lab thermometers (<200°C)

Year	Total Investment costs (€) per device	
	Baseline: Mercury-in-glass Lab Thermometer	Alternative: Liquid-in-glass Thermometer
Investment costs	40	40
Present value (for lifetime)	40	40
Average lifetime (years)	5	5
Annualised	**9**	**9**
Additional annualised		**0**

As the price of the alternative is the same as the mercury-in-glass thermometer, the transition to the alternative results in no additional annualised investment costs per device.

Recurrent costs

Table A5b-3 presents the recurrent costs of the mercury- and liquid-in-glass thermometers for measuring temperature below 200°C.

Table A5b-3: Annualised recurrent costs per device (in 2010 price level) – Mercury-in-glass lab thermometers (<200°C)

Year	**Recurrent costs (€) per device**	
	Baseline: Mercury-in-glass Lab Thermometer	Alternative 1: Liquid-in-glass Thermometer
1	0	0
2	0	0
3	0	0
4	0	0
5	125	125
6	16	2
7	0	0
8	0	0
9	0	0
10	0	0
11	0	0
12	0	0
13	0	0
14	0	0
15	0	0
16	0	0
17	0	0
18	0	0
19	0	0
20	0	0
21	0	0
Present value (for lifetime)	**120**	**108**
Annualised	**27**	**24.4**
Additional annualised		**-2.6**

The lower waste treatment costs result in an annualised savings of recurrent costs of €2.60 per device when the mercury lab thermometer is replaced with a liquid-in-glass thermometer.

Total costs and compliance costs

Table A5b-4 presents the calculations of total costs of mercury thermometers and liquid-in-glass thermometers.

Table A5b-4: Annualised total costs per device (in 2010 price level) – Mercury-in-glass lab thermometers (<200°C)

Year	Total costs (€) per device Baseline: Mercury-in-glass Lab Thermometer	 Alternative: Liquid-in-glass Thermometer
Present value (for lifetime)	160	148
Average lifetime (years)	5	5
Annualised	**36**	**33**
Additional annualised		**-2.6**

Due to lower waste treatment costs of the liquid-in-glass thermometers, it is estimated that the transition to the alternative will result in additional annualised savings per device of €2.60. The results in the table above can be obtained by addition of the investment and recurring costs presented in Tables A5b-2 and A5b-3.

Table A5b-5 presents the compliance costs from replacing the mercury-in-glass lab thermometer with a liquid-in-glass thermometer.

Table A5b-5: Annualised and present value compliance costs (in 2010 price level) – Mercury-in-glass lab thermometers (<200°C)

	Compliance costs (€) Alternative 1: Liquid-in-glass Thermometer
2015	-44960
2016	-87780
2017	-128560
2018	-167399
2019	-204388
2020	-194655
2021	-185386
2022	-176558
2023	-168150
2024	-160143
2025	-152517
2026	-145255
2027	-138338
2028	-131750
2029	-125476
2030	-119501
2031	-113811
2032	-108391
2033	-103230
2034	-98314
Compliance cost (present value 2015-2034)	**-1,963,574**
Annualised compliance cost (2024)	**-160,143**

Assuming that approximately 22,200 mercury thermometers are placed on the market annually (with a 5% declining rate over the study period), the compliance costs savings of replacing the mercury-filled with liquid-in-glass thermometers over the study period is close to €2 million (NPV) or €160 thousand as of 2024 on the representative year basis.

This tendency to replace the mercury containing thermometers with liquid-in-glass alternatives is already observed in the market. The reasons for continued use of the mercury containing thermometers can be explained with perceived higher level of quality of the mercury thermometers (which is a trusted, time tested method of measuring temperature) or customers' failure to take into account the long-term (recurrent) costs associated with the mercury thermometers.

5.1.1.3. Cost effectiveness

As the alternative has lower recurring costs, reducing the marketed volume of mercury by 1kg when replacing mercury lab thermometers with liquid-in-glass thermometers results in cost savings of approximately €3,700. The calculation is based on the present value compliance costs and on the assumption that one mercury thermometers contains 3.5g of mercury.

Table A5b-6 presents a summary of the compliance cost calculations associated with the transition from mercury-in-glass thermometers to liquid-in-glass thermometers.

Table A5b-6: Annualised and present value compliance costs (in 2010 price level) – Mercury-in-glass lab thermometers (<200°C)

Main assumptions for device			
Number of devices per year (2010)		22,200	
Trend		-5%	per year
Amount of mercury per device		0.0035	kgs
Lifetime of device		5	years
Costs (€)		**Baseline: Mercury-in-glass Lab Thermometer**	**Alternative 1: Liquid-in-glass Thermometer**
Investment cost	annualised	9	9
Recurrent cost	annualised	27	24
Total cost	annualised	36	33
Additional total cost	annualised		-2.6
Cost effectiveness	**per kg of Hg**		**-3,693**
Compliance cost	2024		-160,143
Compliance cost	total		-1,963,574

5.1.1.4. Sensitivity analysis

If waste treatment costs are ignored in the cost calculations, the transition to the liquid-in-glass alternative will be cost neutral, i.e., total compliance costs and the cost effectiveness will be 0€/kg Hg.

If we assume that the price of the liquid-in-glass alternatives is approximately 10% lower than the mercury containing device (Lassen et al., 2010), the transition to the alternative will result in higher cost savings: €5,000 per 1kg of mercury (cost effectiveness) or a total compliance cost for 22,200 mercury devices of €2.7 million (NPV) or €216 thousand (as of 2024).

Depending on the size of this market segment, the total compliance costs can range from €0 (assuming that all lab thermometers are used to measure temperature above 200°C) to €3.9 million savings on NPV basis or €320 thousand as of 2024 on representative year basis when it is assumed that this market segment represents 40% of all lab mercury-in-glass thermometers (44,400 devices as of 2010). The cost-effectiveness under this scenario will remain the same.

5.1.2. Mercury-in-glass lab thermometers (resolution better than 0.1°C or >200°C)

5.1.2.1. Introduction

This section addresses thermometers used in laboratory applications where an accuracy of 0.1°C or better is needed or to measure temperature above 200-250°C. Other technical requirements may include: a broad temperature range, high maximum temperature, and certification requirements for quality management (related to standards and calibration).

Assuming mercury content of 3.5g per thermometer, it is estimated that in the European Union, in 2010 there are approximately 88,900 mercury-in-glass thermometers in this market segment (assuming the segment represents 80% of total mercury-in-glass lab thermometers). The impact of this assumption on the compliance cost calculations is tested in the sensitivity analysis.

There are a number of technically feasible alternatives that have replaced mercury-in-glass lab thermometers with accuracy <0.1°C or for the temperature range above 200°C. These mainly include electronic thermometers such as thermocouples and platinum resistance thermometers (PRTs), as described in Section C: Technical feasibility.

Thermocouples and PRTs are three to five times more expensive and require additional data readers, which cost three to four times the cost of the mercury thermometers (Lassen et al., 2010). However, their higher prices are partially attributable to additional features such as data logger, possibilities for remote reading, alarm systems, etc. Due to lack of detailed information no attempt has been made to quantify the value of these additional features. For the purposes of this analysis, it is assumed that the price of the electronic system is €450.

An electronic thermometer typically has a much broader temperature range than mercury thermometers. It can be assumed that more than one mercury thermometers can be replaced by one electronic thermometer (probe with a data reader). One electronic thermometer could replace a whole set of narrow range (high) precision mercury thermometers, or even several of those sets. Such sets typically consist of six to 11 thermometers. However, other factors come into play and the actual replacement rate will be highly dependent on the needs of a lab.

In addition, several probes may be connected to one indicator (data reader), but on the other hand measurements might have to be done simultaneously on different locations in the lab. It was not considered possible to estimate the respective influence of these parameters.

Therefore, the analysis assumes a moderate replacement ratio of 2.5:1 for both the probe and the data reader. The impact of this assumption on cost effectiveness and compliance cost calculations is tested in the sensitivity analysis.

Table A5b-7 below presents the input data used in the analysis.

Table A5b-7: Input data used in the analysis – Mercury-in-glass lab thermometers (>200°C)

Parameter	Device	Central case
Discount rate		4%
Mercury devices sold per year 2010		88,900
Annual decrease in number of devices sold		5%
Mercury per device (kg)		0.0035
Average lifetime (years)	Mercury Electronic	5 5
Investment cost (price of device)	Mercury Electronic	€ 80 € 240
Calibration costs (per calibration)	Mercury Electronic	€ 125 € 125
Calibration frequency (once in *x* years)	Mercury Electronic	2 1
Batteries (per year)	Mercury Electronic	€ 0 € 3
Waste treatment (per device)	Mercury Electronic	€ 16 € 2
Investment cost (price of data reader)	Mercury Electronic	€ 0 € 210
Average lifetime per data reader (years)	Mercury Electronic	0 10
Replacement (Hg : electronic)		2.5:1

5.1.2.2. Cost calculations

Investment costs

Table A5b-8 presents the calculation of investment costs of mercury-in-glass lab thermometers and electronic thermometers.

Table A5b-8: Annualised investment costs per device (in 2010 price level) – Mercury-in-glass lab thermometers (>200°C)

Year	Total Investment costs (€) per device	
	Baseline: Mercury-in-glass Thermometer	Alternative: Electronic (probe & data reader)
Investment costs	80	180
Present value (for lifetime)	80	180
Average lifetime (years)	5	5
Annualised	**18**	**32**
Additional annualised		**14**

Due to higher price compared to mercury-containing devices, the additional annualised investment cost is estimated to be €14 for the alternative.

Recurrent costs

Table A5b-9 presents the calculations of recurrent costs for mercury-in-glass lab thermometers and electronic thermometers. The assumed lower waste disposal costs and the replacement ratio of the electronic thermometer result in small savings per device of an estimated €11 annually.

Table A5b-9: Annualised recurrent costs per device (in 2010 price level) – Mercury-in-glass lab thermometers (>200°C)

Year	Recurrent costs (€) per device	
	Baseline: Mercury-in-glass Thermometer	Alternative: Electronic
1	0	0
2	0	51
3	125	51
4	0	51
5	125	51
6	16	1
7	0	0
8	0	0
9	0	0
10	0	0
11	0	0
12	0	0
13	0	0
14	0	0
15	0	0
16	0	0
17	0	0
18	0	0
19	0	0
20	0	0
21	0	0
Present value (for lifetime)	**236**	**187**
Annualised	**53**	**42**
Additional annualised		**-11**

Total costs and compliance costs

Table A5b-10 presents the calculations of total costs of mercury-containing thermometers and the alternative device. The results in the table above can be obtained by the addition of the investment and recurring costs presented in Tables A5b-8 and A5b-9.

Table A5b-10: Annualised total costs per device (in 2010 price level) – Mercury-in-glass lab thermometers (>200°C)

Year	Total costs (€) per device	
	Baseline: Mercury-in-glass Thermometer	Alternative: Electronic
Present value (for lifetime)	**316**	**367**
Average lifetime (years)	**5**	**5**
Annualised	**71**	**74**
Additional annualised		**3**

When taking into account the replacement ratio of the probe and the data reader, the shorter lifespan and the higher investment costs of the alternative result in annualised cost of €3 per mercury device.

Table A5b-11 presents the compliance costs from replacing the mercury-in-glass lab thermometer with an electronic thermometer. The calculations are made assuming 5% annual decrease in the number of mercury-containing thermometers sold per year in the next 20 years, i.e. approximately 44,900 devices in 2024.

Table A5b-11: Annualised and present value compliance costs (in 2010 price level) – Mercury-in-glass lab thermometers (>200°C)

	Compliance costs (€)
	Alternative: Electronic
2015	204,067
2016	398,416
2017	583,511
2018	759,791
2019	927,677
2020	883,502
2021	841,431
2022	801,363
2023	763,203
2024	726,860
2025	692,247
2026	659,283
2027	627,889
2028	597,989
2029	569,514
2030	542,394
2031	516,566
2032	491,967
2033	468,540
2034	446,229
Compliance cost (present value 2015-2034)	**8,912,294**
Annualised compliance cost (2024)	**726,860**

The present value compliance costs for 2015-2034 are estimated at close to €8.9 million and the annualised compliance costs (2024) at approximately €727 thousand.

5.1.2.3. Cost effectiveness

As the alternatives have higher investment costs, reducing the marketed volume of mercury by 1kg when replacing mercury lab thermometers with electronic thermometers results in compliance costs of approximately €4,185. The calculation is based on the present value compliance costs and on the assumption that one mercury thermometer contains 3.5g of mercury. It is important to note that due to the additional features of the electronic thermometers (such as automatic data-logging, alarm, etc.), the mercury and electronic alternatives are not completely comparable, and that the compliance cost might be slightly overestimated because this factor is not quantified.

Table A5b-12 presents a summary of the main results of the compliance cost calculations associated with the transition from mercury-in-glass lab thermometers (>200°C) to an electronic alternative.

Table A5b-12: Cost effectiveness of replacing the mercury thermometers (in 2010 price level) – Mercury-in-glass lab thermometers (>200°C)

Main assumptions for device			
Devices per year (2010)		88,900	number
Trend		-5%	per year
Amount of mercury per device		0.0035	kgs
Lifetime of device (probe)		5	years
Costs (€)		**Baseline: Mercury-in-glass Thermometer**	**Alternative: Electronic**
Investment cost	Annualised	18	32
Recurrent cost	Annualised	53	42
Total cost	Annualised	71	74
Additional total cost	Annualised		3
Cost effectiveness	**per kg of Hg**		**4,185**
Compliance cost	2024		726,860
Compliance cost	total		8,912,294

It is important to note that the analysis above does not take into account the need to use mercury devices to meet requirements set in certain standards.

5.1.2.4. Sensitivity analysis

The mercury content of high precision lab thermometers can range between 1 and 20g (Lassen et al. 2008). Assuming a higher average mercury content for lab thermometers in this market segment – 11g (Lassen et al., 2010), the costs of reducing the volume of mercury placed on the EU market will be three times lower or €1,330 per kg (see also section 2 of this annex). The total compliance costs under this scenario will remain the same as in the central case.

When relaxing the central case assumptions for the replacement ratio, i.e., assuming a one-to-one relationship between the mercury thermometer and the probe and data reader of the electronic thermometer, the costs of reducing the marketed volume of mercury can reach €162,400 per kg. The total compliance costs are €345.7 million (NPV) and €28.2 million (2024 on annualised basis). The plausibility of this scenario is difficult to assess due to lack of information of the replacement rate of mercury thermometers with electronic alternatives.

Depending on the size of this market segment (based on central case assumptions), the total compliance costs can range (on NPV basis) from €6.7 million (assuming that this market segment represents 60% of all mercury-in-glass lab thermometers or 66,600 devices as of 2010) to €11 million, assuming that this market segment represents 100% of all lab mercury-in-glass thermometers (111,100 devices as of 2010). Under this scenario, as of 2024, on representative year basis, the total compliance costs will range from €545 thousand to €908 thousand. The cost effectiveness under these scenarios will remain the same, as this measure is not impacted by the number of devices on the market.

5.1.3. Mercury thermometers used in meteorological applications

As stated in section 3.4 of Annex 5a, mercury-in-glass thermometers for ambient air temperature measurements (including for min/max measurements) are almost fully substituted by liquid-in-glass thermometers or, where additional accuracy and features (e.g., remote reader) are desired, by electronic thermometers.[117] Similarly, electronic and liquid-filled alternatives to psychrometers with mercury thermometers dominate the market. Psychrometers represent a small market segment of the mercury market: the mercury volume in psychrometers placed on the EU-market is estimated at 0.01-0.1 tonnes in 2007 (Lassen et al., 2008). A proportion of psychrometers may require higher accuracy. These are considered to be included in the assessment for mercury-in-glass lab thermometers with resolution better than 0.1°C or for temperatures >200°C.

Because the residual market is thought to be very limited, detailed information for this market segment was not gathered; and therefore, no compliance cost calculations could be prepared. However, the transition from the mercury-containing ambient thermometers for meteorological applications is expected to result in additional annualised savings because:

- the price of the liquid-in-glass alternatives for ambient temperature measurement is similar to the mercury-containing thermometers (when no resolution <0.1°C needed);
- Six's thermometers with organic liquids are available at similar or lower prices than the mercury filled counterparts (Lassen et al., 2010);
- electronic or spirit-filled psychrometers are available for most applications at approximately the same price as mercury psychrometers (Lassen et al., 2010);

[117] This is also true for hydrometers that have a mercury thermometer inside.

- it costs less to dispose of a mercury-free device at the end of its useful life;
- the calibration frequency and costs of the mercury and liquid-in-glass devices are similar; and
- the lifetime of the mercury and liquid-in-glass devices is similar.

For the purpose of exploring restriction options, the meteorological applications are included in the laboratory assessment.

5.2. Mercury-in-glass industrial thermometers

5.2.1. Mercury-in-glass industrial thermometers (<200°C)

5.2.1.1. Introduction

This section discusses thermometers measuring temperature typically from -58°C to up to 200°C, i.e., generic thermometers which do not require certification and high precision. For the purpose of this analysis it is assumed that the price of the mercury-in-glass industrial thermometers (<200°C) is about half of the industrial thermometers (>200°C) to reflect the lower temperature range (and lower level of protection needed in the form of high quality encasings, which is included in the price of the industrial thermometers for above 200°C). Assuming 3.5g of mercury content for thermometers in this market segment, it is estimated that there are approximately 22,200 thermometers in the EU in 2010 (20% of the total number of mercury-in-glass industry thermometers).

The liquid-in-glass thermometers can directly replace mercury thermometers to measure temperature in industrial processes where high temperature and accuracy are not a requirement. Their price is roughly the same as for mercury thermometers or about 10% lower (Lassen et al., 2010). Mercury-free liquid-in-glass thermometers are not suitable for accurate measurements at better than 0.1°C resolution, but in industrial processes it is generally not necessary to measure the temperature at this high resolution (Lassen et al., 2010).

Other thermometers that can replace mercury devices in this marker segment include electronic thermometers and gallium-containing thermometers. These thermometers command higher prices (up to 10-times the price of mercury thermometers) due to their additional features such as data logger (for electronic thermometers) or broader temperature range (gallium thermometers). Therefore, for the purposes of evaluating the cost effectiveness of substituting the mercury-in-glass industrial thermometers measuring temperature below 200°C, only the cheapest alternative, being the liquid-in-glass thermometers are considered. If more expensive electronic thermometers are used as replacement, it is assumed that this would be because of their advantages of automatic reading and other features not directly applicable to mercury-containing devices.

The Table A5b-13 presents the input data used in the analysis.

Table 5b-13: Input data – Mercury-in-glass industrial thermometers (<200°C)

Parameter	Device	Central case
Discount rate		4%
Mercury devices sold per year 2010		22,200
Annual decrease in number of devices sold		5%
Mercury per device (kg)		0.0035
Average lifetime (years)	Mercury Liquid-in-glass	13 13
Investment cost (price of device)	Mercury Liquid-in-glass	€ 23 € 23
Calibration costs (per calibration)	Mercury Liquid-in-glass	€ 125 € 125
Calibration frequency (once in *x* years)	Mercury Liquid-in-glass	4 4
Batteries (per year)	Mercury Liquid-in-glass	€ 0 € 0
Waste treatment (per device)	Mercury Liquid-in-glass	€ 16 € 2

5.2.1.2 Cost calculations

Investment costs

Table A5b-14 presents the investment costs of the mercury-in-glass industrial thermometer (<200°C) and the lowest cost alternative: liquid-in-glass thermometers. As the price of the alternative is the same as the mercury-in-glass thermometer, the transition to the alternative results in no additional annualised investment costs per device.

Table A5b-14: Annualised investment costs per device (in 2010 price level) – Mercury-in-glass industrial thermometers (<200°C)

Year	**Total Investment costs (€) per device**	
	Baseline: Mercury-in-glass Industrial Thermometer	Alternative: Liquid-in-glass Thermometer
Investment costs	23	23
Present value (for lifetime)	23	23
Average lifetime (years)	15	15
Annualised	**2**	**2**
Additional annualised		**0**

Recurrent costs

Table A5b-15 presents the recurrent costs of the mercury-in-glass industrial thermometer (<200°C) and the lowest cost alternative: liquid-in-glass thermometers.

The lower waste disposal costs of the alternative result in small savings per device of an estimated €0.80 annually.

Table A5b-15: Annualised recurrent costs per device (in 2010 price level) – Mercury-in-glass industrial thermometers (<200°C)

Year	Recurrent costs (€) per device	
	Baseline: Mercury-in-glass Industrial Thermometer	Alternative 1: Liquid-in-glass Thermometer
1	0	0
2	0	0
3	0	0
4	0	0
5	125	125
6	0	0
7	0	0
8	0	0
9	125	125
10	0	0
11	0	0
12	0	0
13	125	125
14	16	2
15	0	0
16	0	0
17	0	0
18	0	0
19	0	0
20	0	0
21	0	0
Present value (for lifetime)	286	277
Annualised	**29**	**27.8**
Additional annualised		**-0.8**

Total costs and compliance costs

Table A5b-16 presents the calculations of total costs of mercury-containing thermometers and the alternative device for this industry segment (<200°C). The results in the table can be obtained by the addition of the investment and recurring costs presented in Tables A5b-14 and A5b-15.

Table A5b-16: Annualised total costs per device (in 2010 price level) – Mercury-in-glass industrial thermometers (<200°C)

Year	Total costs (€) per device	
	Baseline: Mercury-in-glass Industrial Thermometer	Alternative 1: Liquid-in-glass Thermometer
Present value (for lifetime)	308	300
Average lifetime (years)	15	15
Annualised	**30.9**	**30.0**
Additional annualised		**-0.8**

The additional annualised savings per device is estimated to be €0.80 compared to the mercury-containing device.

Table A5b-17 presents the compliance costs from replacing the mercury-in-glass industrial thermometer with a liquid-in-glass thermometer. The results are based on the assumption that this market segment represents 20% of the industrial mercury-in-glass thermometers, i.e. 11,200 in 2024, assuming 5% annual decline of mercury thermometers on the market.

Table A5b-17: Annualised and present value compliance costs (in 2010 price level) – Mercury-in-glass industrial thermometers (<200°C)

	Compliance costs (€) Alternative: Liquid-in-glass Thermometer
2015	-14646
2016	-28595
2017	-41879
2018	-54531
2019	-66581
2020	-78057
2021	-88986
2022	-99395
2023	-109308
2024	-118749
2025	-127740
2026	-136304
2027	-144459
2028	-137580
2029	-131029
2030	-124789
2031	-118847
2032	-113188
2033	-107798
2034	-102664
Compliance cost (present value 2015-2034)	**-1,275,721**
Annualised compliance cost (2024)	**-118,749**

The compliance cost savings of replacing the mercury-filled with the mercury-free alternative over the study period is close to €1.3 million (NPV) or €119 thousand as of 2024 on the representative year basis.

A tendency to replace the mercury containing thermometers with liquid-in-glass alternatives is already observed on the market (Lassen et al., 2008). The reasons for continued use of the mercury containing thermometers can be explained with perceived higher level of quality of the mercury thermometers (trusted, time tested method of measuring temperature) or customers' failure to take into account the long-term (recurrent) costs associated with the use of mercury thermometers.

5.2.1.3. Cost effectiveness

As the alternative has lower recurring costs, reducing the volume of mercury placed on the EU market by 1kg when replacing mercury industrial thermometers with liquid-in-glass thermometers results in cost savings of approximately €3,130. The calculation is based on the present value compliance costs and on the assumption that one mercury thermometer contains 3.5g of mercury.

Table A5b-18 presents a summary of the compliance cost calculations associated with the transition from mercury-in-glass thermometers (<200°C) to liquid-in-glass thermometers.

Table A5b-18: Cost effectiveness of replacing the mercury thermometers (in 2010 price level) – Mercury-in-glass industrial thermometers (<200°C)

Main assumptions for device			
Devices per year (2010)		22,200	number
Trend		-5%	per year
Amount of mercury per device		0.0035	kgs
Lifetime of device		13	years
Costs (€)		**Baseline: Mercury-in-glass Industrial Thermometer**	**Alternative 1: Liquid-in-glass Thermometer**
Investment cost	annualised	2	2
Recurent cost	annualised	29	28
Total cost	annualised	31	30
Additional total cost	annualised		-0.8
Cost effectiveness	**per kg of Hg**		**-3,127**
Compliance cost	2024		-118,749
Compliance cost	total		-1,275,721

It is important to note that the analysis above does not take into account the need to use mercury devices to meet requirements set in certain standards.

5.2.1.4. Sensitivity analysis

If waste treatment costs are ignored in the cost calculations, the transition from a mercury-in-glass industrial thermometer to the liquid-in-glass alternative for measuring temperature up to 200°C is cost neutral, i.e., total compliance costs and the cost effectiveness will be zero.

If we assume that the price of the liquid-in-glass alternatives is approximately 10% lower than the mercury containing device (Lassen et al., 2010), the transition to the alternative will result in higher cost savings: €3,960 per 1kg of mercury (cost effectiveness) or a total compliance savings of €1.6 million (NPV) or €150.5 thousand (as of 2024).

Depending on the size of this market segment, the total compliance savings range (on NPV basis) from €0 (assuming that all industrial thermometers are used to measure temperature above 200°C) to €2.6 million or €237.5 thousand as of 2024 on a representative year basis when it is assumed that this market segment represents 40% of all industrial mercury-in-glass thermometers (44,400 devices as of 2010).

5.2.2. Mercury-in-glass industrial thermometers (>200°C)

5.2.2.1. Introduction

A number of mercury-in-glass thermometers are used to measure temperature in industrial processes. The technical requirements include high temperature measurements (up to 800°C), endurance to aggressive environments, and certification requirements for quality management (related to standards and calibration).

The mercury content of the industrial thermometers ranges from about 1 to 20 g with an average content of 3-4 g (Lassen et al. 2008). Assuming mercury content of 3.5g per thermometer, it is estimated that in the European Union, in 2010 there are approximately 88,900 mercury-in-glass thermometers in this market segment (assuming the segment represents 80% of total mercury-in-glass industrial thermometers). The impact of this assumption on the compliance cost calculations is tested in the sensitivity analysis.

The price of a typical mercury thermometer for industry in this segment is reported to be €30 - 60 (Lassen et al., 2010) inclusive of the casing for the thermometer. The mid-point is selected for the purpose of this analysis.

There are a number of technically feasible alternatives that have replaced mercury-in-glass thermometers for the temperature range above 200°C. The analysis focuses on two: mechanical (liquid- or gas-filled or bi-metal dial) thermometers and electronic thermometers (thermocouples).

Producers of mercury thermometers have indicated that the prices of the mechanical (dial) thermometers are typically 3-5 times the price of the mercury thermometer. Other data shows that the price of the dial thermometers replacing the assumed typical industrial thermometer (>200°C) ranges between €100 and €150 (Lassen et al., 2010).[118] The mid-point is selected as the price of a typical dial replacement for the purpose of this analysis.

Thermocouples are three to five times more expensive and require additional data readers, which costs three to four times the price of the mercury thermometers (Lassen et al., 2008). The analysis assumes an average price for electronic alternatives of €175. Their higher prices are partially attributable to additional features such as data logging, possibilities for remote reading, real-time monitoring and feedback mechanisms, alarm systems, etc. No data have been available by which it can be estimated how the price of the data acquisition systems can be allocated to the individual thermometers (Lassen et al., 2010). To obtain such data extensive market

[118] This is consistent with the estimate that prices of the electronic alternatives are three to five times higher than the mercury containing device.

surveys need to be conducted. Therefore, taking into account that several probes and other inputs such as pressure gauges can be connected to one data reader, a replacement ratio of 2:1 is used in the central case for the data reader. This replacement ratio is not applied to the probes as in most if not all circumstances they are installed in equipment.

In addition, it is generally known that the life of the probe is shorter than for the rest of the system, as the probes are often placed in more harsh environments (vibration, temperature, humidity, corrosive gases, etc.) (Lassen et al., 2010). As no specific information is available, for the purpose of the analysis, it is assumed that the lifetime of the data reader is twice as long as that of the probes.

As mentioned in section 4 (Main assumptions), electronic alternatives have several additional benefits that mercury thermometers do not possess and that may lead to cost savings. These additional benefits are considered in fact the main drivers for replacing mercury thermometers with electronic devices (Lassen et al., 2010). Insufficient information was available to estimate the value of these additional features to take it into account in the central case of the compliance cost calculations. However, since the real-life situation is that the market has moved (and is moving) to the use of electronic alternatives for the additional benefits they bring, the impact of the value of these benefits on the cost effectiveness has been estimated by taking into account assumptions for labour time savings[119] due to automatic reading and monitoring.[120] On the basis of qualitative indication, labour cost savings due to replacement of a mercury industrial thermometer measuring temperature above 200°C with an electronic alternative was estimated to be on average 4 hours a year (or 40 seconds per day). Due to the substantial uncertainty on the true average labour cost savings in the whole market segment of the industrial thermometers measuring temperature over 200°C, the estimated average impact on the cost calculations is reported with an uncertainty margin of ±2 hours per annum (see section 5.2.2.4).

Table A5b-19 below presents the input data used in the compliance costs calculations associated with the transition from mercury industrial thermometers to mercury-free dial thermometers and thermocouples.

[119] Other possible benefits are: energy savings; minimisation of human reading errors; higher efficiency of chemical reactions; a better quality of the end-product; reduced risks of damage (automated warning/alarm function); etc.

[120] A similar approach was not taken for laboratory thermometers because economic feasibility and cost effectiveness of restricting the market segment was already clearly shown without taking it into account the value of these additional benefits.

Table A5b.19: Input data used in the analysis – Mercury-in-glass industrial thermometers (>200°C)

Parameter	Device	Central case
Discount rate		4%
Mercury devices sold per year 2010		88,900
Annual decrease in number of devices sold		5%
Mercury per device (kg)		0.0035
Average lifetime (years)	Mercury	13
	Dial	3
	Electronic	5
Investment cost (price of device)	Mercury	€ 45
	Dial	€ 125
	Electronic	€ 93
Investment cost (price of data reader)	Mercury	€ 0
	Dial	€ 0
	Electronic	€ 82
Calibration costs (per calibration)	Mercury	€ 125
	Dial	€ 125
	Electronic	€ 125
Calibration frequency (once in *x* years)	Mercury	4
	Dial	1
	Electronic	1
Batteries (per year)	Mercury	€ 0
	Dial	€ 0
	Electronic	€ 3
Waste treatment (per device)	Mercury	€ 16
	Dial	€ 2
	Electronic	€ 2
Average lifetime per data reader (years)	Mercury	0
	Dial	0
	Electronic	10
Replacement (Hg : electronic probe)		2:1

5.2.2.2. Cost calculations

Investment costs

Table A5b-20 presents the calculation of investment costs of mercury-in-glass industrial thermometers (>200°C) and two alternative devices.

Recurrent costs

Table A5b-21 presents the calculations of recurrent costs for different devices. The values of different parameters of recurrent costs are listed in Table A5b-19. The more frequent calibrations and shorter lifespan of the alternatives result in higher recurrent costs in comparison to the mercury thermometer: additional annualised costs per device of €57 for Alternative 1 and €76 for Alternative 2.

Due to the shorter lifetime and higher price compared to the mercury-containing device, the additional annualised investment cost for the alternatives are estimated to be €41 for Alternative 1 and €21,5 for Alternative 2.

Table A5b-20 Annualised investment costs per device (in 2010 price level) – Mercury-in-glass industrial thermometers (>200°C)

Year	Total Investment costs (€) per device Baseline: Mercury-in-glass Thermometer	Alternative 1: Mercury-free Dial Thermometer	Alternative 2: Electronic (probe & data reader)
Investment costs	45	125	134
Average lifetime (years)	13	3	5
Annualised	**5**	**45**	**26**
Additional annualised		**40.5**	**21.5**

Table A5b-21: Annualised recurrent costs per device (in 2010 price level) – Mercury-in-glass industrial thermometers (>200°C)

Year	Recurrent costs (€) per device Baseline: Mercury-in-glass Thermometer	Alternative 1: Mercury-free Dial Thermometer	Alternative 2: Electronic
1	0	0	0
2	0	125	128
3	0	125	128
4	0	2	128
5	125	0	128
6	0	0	2
7	0	0	0
8	0	0	0
9	125	0	0
10	0	0	0
11	0	0	0
12	0	0	0
13	125	0	0
14	16	0	0
15	0	0	0
16	0	0	0
17	0	0	0
18	0	0	0
19	0	0	0
20	0	0	0
21	0	0	0
Present value (for lifetime)	286	238	466
Annualised	**29**	**86**	**105**
Additional annualised		**57**	**76**

Total costs and compliance costs

Table 5b.22 presents the calculations of total costs of mercury-containing thermometers and the two alternative devices. The results in the table above can be obtained by the addition of the investment and recurring costs presented in Tables A5b-20 and A5b-21.

The more frequent calibrations, shorter lifespan and higher investment costs of the alternatives result in additional annualised costs per device in comparison to the mercury-containing device: respectively €97.50 for Alternative 1 and €97.60 for Alternative 2.

Table A5b-22 Annualised total costs per device (in 2010 price level) – Mercury-in-glass industrial thermometers (>200°C)

Year	Total costs (€) per device		
	Baseline: Mercury-in-glass Thermometer	Alternative 1: Mercury-free Dial Thermometer	Alternative 2: Electronic
Present value (for lifetime)	331	363	600
Average lifetime (years)	13	3	5
Annualised	**33.1**	**130.6**	**130.7**
Additional annualised		**97.5**	**97.6**

Table A5b-23 presents the compliance costs from replacing the mercury dial thermometer with the mercury-free dial or electronic alternative as described above.

Table 5b-23: Annualised and present value compliance costs (in 2010 price level) – Mercury-in-glass industrial thermometers (>200°C)

	Compliance costs (€)	
	Alternative 1: Mercury-free Dial Thermometer	Alternative 2: Electronic
2015	6791832	6798510
2016	13260244	13273281
2017	19420637	19439730
2018	25287677	25312539
2019	30875334	30905690
2020	36196913	36232500
2021	41265083	41305653
2022	46091911	46137227
2023	50688891	50738726
2024	55066966	55121106
2025	59236562	59294801
2026	63207606	63269749
2027	66989552	67055414
2028	63799574	63862299
2029	60761499	60821237
2030	57868094	57924988
2031	55112471	55166655
2032	52488067	52539671
2033	49988635	50037782
2034	47608224	47655031
Compliance cost (present value 2015-2034)	**591,585,833**	**592,167,456**
Annualised compliance cost (2024)	**55,066,966**	**55,121,106**

Assuming that 88,900 new mercury containing industrial thermometers are placed on the market in 2010 (with 5% annual rate of decline), the present value of the compliance costs for the period 2015-2034 are estimated to range between €591.6 million and €592.2 million and on annualised compliance costs (2024) basis between close to €55.07 million and €55.12 million depending on whether the mercury thermometer is replaced exclusively with Alternative 1 or Alternative 2.

5.2.2.3. Cost effectiveness

The analysis in this section assumes that 100% of the mercury-containing thermometers will be replaced with the slightly cheaper alternative - the mercury-free dial thermometer, even though in reality some of the users would replace the mercury thermometer with mercury-free dial thermometer, some with electronic devices and some with alternatives not covered in this analysis. In fact, it is thought that users will in most circumstances prefer the electronic alternative because of the low price difference between the two alternatives in combination with the additional features the electronic alternative offers (such as automation).

As the alternatives have higher investment costs, reducing the volume of mercury placed on the EU market by 1kg when replacing mercury industrial thermometers (>200°C) with mercury-free dial thermometers results in compliance costs of close to €362,200. The calculation is based on the present value compliance costs and on the assumption that one mercury thermometer contains 3.5g of mercury and 100% of the mercury-containing thermometers will be replaced with the slightly cheaper alternative: the mercury-free dial thermometer.

Table A5b-24 presents a summary of the main results of the compliance cost calculations associated with the transition from mercury-in-glass industrial thermometers (>200°C) to a mercury-free dial thermometers. These figures do not take into account additional benefits from the use of more accurate (electronic) alternatives.

Table A5b-24 Cost effectiveness of replacing the mercury thermometers (in 2010 price level) – Labour time savings for electronic alternatives not included – Mercury-in-glass industrial thermometers (>200°C)

Main assumptions for device				
Devices per year (2010)			88,900	number
Trend			-5%	per year
Amount of mercury per device			0.0035	kgs
Lifetime of device			13	years
Costs (€)		**Baseline: Mercury-in-glass Thermometer**	**Alternative 1: Mercury-free Dial Thermometer**	**Alternative 2: Electronic (probe)**
Investment cost	annualised	5	45	26
Recurrent cost	annualised	29	86	105
Total cost	annualised	33	131	131
Additional total cost	annualised		97.5	97.6
Cost effectiveness (per kg of Hg)			**362,165**	**362,522**
Compliance cost	2024		55,066,966	55,121,106
Compliance cost	total		591,585,833	592,167,456

5.2.2.4. Effect of labour time savings on cost effectiveness

When labour time savings are taken into account, the electronic alternative becomes the cheaper alternative. Table 5b-25 shows the impact of the estimated value of additional benefits, i.e., labour time savings[121] due to automatic reading and monitoring, on the cost effectiveness.

Table A5b-25 Cost effectiveness of replacing the mercury thermometers (in 2010 price level) – Labour time savings for electronic alternatives included – Mercury-in-glass industrial thermometers (>200°C)

Main assumptions for device				
Devices per year (2010)			88,900	number
Trend			-5%	per year
Amount of mercury per device			0.0035	grams
Lifetime of device			13	years
Costs (€)		**Baseline: Mercury-in-glass Thermometer**	**Alternative 1: Mercury-free Dial Thermometer**	**Alternative 2: Electronic (probe)**
Investment cost	annualised	5	45	26
Recurrent cost	annualised	29	86	20
Total cost	annualised	33	131	46
Additional total cost	annualised		98	13
Cost effectiveness	annualised		27,859	3,785
Cost effectiveness (per kg of Hg)			**362,165**	**49,201**
Compliance cost	2024		55,066,966	7,480,953
Compliance cost	total		591,585,833	80,368,074

Assuming average labour time savings of 4 hours per year (or 40 seconds per day) due to automatic and remote reading/monitoring and €20 per hour wage cost, the additional annual total cost of the cheaper alternative – in this scenario the electronic alternative – is €13 – about 85% lower than under central case assumptions. The cost of reducing mercury use by 1 kg is €49,200 or seven times lower than under the central case assumptions.

To reflect the substantial uncertainty on the true average labour cost savings in the whole market segment of the industrial thermometers measuring temperature over 200°C, the estimated average impact on the cost calculations is reported with an uncertainty margin of ±2 hours per annum. Assuming in the lower bound 2 hours of labour time savings per year (20 second per day), the additional annualised cost associated with the transition are €55.40 annually over the lifetime of the electronic alternative. The cost effectiveness under this scenario is approximately €205,900 per

[121] Other possible benefits are: energy savings; minimisation of human reading errors; higher efficiency of chemical reactions; a better quality of the end-product; reduced risks of damage (automated warning/alarm function); etc.

kg of mercury reduced or about 40% less than under the central case. Assuming 6 hours of labour time savings annually (i.e., 60 seconds per day), the transition to the alternative electronic thermometer is associated with cost savings to users of approximately €28.90 annually over the lifetime of the electronic alternative. This translates into cost savings of reducing mercury use by 1 kg of approximately €107,500. The "break-even" point of using an electronic thermometer would be if the employer would save 4.7 hours of work per year.

It is important to note that the analysis above considers only labour time savings and does not fully reflect all additional benefits from the use of the more accurate (electronic) alternatives. These other benefits may lead to energy savings, minimisation of human reading errors, higher efficiency of reactions, a better quality of the end-product, reduced risks of damage, etc.

5.2.2.5. Sensitivity analysis

Relaxing the assumption of replacement ratio
Relaxing the replacement ratio assumption (of 2:1) for the data reader of the thermocouple does not change the cost effectiveness and total compliance costs for the transition from mercury-in-glass industrial thermometers (>200°C) to alternatives, as the analysis assumes that the mercury devices are replaced with the slightly cheaper alternative: mercury-free dial thermometers to which the replacement ratio does not apply. However, when labour time savings are taken into account, the electronic alternative becomes the cheaper alternative; therefore, when assuming no replacement ratio, the cost effectiveness and the compliance costs increase by 38% to €67,900 and €10.3 million in 2024 (annualised) or €111 million for the period 2015-2034.

Relaxing the assumption for market size
Depending on the size of this market segment, the total compliance costs can range from €443.2 million (assuming that this market segment represents 60% of all industrial thermometers or 66,600 devices as of 2010) to €739.3 million on NPV basis when it is assumed that this market segment represents 100% of all industrial mercury-in-glass thermometers (111,100 devices as of 2010). Under this scenario, as of 2024, on representative year basis, the total compliance costs will range from €41.3 million to €68.8 million.

Assuming labour time savings, the total compliance costs range from €60.2 million (assuming that this market segment represents 60% of all industrial thermometers or 66,600 devices as of 2010) to €100.4 million on NPV basis when it is assumed that this market segment represents 100% of all industrial mercury-in-glass thermometers (111,100 devices as of 2010). Under this scenario, as of 2024, on representative year basis, the total compliance costs will range from €5.6 million to €9.3 million or 25% lower.

The cost effectiveness under these scenarios will remain the same as it is not impacted by the number of devices on the market.

Relaxing the assumption for calibration

During the data gathering stage of preparation of the Annex XV restriction report, it was noted that some users do not follow the recommended frequency of calibrations. Assuming that there are no calibration costs for the mercury-in-glass and the cheaper under this scenario alternative - dial thermometer, the cost effectiveness is lower by 2.5 times or €149,000 per kg mercury.

When labour time savings are taken into account, the electronic alternative becomes the cheaper alternative; therefore, when it is assumed that there are no calibration costs, the cost effectiveness ratio and the compliance costs translate into savings of €226,600 and €34.5 million in 2024 (annualised) or €370 million for the period 2015-2034.

5.3. Mercury dial thermometers

5.3.1. Introduction

The mercury content of dial thermometers depends largely on whether the dial thermometer is of the "rigid" or "remote" type (whether it has a capillary or not). It can range from about 5g to 200g (Lassen et al. 2008). Between 0.1 and 0.3 tonnes/year of mercury was used in mercury dial thermometers for the European market in 2007. For the purpose of this analysis, the mid-point in these ranges are taken, i.e., 102.5g of mercury per thermometer or 150kg of mercury used in mercury dial thermometers for the EU-market in 2010 (assuming 5% annual decline in volume).

A number of bi-metal and liquid- and gas-actuated dial thermometers are available as alternatives to mercury dial thermometers (Lassen et al. 2008). Other technically feasible alternatives include electronic thermometers such as thermocouples and RTDs (resistance temperature device). From the available information, there is no indication that liquid-in-glass thermometers would be alternatives to the dial thermometers for measurement below 200°C[122]. Taking into account that several probes and other inputs such as pressure gauges can be connected to one data reader, a replacement ratio of 2:1 is used in the central case for the data reader, similar to the industrial mercury-in-glass thermometers (>200°C). This replacement ratio is not applied to the probes as in most if not all circumstances they are installed in equipment. In addition, it is assumed that the lifetime of the data readers of the electronic devices is twice as long as that of the probes.

The Table A5b-25 below presents the input data used in the compliance costs calculations associated with the transition from mercury dial thermometers to mercury-free dial thermometers and thermocouples. As no specific pricing

[122] Lassen et al. 2008 report (Table 2-23) suggests that liquid-in-glass thermometers are not used as replacements for mercury dial thermometers. However, it cannot be entirely excluded that in some applications liquid-in-glass thermometers might be replacements for dial thermometers for temperature measurements <200°C. Given the small market size of this segment and the almost full replacement of the mercury dial thermometers (Lassen et al., 2008), the analysis assumes that if a substitution with liquid-in-glass was possible it was already adopted by users. Therefore, for the purpose of this analysis, we examine the transition from mercury dial thermometers to mercury-free dial thermometers and thermocouples.

information is available for mercury dial thermometers, it is assumed that these thermometers and their alternatives will have similar costs as the mercury-in-glass industrial thermometers (>200°C).

Table 5b-25: Input data used in the analysis – Mercury dial thermometers

Parameter	Device	Central case
Discount rate		4%
Mercury devices sold per year 2010		1,700
Annual decrease in number of devices sold		5%
Mercury per device (kg)		0.1025
Average lifetime (years)	Mercury Dial Thermocouple	13 3 5
Investment cost (price of device)	Mercury Dial Thermocouple (probe)	€ 45 € 125 € 93
Investment cost (price of data reader)	Mercury Dial Thermocouple	€ 0 € 0 € 82
Calibration costs (per calibration)	Mercury Dial Thermocouple	€ 125 € 125 € 125
Calibration frequency (once in *x* years)	Mercury Dial Thermocouple	4 1 1
Batteries (per year)	Mercury Dial Thermocouple	€ 0 € 0 € 3
Waste treatment (per device)	Mercury Dial Thermocouple	€ 16 € 2 € 2
Average lifetime per data reader (years)	Mercury Dial Thermocouple	0 0 16
Replacement (Hg : electronic)		2:1

5.3.2. Cost calculations

Investment costs

Table A5b-26 presents the calculation of investment costs of mercury-containing dial thermometers and two alternative devices.

Due to their assumed shorter lifetime (respectively three and five years) and higher price compared to mercury-containing devices, the additional annualised investment cost is estimated to be €40.5 for Alternative 1 and €21.5 for Alternative 2.

Table A5b-26: Annualised investment costs per device (in 2010 price level) – Mercury dial thermometers

Year	Total Investment costs (€) per device Baseline: Mercury Dial Thermometer	Alternative 1: Mercury-free Dial Thermometer	Alternative 2: Thermocouple (probe & data reader)
Investment Cost	45	125	134
Average lifetime (years)	13	3	5
Annualised	**5**	**45**	**26**
Additional annualised		**40.5**	**21.5**

Recurrent costs

Table A5b-27 presents the calculations of recurrent costs for the three devices.

Table A5b-27 Annualised recurrent costs per device (in 2010 price level) – Mercury dial thermometers

Year	Recurrent costs (€) per device Baseline: Mercury Dial Thermometer	Alternative 1: Mercury-free Dial Thermometer	Alternative 2: Thermocouple
1	0	0	0
2	0	125	128
3	0	125	128
4	0	2	128
5	125	0	128
6	0	0	2
7	0	0	0
8	0	0	0
9	125	0	0
10	0	0	0
11	0	0	0
12	0	0	0
13	125	0	0
14	16	0	0
15	0	0	0
16	0	0	0
17	0	0	0
18	0	0	0
19	0	0	0
20	0	0	0
21	0	0	0
Present value (for lifetime)	286	238	466
Annualised	**29**	**86**	**105**
Additional annualised		**57**	**76**

The values of different parameters of recurrent costs are listed in Table A5b-25. The more frequent calibration and shorter lifespan of the alternatives result in higher additional recurrent costs in comparison to the mercury dial thermometer: an estimated €57 for Alternative 1 and €76 for Alternative 2.

Total costs and compliance costs

Table A5b-28 presents the calculations of total costs of the mercury dial thermometers and the two alternative devices.

Table A5b-28 Annualised total costs per device (in 2010 price level) – Mercury dial thermometers

Year	Total costs (€) per device		
	Baseline: Mercury Dial Thermometer	Alternative 1: Mercury-free Dial Thermometer	Alternative 2: Thermocouple
Present value (for lifetime)	**331**	**363**	**600**
Average lifetime (years)	13	3	5
Annualised	**33**	**131**	**131**
Additional annualised		**97.5**	**97.6**

The assumed more frequent calibration, shorter lifespan and higher investment costs of the alternatives result in additional annualised costs per device in comparison to the mercury-containing device: respectively €97.5 for Alternative 1 and €97.6 for Alternative 2. These results can be derived from Tables A5b-26 and A5b-27 as sums of additional investment and recurrent costs.

Table A5b-29 presents the compliance costs from replacing the mercury dial thermometer with alternatives as described above.

The present value compliance costs for 2015-2034 are estimated to be between €11.31 million and €11.32 million depending on whether all mercury dial thermometers are replaced only by Alternative 1 or Alternative 2. In reality some of the users would replace the mercury dial thermometer with a mercury-free dial thermometer, some with electronic devices and some with alternatives not covered in this analysis.

Further on this analysis assumes that 100% of mercury dial users will replace the devices with the cheaper alternative – the mercury-free dial whose recurrent cost are slightly lower than those of thermocouple.

Table A5b-29 Annualised and present value compliance costs (2010 price level) – Mercury dial thermometers

	Compliance costs (€)	
	Alternative 1: Mercury-free Dial Thermometer	Alternative 2: Thermocouple
2015	129878	130005
2016	253570	253820
2017	371373	371738
2018	483566	484042
2019	590417	590997
2020	692179	692860
2021	789096	789872
2022	881398	882264
2023	969304	970257
2024	1053024	1054059
2025	1132758	1133871
2026	1208694	1209883
2027	1281015	1282275
2028	1220014	1221214
2029	1161918	1163061
2030	1106589	1107677
2031	1053894	1054930
2032	1003709	1004696
2033	955913	956853
2034	910393	911289
Compliance cost (present value 2015-2034)	**11,312,665**	**11,323,787**
Annualised compliance cost (2024)	**1,053,024**	**1,054,059**

5.3.3. Cost effectiveness

As the alternative has higher annualised costs, reducing the use of mercury by 1kg when replacing mercury dial thermometers with thermocouples results in compliance costs of approximately €12,370. The calculation is based on the present value compliance costs and on the assumption that one mercury dial thermometer contains 102.5 g of mercury.

Table A5b-30 presents a summary of the main results of the compliance cost calculations associated with the transition from mercury dial to mercury-free dial thermometers.

Table A5b-30 Cost effectiveness of replacing the mercury thermometers (in 2010 price level) – Mercury dial thermometers

Main assumptions for device				
Devices per year (2010)			1,700	number
Trend			-5%	per year
Amount of mercury per device			0.1025	kilograms
Lifetime of device			13	years
Costs (€)		**Baseline: Mercury Dial Thermometer**	**Alternative 1: Mercury-free Dial Thermometer**	**Alternative 2: Thermocouple (probe)**
Investment cost	annualised	5	45	26
Recurrent cost	annualised	29	86	105
Total cost	annualised	33	131	131
Additional total cost	annualised		98	98
Cost effectiveness	**per kg of Hg**		**12,367**	**12,379**
Compliance cost	2024		1,053,024	1,054,059
Compliance cost	total		11,312,665	11,323,787

5.3.4. Sensitivity analysis

In the absence of information, the assessment used a conservative estimate of a lifetime of 13 years for mercury dial thermometers vs. three years for gas or liquid-actuated dial alternatives, and a yearly calibration of the alternatives vs. once every 4 years for the mercury dial thermometer. It appears, however, that the technology is not very different, and the lifetimes and calibration frequencies might be equal or similar of the mercury and gas- or liquid-actuated thermometers. Assuming that the mercury dial thermometers have the same lifetime and calibration frequency as their gas-actuated alternative systems, the cost effectiveness is lower by 94% or €710. The total compliance costs are also much lower as under this scenario mercury dial thermometers have higher annualised total costs per device (€106) and due to the early retirement of the mercury thermometers. They are €0.9 million (NPV) or €66 thousand on a representative year basis (2024).

The assumption of an annual decrease of 5% of the thermometer market might be conservative, as according to the manufacturers of mercury dial thermometers, there is a very limited remaining market (see section 3.4). Assuming a faster replacement of mercury dial thermometers of 10% annually, the total compliance costs are more than five times lower than the central case scenario: €2.2 million (NPV) or €144 thousand on a representative year basis (2024).

Relaxing the replacement ratio assumption (of 2:1), i.e., no replacement ratio, for the data reader of the thermocouple, will result in an increase of the annualised investment cost of the alternative. Under this assumption, the mercury-free dial will remain the cheaper alternative; therefore, the total compliance costs will remain as presented in Table 5b-29.

During the data gathering stage of preparation of the Annex XV restriction report, it was noted that some users do not follow the recommended frequency of calibrations. Assuming that there are no calibration costs for the thermocouple and the cheaper alternative (mercury-free dial), the cost effectiveness of decreasing the volume of mercury placed on the EU-market by 1kg is 60% lower or €5,100. Total compliance costs under this scenario are €1.5 million (NPV) or €109 thousand on a representative year basis (2024).

6. Summary

Table A5b-31 presents a summary of the main results of the compliance cost calculations associated with the transition from mercury-containing thermometers to feasible alternatives.

Table A5b-31 Cost effectiveness and total compliance costs related to the transition from mercury-containing thermometers to feasible alternatives (in 2010 price level)[123]

Thermometer Market Segment	Mercury volume in 2010 (kg)	Estimated cost Effectiveness (€/kg)	Total Compliance Cost for 2024 (€)
Industry (T<200°C)	80	-3,127	-118,749
Industry (T>200°C)			
- excl. labour time savings	310	362,165	55,066,966
- incl. labour time savings	310	49,201	7,480,953
Dial	170	12,367	1,053,024
Industry - total			
- excl. labour time savings	390	203,956	56,001,242
- incl. labour time savings	390	30,622	8,415,229
Lab (>0.1°C res T<200°C)	80	-3,693	-160,143
Lab (<0.1°C res or T>200°C)	310	4,185	726,860
Lab - total	390	2,610	566,717
Total (excluding labour time savings)	**950**	**121,587**	**56,567,958**
Total (including labour time savings)		**19,162**	**8,981,945**

[123] Excludes psychrometers and ambient thermometers.

Table A5b-31 shows that the transition from mercury industrial thermometers, in particular of thermometers designed to measure temperature above 200°C, to feasible alternatives, will be associated with substantial costs for users if no labour time savings are assumed. If labour time savings of 4 hours with an uncertainty margin of ±2 hours per year are assumed, the cost effectiveness is 49,200 ± 156 500 €/kg.

Lab and dial thermometers will have lower compliance costs with the proposed restriction of the placing on the market of mercury-containing devices. Although there are a number of similarities in the assumptions for industry and lab segments for thermometers measuring temperature above 200°C, the compliance cost for lab thermometers is calculated to be lower. The main factors influencing this outcome include: the lower long-term investment cost of the alternative due to the assumption that 2.5 mercury lab thermometers can be replaced by one electronic alternative; and the shorter (5 years instead of 13 years in industry) and equal lifetime of both mercury and alternative lab thermometers.

The transition to the alternatives from thermometers designed to measure temperature up to 200°C (including ambient thermometers and psychrometers) will likely result in long-term savings for users.

Annex 6: Mercury electrodes used in voltammetry

Content

1. Technical description of mercury electrodes[124]

Voltammetry

Voltammetry is an analytical technique, measuring the current flowing through an electrode dipped in a solution containing the sample, under an applied potential (Amel, 2001).

The voltammetric techniques allow to distinguish between the different oxidation status of metals, the differentiation between the free and bound metal ions, (Amel, 2001, Lassen et al., 2010) the analysis of the environmentally relevant anions like cyanides, sulphides, nitrites and nitrates and the specification of the biological availability of heavy metals (UNESCO, 2002, Lassen et al., 2010).

Measuring devices based on voltammetry

The *polarograph* comprises of a potentiometer for adjusting the potential, a galvanometer for measuring the current and a polarographic cell (made of glass or teflon) containing three electrodes, a reference one with a constant potential, an auxiliary electrode (a platinum wire inserted on a teflon rod) and the working electrode, a capillary connected to a mercury reservoir. A tube for bubbling nitrogen is inserted into the polarographic cell. (Lassen et al., 2008)

Example of a Modern polarograph from Metrohm

During the polarographic measurements the voltage is increased linearly with time (a voltage ramp) and the current variations are recorded automatically. The working electrode can be for instance mercury electrode. If the electrode is formed by a drop of mercury hanging from a tip or capillary, the technique is called *polarography* (Amel, 2001).

[124] Mercury reference electrodes are not covered by this title, and are not assessed because they are dependant on electric current and contain mercury as an integral part of the device (See also appendix 4).

Besides polarography, mercury electrodes are used in the *stripping voltammetry*, and they usually consist of either a drop or a film of mercury. This technique follows two main steps: a preconcentration of the analyte onto the electrode and the successive stripping of the accumulated compound in an inverse direction, onto the electrode towards the solution (it is also named inverse voltammetry). It allows to considerably enhance the sensitivity during the preconcentration stage and to reduce the quantity of the mercury used as electrode. (Amel, 2001)

The devices based on voltammetry are relatively simple, fast, and the theoretical background is precise. All together with the high reproducibility of the curves (current-voltage or current-potential) makes the method one of the most sensitive and versatile one (Electrochemistry Encyclopedia, 2010).

Mercury electrodes

The mercury electrodes used in voltammetry (e.g. with above mentioned devices), serve as sensor electrodes. According to a producer of polarographs, mercury is considered the best metal for cathodic scanning because of its large overpotential and for the possibility to be renewed before each analysis (Amel, 2001).

The mercury electrode is a drop of mercury hanging at the orifice of a fine-bore glass capillary. The capillary is connected to a mercury reservoir so that mercury flows through it at the rate of a few milligrams per second. The outflowing mercury forms a drop at the orifice, which grows until it falls off. The lifetime for each drop is 2 to 5 seconds. Each drop represents a new electrode with the surface practically unaffected by processes taking place on the previous drop. The dropping electrode is immersed in the investigated solution from the cell. (Electrochemistry Encyclopedia, 2010)

The Metrohm 3 electrode system. (the real physical diameter of the mercury drop is typically between 0.3 mm and 0.4 mm; the size is adjustable in certain narrow limits).

The modern versions of mercury electrodes used in polarography are:

- *The dropping mercury electrode* (DME); a flow of mercury passes through an insulating capillary producing a droplet which grows from the end of the capillary in reproducible way. Each droplet grows until it reaches a diameter of about a millimeter and releases. As the electrode is used mercury collects in the bottom of the cell (Amel 2001).
- *The hanging mercury drop electrode* (HMDE) is a variation on the dropping (DME). It consists of a partial mercury drop of controlled geometry and surface area at the end of a capillary in contrast to the dropping mercury electrode (DME) which steadily releases drops of mercury during an experiment; the whole potential sweep takes place at this single drop.

- *The static mercury electrode* (SMDE) combines the properties of the dropping mercury electrode (DME) and the hanging mercury electrode (HMDE). It comprises of a capillary (0.15 to 0.2 mm ID) connected to the mercury container. A valve, operated by a PC, adjusts the dimension of the drop, while a platinum wire ensures the electrical connection with the electrical circuit. The drop surface is constant during the measurement (Amel 2001).

The modern instruments allow the use of any of these electrodes, depending on the application they are used for (Schröder &Kahlert, 2002).

The mercury electrodes used in voltammetry usually have very small surfaces in order to assume quickly and accurately the potential imposed by the electrical circuit. (Amel, 2001)

Application areas

As voltammetry is a non-destructive technique it allows the sample to be analyzed for several times and with different analytes. It also allows the determination of metals at different oxidation numbers (e.g. Cr(III), Cr(IV), Fe(II), Fe(III), As(III), As(V)) and has a high sensitivity for Pb, Cd and Se. (Amel, 2001)

Nickel (Amel 2001), Cd, Pb, Cu, Cr and Fe (Metrohm, 2009) can be analysed (and the speciation is also possible) in sea water only using voltammetry and by this the ability of the water sample to form heavy metal complexes can be characterized (the complexing agents like natural organic compounds of anthropogenic origin, humic acids can mobilize heavy metals) (Metrohm, 2009).

The voltammetric method for metal trace analyses are recommended for small and medium sized laboratories with a low number of samples and a large variety of elements or other compounds to be determined and it has to be used in large laboratories for sensitivity or matrix problems or when a validation of the method is required (Amel, 2001).

The applications for mercury electrodes used in voltammetry are for instance:

- Mechanistic studies (especially of organic compounds) which are important for basic research, structure-activity relationship investigation, study of supramolecular interactions etc.
- Trace metal determination and speciation (information on the oxidation state of the metal, free metal and metal ion in different individual complexes)
- Trace determination of organic substances in the field of pharmaceutical analysis, food analysis, forensic analysis, toxicology and environmental analysis
- Voltammetric immuno assays (UNESCO, 2002, Metrohm, 2009)

2. Description of release and exposure

As described in the approach to assess the risks related to measuring devices using mercury as described in Section B.4 of the main document, there is no single parameter to sufficiently describe the potential release and exposure from either the use or the waste phase. However, according to Lassen et al. (2008) around 0.1-0.5 tonnes of mercury is used per year in polarography.

During the service-life of the polarograph, the mercury has to be continuously added to the device (Lassen et al., 2008), indicating that the use phase may cause both occupational exposure and releases to the environment. The amount of mercury used in measurements is used to describe the potential release and exposure from both the use and the waste phase.

Box 1: General qualitative description of potential release and exposure

<u>Production phase</u>

The mercury is not included in the polarographs during the production of the devices, thus the production phase of polarographs is not relevant for potential release and exposure.

<u>Use phase</u>

Mercury has to be continuously added to the polarographs (Lassen et al., 2008). According to Lassen et al. (2008) around 0.1-0.5 tonnes of mercury is used per year in polarography. This is in the same order of magnitude as the estimation of world-wide use of 0.35 tonnes per year by a producer of devices containing mercury electrodes and used in voltammetry (Metrohm, 2009).

The amount of mercury used is significantly reduced in the modern instruments and one filling requires 6 ml of mercury (81g). This can be used to create 200,000 drops necessary for 0.5 to 1 year of use (Metrohm, 2009). According to one manufacturer, the modern instruments are fully sealed (Amel, 2001).

According to a user of a polarograph, the mercury drops are collected during the analysis in the polarography cell. After the analysis the whole liquid including the mercury amalgam is collected in a special vessel for mercury waste and covered by a water layer. When the accumulated waste reaches a reasonable quantity, the mercury can be either distilled in- house, or sent to external specialized companies. Only pure mercury can be used in polarography (Diacu, 2010).

There is no data available to quantify or assess further the emissions from the use phase. Due to relatively low tonnages (e.g. compared to mercury used in porosimeters) and the way the mercury is used in the measurements, the exposure of workers and releases to the environment from the use phase are assumed to be limited and in any case covered by the occupational limit value (coming into force in December 2010).

Waste phase

As the mercury is used in the analysis the waste stage of the device is not relevant, but the waste handling of mercury is, according to a polarograph user (Diacu, 2010), the mercury used in polarography is either distilled in-house, or sent to specialised companies after measurements. There is no data available to assess further the waste stage and the situation may vary between users and possibly also between Member States.

3. Available information on alternatives (Part C)

3.1 Identification of potential alternative techniques

There are several methods and combinations of methods which can replace polarography or mercury electrodes used in voltammetry only in certain applications. They can be divided in the following categories.

Spectroscopic techniques (usually coupled with another separation technique):

- Atomic absorption/emission spectroscopy (AAS/AES) is an instrumental technique for detecting concentrations of atoms to parts per million by measuring the amount of light absorbed/emitted by atoms or ions vaporized in a flame or an electrical furnace.
- Inductively coupled plasma (ICP), an analytical technique used for the detection of trace metals with A(O)ES atomic (optical) emission spectroscopy (ICP-A(O)ES). A(O)ES is a type of emission spectroscopy that uses the inductively coupled plasma to produce excited atoms and ions emitting characteristic electromagnetic radiation http://www.answers.com/topic/electromagnetic-radiation of a particular element. Its intensity is used to determine the concentration of the element.
- Mass Spectrometry (MS) is an analytical technique by which substances are identified by sorting the mass of gaseous ions using electric and magnetic fields. The molecules ionized in the target sample, are accelerated in the mass spectrometer. The speed of the molecules attain during acceleration is proportional to their mass (their mass-charge ratio), which thus can be calculated (answers.com, 2010).

Other non-electrochemical techniques (than spectroscopic techniques)

- High performance liquid chromatography (or high pressure liquid chromatography (HPLC) usually coupled with mass spectrometry (MS) (HPLC-MS) is a form of column chromatography to separate, identify, and quantify compounds based on their polarities and interactions with the column's stationary phase.

- Neutron Activation Analysis (NAA) is a sensitive multi-element analytical technique used for both qualitative and quantitative analysis of major, minor, trace and rare elements, via the element characteristic emission of particles, or gamma-rays. The activation nuclear process is used for very accurately determining certain concentrations of elements in a vast amount of materials.
- X-ray emission; measure these X-rays having characteristic energy of elements . E.g. following X-ray emission methods exist:
  - X-ray fluorescence (XRF) is the emission of characteristic "secondary" (or fluorescent) X-rays from a material that has been excited by bombarding with high-energy X-rays or gamma rays.
  - Particle-Induced X-ray Emission or Proton Induced X-ray Emission (PIXE) analyses atomic interactions occurring in the X-ray part of the electromagnetic spectrum specific to elements.
  - microPIXE; Recent extensions of PIXE using tightly focused beams (down to 1 µm) gives the additional capability of microscopic analysis. This technique can be used to determine the distribution of trace elements in a wide range of samples (answers.com, 2010).

Electrochemical techniques using electrodes (others than mercury electrodes):

Other electrochemical techniques exist that work on the same voltammetry principle but use different types of electrodes.

- voltammetric solid sensors (gold, carbon silver or bismuth electrodes),
- rotating disk electrodes,
- disposable electrodes (Metrohm, 2009).

Using alternative electrodes in polarography

Galinstan, a registered trademark of the German company Geratherm Medical AG, is an eutectic alloy of gallium, indium, and tin, liquid at room temperature, and is considered to be a promising alternative to the commonly used mercury electrodes in polarography (Surmann, P. and Zeyat, H., 2005, Channaa,H. and Surmann, P.,2009). It can be employed as a liquid electrode instead of mercury in the voltammetric analysis of different metal ions, such as lead and cadmium, in supporting electrolytes.

3.2 Human health and environment risks related to alternatives

The risks associated with the alternative devices/methods vary, as the methods/techniques are very different.

Due to its low toxicity and low reactivity of its compounds, galinstan is considered to be safer than mercury (reachinformation.com, 2010). For more information on gallium and indium see Annex 4.

The other substances used in the alternative electrodes have lower toxicity compared to mercury: gold is well-known as a non-toxic substance and for its inertness, the carbon-silver electrodes are safely used in health-care devices and bismuth is one of the least toxic heavy metals. The other alternative methods include mechanical and electronic parts, not posing notable risks to human health or the environment (see description in part C).

Since the technical feasibility of alternatives could not be established (see further in section 3.3), it has not been possible to compare the risks of mercury electrodes used in voltammetry and their non-mercury alternatives.

3.3 Technical feasibility of alternatives

As some of the alternatives apply totally different methods and principles than the mercury electrodes used in voltammetry, their technical feasibility is difficult to be assessed. Nevertheless, below are presented some problems and limitations related to alternative methods.

Spectroscopic techniques

The ion matrices analyzed by spectroscopic techniques require custom-designed analysis, usually an additional pre-separation phase (by co-precipitation, extraction, hydride generation, separation on cathion exchange resin, adsorption) and often pre-concentration are required to provide acceptable levels of detection when using AAS or HPLC. The flame emission instruments (used in AES) lack the sensitivity offered by the mercury devices (Thompson, 1991).
The spectroscopic techniques allow only the total metal content determination, and they do not distinguish between different oxidation stages of metal ions, or between free and bound metals (Lassen et al., 2010).

Other non electrochemical methods

All the non-electrochemical methods (excluding spectroscopic techniques) described above are well accepted. Nevertheless, most of them allow only the total element detection and need high investments (for purchasing, running and maintenance), have limited mobility and require special laboratory infrastructure. There are some problems with some sample matrices (sea water, pure chemicals), as they can generate more interferences and by this, they are less sensitive.

When using Neutron Activation Analysis (NAA) the irradiated sample remains radioactive for many years. As the number of suitable activation nuclear reactors is declining, the technique may become more expensive.

Other electrochemical techniques using other types of electrodes (than mercury hanging drop electrodes)

Other electrochemical techniques have high sensitivity and may replace some mercury applications but have limited analytical performance due to dynamic range and versatility (less elements can be determined). In addition they generate more interference and by this, they are less sensitive. The lifetime of sensors is limited and they need more electrode maintenance (Metrohm, 2009).

Using alternative materials for the hanging drop electrodes

Galinstan tends to wet and adhere to many materials, including glass, which limits its use compared to mercury (HERC, 2010). The inner glass tubes must be coated with gallium oxide to prevent the alloy from wetting the glass surface. In addition, its aggressiveness could be a major obstacle for its use: it corrodes many other metals by dissolving them (Cadwallader, 2003). With the existing information it is difficult to assess the technical feasibility of galinstan in polarography.

3.4 Economic feasibility

The modern voltammetry instruments using mercury electrodes have a low price, low running costs and compact dimensions (they do not require special build laboratory space) (Lassen et al., 2010, Metrohm, 2009).

Two most relevant and widely used alternative techniques could in principle be assessed against their economic feasibility, namely, atomic absorption spectroscopy (AAS) and Inductive coupled plasma (ICP) spectrometers with OES (Optical emission detection) or with MS (Mass spectrometric detection). However, even these alternatives can replace the mercury electrodes only in certain subsets of applications not necessarily in all uses (Metrohm, 2010).

Secondly, there is not enough data available for either of the alternatives for the full economic comparison. However, below we sketch a comparison given the existing data.

The one-time investment cost of one polarograph is €20,000 compared to over €40,000 for AAS and €40,000-100,000 for ICP (Lassen et al., 2010). The comparison of the numbers is hindered as the average lifetime of the two alternatives is not available. Furthermore, the difference in the investment costs is underlined as the two aforementioned alternatives i) generally require laboratory infrastructure, ii) are less mobile and iii) have smaller number of suitable applications.

Recurrent costs for polarography is suggested to be about €2000-2500 annually translating to about €1 per analysis given generally 100-5000 analysis per year. A full comparison of the recurrent costs can neither be done as the data for recurrent costs and annual number of analysis is missing for alternatives. However, first one of the alternatives, AAS, is reported to require costly accessories (lamps, graphite furnaces), and users of the ICP alternatives are reported to need to spend € 20 000 – 30 000 per year only for argon gas needed in the process. (Lassen et al., 2010)

Given the scarcity of the data it can only be said, that the relatively higher investment costs, more narrow uses and special needs for laboratory infrastructure in case of the two alternatives would require that the lifetime and/or the productivity of the alternatives would need to be considerably higher in order for those to be able to compensate the limitations.

4. Justification why the proposed restriction is the most appropriate Community-wide measure (PART E)

4.1 Identification and description of potential risk management options

4.1.1 Risk to be addressed – the baseline

As discussed in Part B, the current pool of mercury in measuring devices is used as an indicator of maximum emission potential for most of the devices in this report. For the mercury drop electrodes there is not such a pool as the mercury is used in the measurements, and it does not accumulate in the products. For mercury drop electrodes the maximum potential for emissions is the amount of mercury used annually by the users. As described in Chapter B.4. it is estimated to be 0.1-0.5 tonnes yearly. According to the only identified European producer, the world-wide use of mercury is estimated to be 350 kg per year (Metrohm, 2009).

According to a producer of the devices (Metrohm, 2009) the risks related to both use and waste phase are very much reduced in the most modern devices as a result of the minimization of the mercury used (around 80 grams for one filling, necessary for 0.5 to 1 year of use). As a result of the replacing existing devices by modern equipments, the trend of mercury used in voltammetry is likely to be declining. Nevertheless, there is no information available to assess the trend in the number of mercury drop electrodes used in voltammetry, placed on the market annually.

4.1.2 Options for restrictions

As a result of the low quantities of mercury used in voltammetry and strong evidence suggesting that feasible alternatives do not exist, only one restriction option is assessed:

> Restriction on the placing on the market of mercury to be used as mercury electrodes in voltammetry.

4.2 Assessment of risk management options

Restriction of the placing on the market of mercury to be used as mercury electrodes in voltammetry

The maximum risk reduction capacity of this option is estimated to be between 0.1 and 0.5 tonnes annually. As described in Part B.2 (Scope and approach), the restrictions do not apply to the manufacture, placing on the market or use of a substance for scientific research and development provided that the conditions in Article 3(23) of REACH are achieved. Article 3(23) of REACH defines scientific research and development as "*any scientific experimentation, analysis or chemical research carried out under controlled conditions in a volume less than 1 tonne per year*". It is possible that some of mercury electrodes used in voltammetry fulfil the above mentioned requirements, namely mercury is used under controlled conditions in a volume less that 1 tonne per year, and consequently benefit from this exemption. If this is a case, the risk reduction capacity would be reduced accordingly, i.e. it would be lower than estimated above.

As described in Section 3.3 the alternatives for polarographs have limitations related to both technical and economic feasibility. Thus no restriction on the placing on the market of mercury used as electrodes in voltammetry is proposed.

Due to obvious limitations on technical and economic feasibility of alternatives, no further efforts have been taken to assess the restriction option.

4.3 The proposed restriction(s) and summary of the justifications

<u>Proposal:</u>

No restriction proposed.

<u>Summary of justification:</u>
Technically feasible alternatives for mercury electrodes used in voltammetry are not available in all applications. In addition two main alternatives seem not to be economically feasible.

Annex 7: Porosimeters

Content

1. Technical description of porosimeters

Porosimeters are instruments that are capable of measuring pore volume and their distribution, based on the principle of either liquid intrusion or extrusion into or from pores. They are used e.g. in automotive, biotechnology, pharmaceuticals, ceramic, catalysis, energy, building materials, geology, agricultural and textile industry. According to a producer of porosimeters around 60% of porosimeters are used for research and 40% for quality control purposes (Commission, 2009b; Lassen et al., 2010). Contrary to devices containing mercury as an integral part, mercury is used when measuring with mercury porosimeters and the equipment must be refilled regularly.

The application of mercury porosimeters is based on the gradual increase in pressure to enable mercury to enter the pores in a sample, as there is a relationship between the applied pressure and the pore diameter. Mercury porosimeters can be used for wide range of pore sizes i.e. routinely from 0.003 µm to ca. 1000 µm. In addition to pore volume and distribution, mercury porosimeters can provide information about the surface area, particle size distribution, tortuosity, permeability, fractal dimension, compressibility, pore shape, network effects and the skeletal and bulk density. (IUPAC task group, 2010)

2. Description of release and exposure

As described in the approach to assess the risks related to measuring devices using mercury in Section B.4 of the main document, there is no single parameter to sufficiently describe the potential release and exposure from either the use or the waste phase.

Waste management of mercury and mercury contaminated samples and other materials is one part of the normal operation of the laboratories performing measurements with these devices. The reported practices in laboratories appear to support the view that the waste handling of mercury used in the measurements would be conducted in accordance with the requirements of the hazardous waste legislation (Lassen et al., 2010, see Appendix 3). Thus, the annual amount of mercury disposed of as a waste does not reflect the emissions that could occur from the uncontrolled waste streams. Nevertheless it describes the magnitude of mercury involved in the waste phase. Similarly, the amount of mercury used annually in the measurements gives an idea of the quantity of mercury involved in the use phase of porosimeters, and thus gives an impression of the magnitude of releases and exposure that can occur in the use phase.

Based on the calculations and information presented in Box 1:

- The amount of mercury bought annually by the users of porosimeters is estimated to be around 5-14 tonnes per year in the EU. However, the amount of mercury used in the measurements is estimated to be 12-58 tonnes per year, as some of the mercury is used several times by the users as described in Box 1.

- The amount of mercury disposed of annually as hazardous waste is estimated to be around 1.2-3.4 tonnes.
- The mercury that is not disposed of as hazardous waste by the users is sent to specialised companies for purification or regeneration.

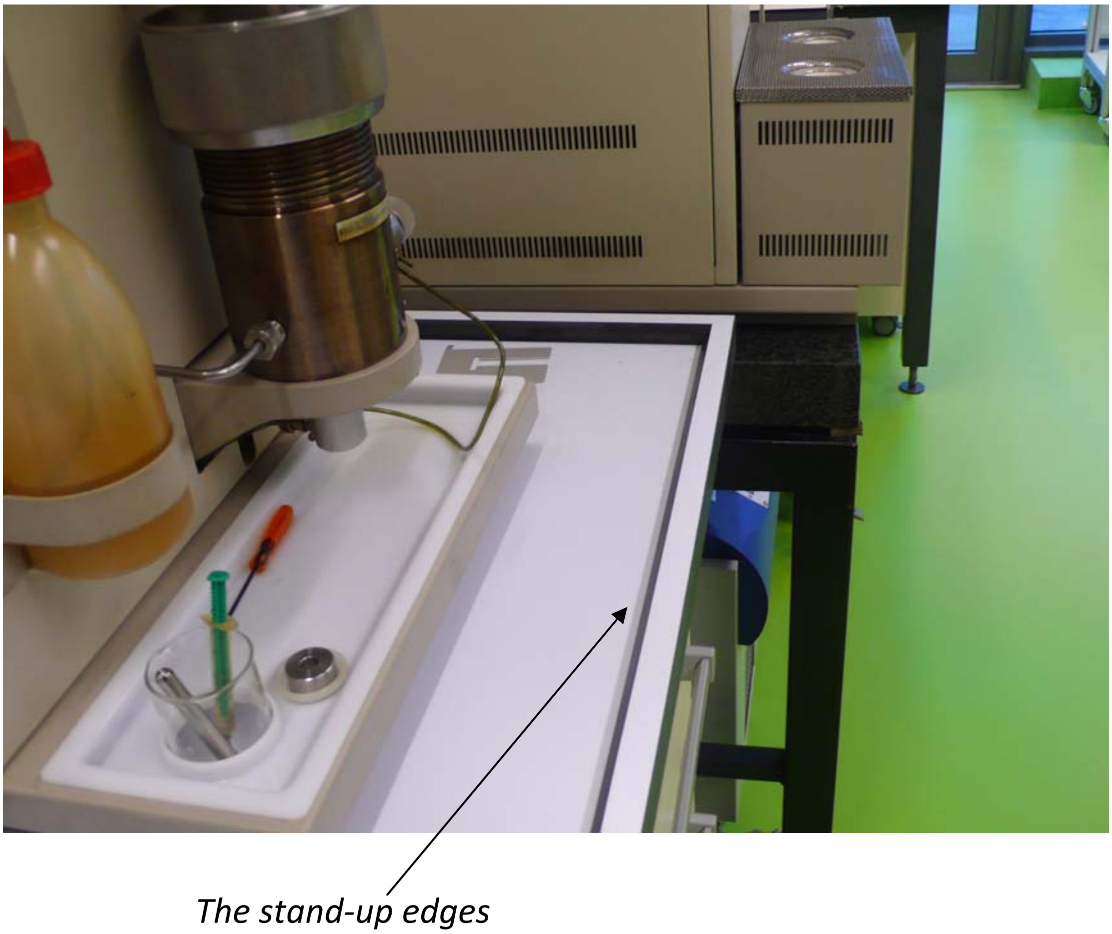
There is no data available to quantify the amounts of mercury released during the normal use of porosimeter or the amounts of mercury ending up to non-controlled waste streams. Nevertheless, based on the information gathered during the preparation of this report, these amounts are likely to be relatively small (Lassen et al. (2010) in Appendix 3).

In addition to general qualitative description of potential release and exposure presented in Box 1, Appendix 3 (Lassen et al. 2010) contains a detailed description of the actual measuring activity and a screening of potential release sources for porosimeters. Furthermore, during the public consultation additional information describing measures taken to prevent mercury releases were provided. The illustrative pictures from the University of Amsterdam (pictures 1, 2 and 3) should be considered together with above mentioned information and pictures presented in the appendix 3.

Picture 1. A thresdhold separating the area were mercury is used from the rest of the laboratory and a special table (see also picture 3) used in the University of Amsterdam.

Source: University of Amsterdam (received during the public consultation)

Picture 2. The suction located below the working area in the University of Amsterdam.
According to the user, a fume hood above the working area is not the best option as the vapours are heavy. Furthermore, using a good filter will create some pressure drop and lower the suction rate.
Source: University of Amsterdam (received during the public consultation)



Picture 3. The stand-up edges in the University of Amsterdam.
Source: University of Amsterdam (received during the public consultation)

Box 1: General qualitative description of potential release and exposure

<u>Amounts of mercury bought and used by the users of porosimeters</u>

According to a survey carried out by the Commission (see Appendix 5), a user of porosimeter buys on average 7.2 kg of new mercury per year. Assuming that 700-2000 porosimeters are in use in the EU (Commission, 2009; Lassen et al., 2008), a total amount of 5-14 tonnes of new mercury is bought annually by these users[125]. This estimate does not consider the fact that some users have a lot of mercury in storage, e.g. 400 kg reported by one user (see Appendix 5), and they do not need to buy new mercury annually.

As visualised in Figure A7-1 below, oil is needed in the measurements. Around 35 %

[125] 7.2 kg (Hg bought annually by user) x 700-2000 (Number of users in EU) = 5-14 t/y

of the users of porosimeters are able to separate the mercury from the oil themselves (see Appendix 5)[126] after the measurement and some laboratories send the mercury and oil to specialised companies for separation. Laboratories can use a batch of mercury 5-10 times or even more often (Lassen et al., 2010). Based on these assumptions it can be estimated that 12-58 tonnes of mercury is used annually for the measurements[127].

The cycle of mercury when using porosimeters

There are several steps in the "cycle of mercury" when using porosimeters as described in the figure A7-1. After measurement some of the mercury can be used again after separation from oil.

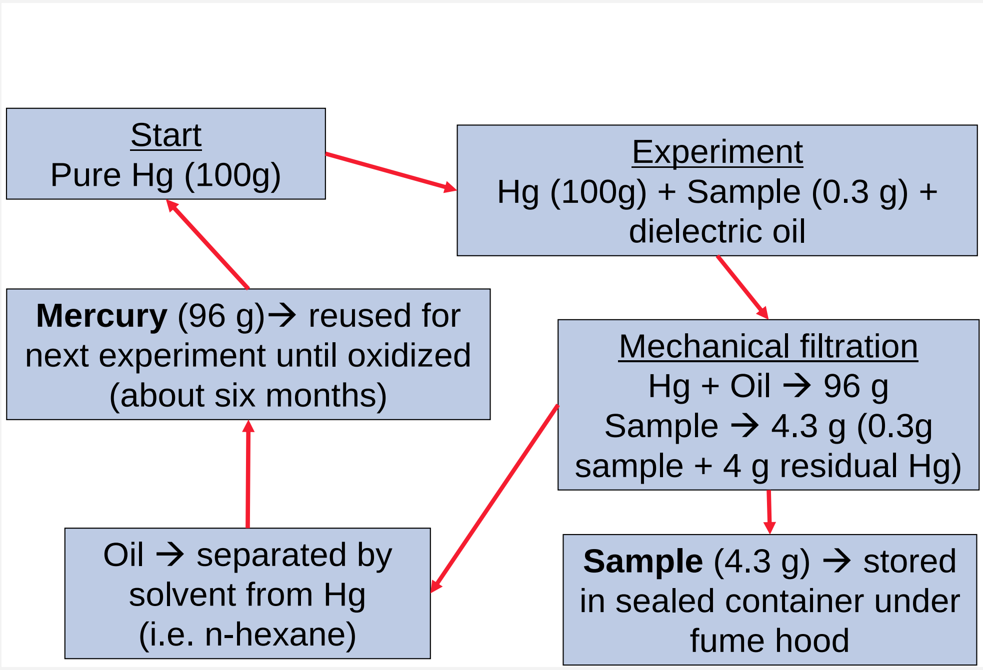


Figure A7-1: The cycle of mercury in measurement with mercury porosimeter
Source: Thermofisher, as cited in Lassen et al., 2010 (see Appendix 3)

Around 4% of mercury used in a measurement will stay in the sample and 96% of mercury is mixed with the oil and needs to be separated. The separated (in-house or externally) mercury can be used in a new measurement until it is oxidised. There is no data available on the rates of oxidation of mercury during or between the measurements, but it is dependant on the material of the measured samples. The oxidised mercury may be sent to specialised companies to be regenerated, i.e. reduced back to the metallic form. (Lassen et al. 2010, see Appendix 3)

[126] This result is not reported in the Commission's review report (COM, 2009), but is based on the individual responses for the survey which have been made available for ECHA.
[127] 5-14 t (Hg bought annually) x 0.35 (35% of laboratories conducting in-house separation of Hg from oil) x 5-10 (Hg reused 5 to 10 times) + 5-14 (Hg bought annually) x 0.65 (65% of laboratories not using Hg several times) = 12-58 t/y
[128] 1.7 kg (Hg disposed as waste by one user) x 700-2000 (number of porosimeters in EU) = 1.2-3.4 t
[129] 0.04 (4% of Hg stays in the sample) x 13-58 t (Hg used for measurements) = 0.5-2.3 t

Production phase

The mercury is not included in the porosimeters during the production of the devices, thus the production phase is not relevant for potential release and exposure of mercury.

Use phase

Some of the mercury is likely to evaporate during the use of porosimeters and causes occupational exposure or ends up in the environment. There is no data available to estimate the possible release from the use, but the relevance can not be excluded due to relatively high volumes of mercury used. The release is highly dependant on the risk management measures and safety procedures used in the laboratories, and may vary significantly between laboratories and Member States. Note that in this respect it is relevant to mention that a Community-wide occupational exposure limit value (IOELV) has been adopted for mercury (0.02 mg/m^3), see also Part B.5 (Summary of existing legal requirements and their effectiveness).

The following release routes of mercury from the use and waste phase are identified by Lassen et al. (2010):

1. Releases from the porosimeter through the exhaust of the porosimeter. From mercury spilled by filling of container, droplets on penetrometer, cleaning of valves, cleaning of high pressure tank, etc.
2. Releases from the fume hood through the exhaust of the fume hood. From mercury spilled or directly evaporated by emptying and cleaning the penetrometer and mercury spilled or directly evaporated by regenerating the mercury. Mercury releases from small droplets on gloves, cleaning pads, etc.
3. Release from the fume hood through the drain of the sink (if the fume hood has a sink). From mercury spilled by emptying and cleaning the penetrometer, mercury spilled by regenerating the mercury, from small droplets on gloves, cleaning pads, etc. the mercury may inter into a sink in the fume hood.
4. Releases from the laboratory's general ventilation system. From mercury spills outside the fume hood or porosimeter.
5. Long term releases from mercury contaminated waste. All mercury contaminated waste (>0.1 % w/w) has to be disposed of as hazardous waste, in accordance with EU waste regulation.
6. Releases from recycling of mercury by recycling companies.
7. Mercury in solvent disposed of as solvent waste. Mercury is not dissolved in the solvents and the waste solvent seems not to be considered mercury containing.

No data has been available for quantification of any of these releases, but according to Lassen et al. (2010) the main source of mercury releases from the use phase of porosimeters is assumed to be from the fume hood, where several operations with mercury are conducted.

A detailed description of the measuring process of porosimeter and description of potential releases can be found in the Appendix 3.

Waste phase

Most of the mercury used in analysis is regenerated to be used again. This regeneration is not recycling as described in the revised waste framework directive (2008/98/EC), as the mercury is not intended to be discarded by the user. In addition, some of the mercury waste disposed of as a hazardous waste will be recycled. It is highly unlikely that the mercury mixed with the oil or the oxidised mercury would end up to non-controlled waste streams, but it can not be excluded either.

The main mercury waste fraction is the contaminated sample. In addition, some mercury ends up in the waste stream from the protecting gloves filters etc. Based on the individual responses to Commission's survey (see Appendix 5) and interviews with users of porosimeters (Lassen et al., 2010) it seems that the users dispose of the mercury in accordance with the requirements of the hazardous waste legislation. Thus the proportion of mercury ending up in non-controlled waste streams seems to be small.

Based on the reported amounts of mercury disposed as waste by users (see Appendix 5), it can be estimated that around 1.2-3.4 tonnes of mercury would be disposed of as waste per year[128]. According to Lassen et al. (2008) most of the mercury losses are expected to be caused by the mercury-saturated samples. Assuming that 4% of mercury stays in the sample after a measurement (Thermofisher as cited in Lassen et al. 2010) results in having around 0.5-2.3 tonnes of mercury in the samples annually[129]. The amount depends on the material of the sample, and a rate as high as 20% has been reported (Lassen et al., 2010)

There is no data to further assess the amounts of mercury ending up in hazardous or non-controlled waste streams from the waste fractions or to assess the recycling rate for the mercury disposed of as waste.

3. Available information on alternatives (Part C)

3.1 Identification of potential alternative techniques

There are several alternatives for mercury porosimeters with different kind of limitations on the feasibility. The following alternative techniques and methods have been identified in a report by IUPAC task group on liquid intrusion and alternative methods for the characterization of macroporous materials (2010).

Intrusion of other non-wetting liquids

Alternative liquid metals e.g. gallium, indium and their alloys can be used instead of mercury in devices relying on the same method as mercury porosimeters.

Methods based on capillary condensation equilibria obtained through drainage and/or evaporation

Liquid porosimetry (i.e. extrusion porosimetry) can utilize any wetting fluid e.g. pure water and hexane. Instead of positive pressure to intrude the liquid into sample, liquid porosimetry applies negative pressure to drain the wetting liquid from the pores. The sample is exposed, in a test chamber, to varying and precisely controlled air pressure. With the variation of pressure, different size pore groups drain the liquid and their pore volume is equal with the one of the liquid.

Gas adsorption porosimeter is based on the adding (or removing) a quantity of gas (nitrogen, argon or krypton, CO_2) to samples, at cryogenic temperatures, where weak molecular attractive forces cause the gas molecules to adsorb on material in order to obtain adsorption-desorption isotherms. The volume of the gas adsorbed by the sample can be determined from the ideal gas law and also the surface area and pore size distribution of the sample can be derived (ZAG Ljubljana, Micromeritics Analytical Services, Green Chemistry Centre of excellence). According to Mitchell et al. (2008) gas adsorption is the most commonly used method for determining pore size distributions in addition to mercury porosimetry.

Contact (or standard) porosimetry is based on the gravimetric measurements of the liquid in the sample and by simultaneously investigating from adsorption and capillary isotherms the pores at the thermodynamic equilibrium conditions. The automated version, automated standard porosimeter (ASP), includes a computer, an electronic balance, an automatic manipulator, a device with electromagnetic valves for a controlled drying of the porous samples by a flow of dry inert gas. It is used e.g. for the investigation of porous materials used in electrochemical devices (electrodes, membranes).

The bulk condensation method consists in the oversaturation of the sample in order to fill all the pores and then the analysis of the desorption branch from the adsorption isotherms.

Water desorption calorimetry consists in the saturation of the porous medium with a liquid which is then slowly desorbed in quasi-equilibrium conditions. The equilibrium relative pressure is deduced from a differential transducer between the sample cell and the reference cell that is filled with pure liquid. The desorbed liquid is determined by using the heat flow.

Permeation of a liquid (permeameters)

Porous samples can be characterized by permeation of a gas or a liquid through the sample material followed by a prediction, or at least correlation of the pressure drop to the flow rate by using various equations for the laminar flow regime. (IUPAC task group, 2010)

Freezing-melting porosimetry

When a liquid fills a porous sample its freezing and melting points are depressed. These changes are connected with the width of the pore. Together with the volume of molten liquid in a given temperature it is possible to get information on pore-size distribution. The method is completed by *Differential Scanning Calorimetry (i.e. Thermoporometry) when* the measured temperature depression is determined and directly related to the pore width or *Nuclear Magnetic Resonance (NMR) cryoporometry,* when the depression of the melting point of a crystalline solid is determined by analyzing the proton NMR signal as function of temperature.

Imaging techniques

Imaging techniques including e.g. *Magnetic Resonance Imaging*, *X-ray Tomography*, *Electron Microscopy*, *Light microscopy/Laser methods*, *Pulsed-field Gradient* and *Hybrid Imaging* allow pore size mapping.

Statistical reconstruction of porous materials

Statistical modelling can be used to characterise a disordered porous medium with several pore shapes presented. Structural correlations aim to correlate the structural state of different points with functions such as bulk, surface autocorrelation or pore-surface correlations functions and use of statistical geometrical analysis, mathematical morphology.

3.2 Human health and environment risks related to alternatives

Some alternatives use other liquids than mercury to measure the porosity of the sample. They vary from water to liquid metals like Indium, Gallium and their alloys (IUPAC task group 2010). The environmental and health risks related alternative substances and methods are not assessed further in this report[130], but there are no indications that risks would be at the same level as related to mercury. For most of the alternatives the risks would be significantly lower.

3.3 Technical and economic feasibility of alternatives

Only one producer of mercury porosimeters (out of four contacted) responded to the questionnaire in the stakeholder consultation. The producer with wide selection of alternative devices did not respond (based in the USA). Thus, the following information is based on a (limited) literature search and one response during the stakeholder consultation. Identified alternatives have different limitations related to e.g. applicable pore sizes, applicable size and material of samples, measured parameters and duration of measurement. The mercury porosimeter has limitations in applicability as well e.g. limited pore size range (0.003-1000 µm) and requirements on the durability of the sample as high pressure is applied. Below some identified limitations and advantages of different alternative devices.

[130] Some information on gallium can be found in Annex 5b (Thermometers).

Intrusion of other non-wetting liquids

According to a brochure of a producer of porosimeters, a specific porosimeter is able to use both mercury and other liquids (only water mentioned) (Porous Materials, 2010). Based to the brochure the only limitation seems to be that the fluid needs to be non-wetting to the tested material. There is no data available on the potential fluids (in addition to water) to be used or their wetting properties in different sample materials (and thus in different application areas).

Intrusion of water is applicable only on hydrophobic samples and the preliminary surface treatment to make the sample hydrophobic (if needed) is a time consuming task. According to a producer of porosimeters, the hydrophobic materials cover less than 5% of applications and the water intrusion porosimeter is only applicable to samples with pore sizes between 0.001-20 µm. (Lassen et al., 2010)

According to a producer of water intrusion porosimeters, potential application areas include automotive, chemical, pharmaceuticals, battery separator, fuel cells, powder metallurgy, ceramic, paper and filtration industries (Porous Materials, 2010).

Methods based on the capillary condensation equilibria obtained through drainage and/or evaporation

Liquid porosimetry (i.e. extrusion porosimetry)
Liquid porosimetry can be used for deformable materials (IUPAC task group, 2010). According to Lassen et al. (2010) a producer of porosimeter has indicated that the method involves a very expensive gravimetric technique and is applicable to pore sizes between 1-1000 µm, even though an application range of 0.06-1000 µm is indicated by another producer. According to a producer of liquid extrusion porosimeters, potential application areas include automotive (particle filters for diesel fuels), filtration, nonwovens, biotechnology & healthcare, geotextiles, pharmaceuticals, ceramic, household & personal hygiene and textiles industries (Porous Materials, 2010).

Adsorption (nitrogen) porosimeter is applicable only for pore sizes below 0.05-0.1 µm. (IUPAC task group, 2010).

Contact (or standard) porosimetry is applicable for pore size between 0.01-100 µm. (IUPAC task group, 2010)

The bulk condensation method is not applicable for pore size above 0.4 µm

Water desorption calorimetry still has some problems related to kinetics and is not applicable for pore sizes above 10 µm.

The methods based on the capillary condensation equilibria are applied at least to some extent for the same pore sizes as mercury porosimetry and are thus possible alternatives to replace the mercury porosimetry in the future. (IUPAC task group, 2010)

Permeation of a liquid (permeameters)

The results can be linked to pore size in the 0.1 to 1000 µm range, or other characteristic of the material. A major problem is with samples composed of different pore sizes, as the flow rate though the larger pores will be more than proportionally larger than flow through smaller pores. In addition no standard equipment is readily available with broad applicability. (IUPAC task group, 2010)

Freezing-melting porosimetry

The freezing-melting porosimetry is applicable for wet and fragile samples which do not withstand drying or outgassing. It has also advantages of being a clean method (usually using water), relatively fast measurement (around 3 hours), requirement of small sample (10 mg) and reasonably comparable results with other methods. (IUPAC task group, 2010)

Nevertheless, the sample must withstand the liquid and avoid any unwanted transformation (IUPAC task group, 2010). In addition, nuclear magnetic resonance cryoporometry has the disadvantage over mercury intrusion of having an upper measurable size limit below1 µm (Vargas-Florencia et al., 2006).

Conclusions on technical and economic feasibility

The IUPAC task group (2010) concludes that there are no technically feasible well-established alternatives to mercury porosimeters in pore sizes between 0.05µm and 400µm. Nevertheless, it has not been possible to rule out during the preparation of this report that a combination of several devices and methods would allow measuring more or less similar parameters as by mercury porosimeters. It is possible that the technical infeasibility is more related to the comparability of the results measured by mercury porosimeters and alternatives than physical limitations like pore sizes. This problem could be solved at least partly by allowing adequate time for the users to run measurements concurrently. According to Lassen et al. (2010) a producer of porosimeters has indicated that some 3 years would be needed for validation and re-calibration of quality control procedures and 4 years for development of new certified reference materials for the results validation. There are no data available on the relevance of the comparability of results for research purposes.

Three national bans in Denmark, Netherlands and Norway have derogations for use in porosimeters. In addition in Sweden companies have a possibility to apply for national authorisation for purchase of porosimeters and between 1996 and 2010 this possibility has been used twice. This indicates that the technical feasibility of alternatives has not been easily established in those Member States which already have wide national restrictions related to mercury in other measuring devices.

It has not been considered proportionate in the framework of this restriction report to fully screen and assess all the alternative devices and methods, and their technical feasibility in each application area. This is due to highly technical nature of the work requiring very specific expertise and a high workload (there are many different application areas, as well as different parameters measured, see section 1). Moreover, it has not been possible to identify a single application or group of applications covering a significant share of measurements, which would allow a targeted restriction. In addition, after identifying technically feasible alternatives (or combination of alternatives) for some application areas, resources would need to be allocated in the assessment of the economic feasibility. In conclusion, a further assessment was not considered proportionate in the framework of preparing this report considering the anticipated workload and results.

As the technical feasibility of alternatives could not be established, the economic feasibility is not assessed in the report either. However, some available information gathered in the stakeholder consultation is reported below. According to Lassen et al. (2010) a mercury porosimeter cost around €20,000-€40,000. At least some alternative devices are cheaper than the mercury porosimeters (Lassen et al., 2008). Nevertheless, several alternative devices may be needed to cover all the measured parameters and all the sample materials that can be measured by a mercury porosimeter. The information received from a producer of porosimeters suggests that the costs of using flow porometer would be in the same magnitude as using mercury porosimeter (Lassen et al., 2010).

4. Justification why the proposed restriction is the most appropriate Community-wide measure (Part E)

4.1 Identification and description of potential risk management options

4.1.1 Risk to be addressed – the baseline

As discussed in Part B, the annual amount of mercury used in measuring devices is used as an indicator of the potential release and exposure in this report. For mercury porosimeters, one way to describe the annual use is the amount of mercury purchased by the users which is estimated to be 5-14 tonnes per year. However, the possibility to reuse the mercury several times means that around 12-58 tonnes of mercury is fed in to porosimeters annually to conduct the measurements. This amount describes the relevance of mercury porosimeters as source of exposure and emissions during the use phase. In addition, it is estimated that around 1.2-3.4 tonnes of mercury is disposed of as waste.

The risk related to both use and waste phase might be slightly reduced over time as devices and instructions, e.g. ISO standard, will be developed further. Nevertheless, these effects would not apply to all the users and old devices. There is no data available to estimate the trend in number of measurements done with mercury porosimeters.

4.1.2 Options for restrictions

The following tentative options to reduce the risks related to use of mercury in porosimeters were identified when preparing this restriction report. Options 1a, 1b and 1c are aimed to reduce the amount of mercury used in porosimeters and thus affect both the use and waste phase. Option 2 is only considering the waste phase, whereas options 3a and 3b concentrates on the use phase. Option 4 is a way to collect information to further assess the technical feasibility of the alternatives, as it was not possible to fully assess it when preparing this report. The variety of options reflects the fact that the mercury used in porosimeters could cause risks at both the use and the waste phase.

After tentative consideration only options 1a and 4 are considered more in detail in Chapter E.2 for the reasons presented below.

Reducing the amount of mercury used in porosimeters

<u>1a) Ban on using the mercury in porosimeters</u>
All the risks from both the use and waste phase would be totally eliminated. However, this option would also introduce high costs as mercury porosimeters would need to be replaced before the end of their service-life. For some applications several alternative devices would be needed to cover the same range of pore size measurements and to measure all the parameters offered by a porosimeter. As no technically feasible alternatives are identified for some applications, it would no longer be possible to carry out certain types of measurements. However, the impacts of this are extremely difficult to assess. Due to lack of technically feasible of alternatives, this option as such is not considered further. The following elements could be considered to reduce the negative impacts described above:

- long transitional period (e.g. 10 years) to allow users to adapt their quality control or research processes
- banning the use of mercury only in the porosimeters placed on the market after entry into force (i.e. ban placing on the market of mercury porosimeters)
- combination of above elements

This option with additional elements is further assessed in section E.2.

<u>1b) Ban on using mercury in porosimeters with derogations for specific applications where technically feasible alternatives do not exist</u>

Compared to 1a this option introduces lower costs as the impacts of not being able to carry out all types of measurements would be avoided. Likewise also the risk reduction capacity would be lower. As some laboratories are using porosimeters for several applications, this option might still introduce additional costs related to the need to buy additional devices to be used concurrently with the mercury porosimeter. The enforcement could be particularly problematic as mercury porosimeters would still be allowed, but only their use for specific applications would be restricted. In addition, it would be very difficult to go through all the applications to definitively assess the technical feasibility of alternatives, running the risk that some important applications could be banned. Thus, this option is not considered further. The additional elements described for option 1a could be included to this option as well.

<u>1c) Ban on using mercury in porosimeters in specific applications</u>

This option is the same as 1b, but allows banning only those uses for which technically feasible alternatives exist for sure. The risk reduction capacity depends on the amount of mercury used for applications with technically feasible alternatives. We have not been able to identify a single application or group of applications covering a significant share of measurements. As in option 1b, some laboratories are using porosimeters for several applications. Thus this option might introduce higher costs as there would be a need to buy additional devices to be used concurrently with the mercury porosimeter. In addition, the enforcement could be problematic if mercury porosimeters would be allowed but only their use for specific applications would be restricted. Thus, this option is not considered further. The additional elements described for option 1a could be included to this option as well.

Promoting appropriate waste handling of mercury

<u>2) Setting waste handling requirements</u>

Risks related to the waste phase of mercury originating from the use of porosimeters could be reduced by promoting appropriate waste handling. However, the current waste legislation requires treating mercury properly, and according to available information there seem not to be problems with the compliance. Without any specific reasons the problems related to waste stage should be addressed through waste legislation and this option is not considered further. Nevertheless, the following two aspects to affect the waste stage were considered:

- The users of porosimeter could be obliged to deposit a pledge (x € per kg of Hg) which would be returned only when the mercury (including mercury in the samples) is returned to the supplier, and all the suppliers of mercury would need to adopt the system. The risk reduction capacity would be highly depending on the value of the pledge. Enforcement of this kind of scheme would be difficult, as mercury will be on the market for other applications than porosimetry without the pledge. In addition, some laboratories use mercury for other purposes than porosimeters as well and they would need to have separate fractions of mercury for different purposes. Setting this kind of system is not regarded necessary as there seem to be high compliance with waste legislation.
- Suppliers of porosimeters could be obliged to arrange take-back scheme for mercury used for porosimeters and the scheme would be obligatory for users. All the mercury for porosimeters would have to be purchased from the suppliers of porosimeters or from a company authorised by the supplier. The involvement of suppliers of porosimeters could make the enforcement easier. It would be also easier to inform these companies about the requirements. This scheme would include all the mercury containing waste fractions. Enforcement of this kind of system could be challenging, as mercury will be on the market from other sources than the suppliers of porosimeters. Setting this kind of system is not regarded necessary as there seem to be high compliance with the existing waste legislation.

In addition to setting waste handling conditions in the Annex XVII of REACH, another option would be to have a voluntary agreement with the users to improve waste handling. However, the reasoning above applies also to some extent to the voluntary agreements with the users of porosimeters. If later on new data becomes available – suggesting significant problems in the waste handling - the voluntary action with the users could be worth examining.

Promoting appropriate handling of mercury during the use phase

3a) Setting use conditions

Laboratories have different safety measures in place to prevent emissions and exposure to mercury e.g. exhaust systems, mercury spill kits and fume hoods. This option would try to promote and codify current best practices to be used by all the users. Use conditions would reduce the risks related to use phase including also the in-house separation of mercury. With the available data it is difficult to estimate the risk reduction capacity and costs related to this option.

There is an ongoing work to revise the ISO-15901-1 standard (Pore size distribution and porosity of solid materials by mercury porosimetry and gas adsorption) to include recommendations on the safe use of mercury. These recommendations could be used as an example when setting the use conditions. However, a straight forward reference to prevailing the ISO standard is not a suitable option as the standards are not available free of charge for actors and they might be amended (or even closed down) without involving chemical authorities. The possible impact of the ISO standard revision on the risk reduction capacity of setting the use conditions is difficult to be assessed as there is no data available on the share of users following the standard in question, nor on how well they already fulfil the recommendations.

Occupational health legislation has already addressed the concern related to exposure at the workplace by setting an occupational exposure limit value for mercury (0.02 mg/m^3). We have not identified reasons why the limit value would not be in a sufficient level or reasons why a condition in Annex XVII entry would be needed to ensure that actors comply with this limit value. Thus this option is not assessed further. See Part B.5 (Summary of existing legal requirements and their effectiveness) for further discussion on the occupation exposure limit value for mercury.

3b) Setting monitoring requirements in the workplace

Laboratories have different safety measures in place to prevent exposure to mercury. Due to relatively high tonnages of mercury used and several steps of measuring with porosimeters where mercury is handled, relevant exposure may take place. To support the implementing of the occupational exposure limit for mercury, monitoring requirement by monitoring batches or urine tests could be required.

As mentioned above, occupational health legislation has already addressed the concern related to exposure at the workplace by setting an occupational exposure limit value for mercury. We have not identified reasons why a condition in Annex XVII entry would be needed to ensure that actors comply with this limit value and this option is not assessed further.

Supporting further assessment of technical feasibility of the alternatives

4) Information gathering

Due to challenges related to assessment of technical feasibility of the alternatives, it was not possible to conclude if technically feasible alternatives for all applications of mercury porosimeters exist or not. This option is aiming to support the collection of additional information to allow full assessment of both technical and economic feasibility by setting a requirement for the users of porosimeters to provide information to competent authorities of the Member States on the technical features needed in their field. This option is assessed further in the next Chapter.

In addition, the users of mercury porosimeters could be obliged to register themselves to competent authorities of Member States. This information could be later on used to collect further information.

4.2 Assessment of risk management options

4.2.1 Option 1: Restriction on the use of mercury in porosimeters that are placed on the market after 5 years of the entry into force

Adopting this restriction option would in practise mean that mercury porosimeters shall not be placed on the market after five years of the entry into force. The reason to introduce this as a use ban, rather than restricting the placing on the market of mercury porosimeters, is that at least one type of device can utilize both mercury and other liquids. Thus it would be possible to argue that the supplier would not be placing on the market mercury porosimeters but porosimeters in general. Nevertheless, to promote effective enforcement, it should be considered to ban also the placing on the market of mercury porosimeters (or porosimeter designed to be used with mercury), as it would be more practical to enforce the placing on the market of the devices than using them. The use of porosimeters placed on the market before the ban would become effective, would still be allowed.

4.2.1.1 Effectiveness

Risk reduction capacity

Following the approach described in Part B, the risk reduction capacity of this restriction option is described as the annual amount of mercury used in porosimeters. As the mercury is regenerated to be used again, the amount used does not reflect the risk reduction capacity for the waste phase. For that, the relevant figure is the amount of mercury disposed annually as waste. For both indicators, the capacity is 1/10 of the annual amount in the first year the restriction is effective, assuming 10 years service-life for porosimeters. In 10 years the restriction would have its full effect and the risk reduction capacity would be the same as the annual amount. Using averages of ranges calculated above, the risk reduction capacity can be estimated to be rising from 0.2 to 2.3 tonnes per year for the waste phase and from 3.6 to 36 tonnes per year for the use phase. Nevertheless, the real emissions from the use of porosimeters are much lower due to relatively high rate of mercury being collected according to hazardous waste legislation and risk reduction measures already in place in laboratories.

As described in Part B.2 (Scope and approach), the restrictions do not apply to the manufacture, placing on the market or use of a substance for scientific research and development provided that the conditions listed in Article 3(23) of REACH are achieved. Article 3(23) of REACH defines scientific research and development as "*any scientific experimentation, analysis or chemical research carried out under controlled conditions in a volume less than 1 tonne per year*". It is possible that some use of mercury porosimeters fulfil the above mentioned requirements, namely mercury is used under controlled conditions in a volume less that 1 tonne per year, and consequently benefit from this exemption. If this is a case, the risk reduction capacity would be reduced accordingly, i.e. it would be lower than estimated above..

Proportionality

Technical feasibility

Even though it has not been possible to fully assess the technical feasibility of the alternatives or combination of alternatives, different devices and methods are available to measure the porosity of the materials. In the product control, it seems that measurements with alternatives can offer adequate data to assure the quality even though the results would not be exactly the same as with mercury porosimeters. The five years transitional period for placing on the market and the possibility to continue using porosimeters already in use would allow users to adapt their quality control procedures.

Economic feasibility (including the costs)

As the technical feasibility of alternatives has not been fully established and the economic feasibility has not been assessed, it is not possible to assess the economic feasibility of this restriction option.

4.2.1.2 Practicality

Implementability and manageability

Because of the limited information on the technical and economic feasibility of alternatives, the implementability of this option is difficult to asses. Nevertheless, problems related to implementability and manageability should be significantly reduced by the five years transitional period and by the possibility to continue using existing devices.

Enforceability

The enforcement would in practise be done by enforcing the placing on the market of porosimeters, even though the restriction entry of this option is formulated to restrict the use of mercury. As there are only few suppliers of porosimeters in the EU, the enforcement should not be a problem.

4.2.1.4 Overall assessment of restriction option 1

Based on the limited information on the technical and economic feasibility of the alternatives it is not possible to draw conclusions on the proportionality of the restriction option. Even though it has not been possible to verify the technical feasibility of alternatives, it is not possible to rule out that technically feasible alternatives may exist. Also the risk reduction capacity of this option is difficult to assess. The comparison of the risk reduction capacity with other mercury measuring devices should not be done directly with annual tonnages, as the waste handling situation seem to be better for porosimeters and the risks related to the use phase seem to be higher.

4.2.2 Option 2: Information gathering with further assessment of the technical and economic feasibility

The assessment of the technical feasibility of the alternatives to mercury porosimeters is not finalised in the framework of this report due to the highly technical nature of the issue. The application areas where mercury porosimeters are used are very diverse and different features from the alternative devices might be required to get the desired results. This is naturally affecting the possibilities to transfer to the alternatives.

In depth assessment of the technical feasibility of the alternative devices would require involvement of both the suppliers of the different alternatives and the users from different application areas. As at least some alternative devices are new for the users of mercury porosimeters, it can be doubted if they would be able to directly argue whether an alternative is feasible without a detailed knowledge on the properties of devices. Thus a research program with possibly a workshop could be beneficial.

To support the further assessment of alternatives the users of mercury porosimeters could be required to provide information on their use as a requirement in the restriction entry. That information could include for instance the results (parameters) needed in each application area, the costs of measuring and also the argumentation on the technical feasibility of alternatives based on the descriptions provided in the questionnaire/reporting format. At the same time it would be possible to get a more detailed picture on the risks related to both use and waste phase of mercury.

4.2.2.1 Effectiveness

Risk reduction capacity

This restriction option does not have a significant risk reduction capacity without further regulatory action. Nevertheless, awareness of alternatives may lead to voluntary replacement of mercury porosimeters. The possible future risk reduction is naturally related to the outcome of the further assessment of the technical and economic feasibility of the alternatives and to the consequent actions taken on the basis of this assessment. If the assessment later on concludes that feasible alternatives exist and a ban is introduced, the future risk reduction would be more or less similar to what is described for restriction option 1 above. It is difficult to estimate the quality of responses that would be received from the user especially related to technical feasibility of the alternatives. Thus it could be argued that the assessment of alternatives could be conducted without the legislative requirement and a voluntary involvement for instance in workshops might be more effective.

Proportionality (technical and economic feasibility)

As described above, the success of this option is related to the quality of data collected. It can be technically challenging to formulate the questions and additional information in a way that allows the users to provide useful information. To achieve a high response rate (compliance), it could be useful to require the users of mercury porosimeters to register themselves to competent authorities as a first step. At least some contact details can also be provided by the suppliers of porosimeters.

This option could support possible other efforts taken to assess the alternatives. The costs of information gathering are related to the time required for preparation of questionnaires and additional information, distributing the questionnaires, answering (time consumed by users) and analysing the data. These costs are not quantified in this report.

4.2.2.2 Practicality

The users of mercury porosimeters should be able to provide the requested information if the questionnaire and additional information is properly drafted. No specific problems related to implementability and manageability have been identified.

The enforcement of this option could be done in the margins of the general enforcements of the laboratories. Enforcement authorities could check if the users have provided the required information to Member State competent authorities when a mercury porosimeter is found in the laboratory. If the register of users would be established it could also be used for targeted enforcement of the users of the mercury porosimeters.

4.3 Comparison of the risk management options

The two restriction options described above are not comparable with each other in terms of risk reduction capacity, proportionality and practicality. The restriction option 1 is not regarded proportional due to uncertainties related to technical feasibility of alternatives. The restriction option 2 is not proposed either as having a legal requirement to provide information which does not automatically lead to receiving helpful data for the further assessment. Nevertheless, the information gathering combined to other suitable efforts to assess the alternatives could be useful.

4.4 The proposed restriction(s) and summary of the justifications

Proposal:

No restriction is proposed for mercury porosimeters.

Summary of justifications:

No restriction is proposed for mercury porosimeters due to high uncertainties in the technical feasibility of the alternatives. Consequently the economic feasibility was not assessed.

The waste handling of mercury used in porosimeters seems to be done in accordance with requirements of hazardous waste legislation. Nevertheless, due to relatively high tonnages of mercury needed for measurements with porosimeters, further assessment of the feasibility of alternatives could be beneficial.

Annex 8: Pycnometers

Content

1. Technical description of pycnometers

Pycnometers are used for accurately measuring the true and bulk densities of materials, by a volume displacement technique based on the fact that mercury at atmospheric pressure will not enter pores smaller than 15 microns in diameter. They are used for instance in battery separators, ceramic and fuel cells industry.

2. Description of release and exposure

As described in the approach to assess the risks related to measuring devices using mercury as described in Section B.4 of the main document, there is no single parameter to sufficiently describe the potential release and exposure from either the use or the waste phase. Waste management of mercury and mercury contaminated samples and other materials is one part of the normal operation of the laboratories performing measurements with these devices. There is no data available on the number of pycnometers in use in the EU, but according to Lassen et al. (2008) the annual use of mercury in pycnometers is estimated to be very small compared to porosimeters. In the stakeholder consultation, no response was received from the only identified producer of mercury pycnometers (based in the USA). According to a producer of mercury porosimeters (not pycnometers), the alternatives have already substituted mercury pycnometers in all the applications (Lassen et al., 2010). This indicates that at least the number of mercury pycnometers placed on the market in the EU annually is very low if not zero.

The mercury is not included in the pycnometers during the production of the devices. Thus the production phase is not relevant for potential release and exposure. The mercury used in measurements is cleaned and dried and returned to the reservoir of the device. The mercury does not end up in the sample, indicating that potential emissions from waste phase are small compared to the situation with porosimeters. (Lassen et al., 2008).

3. Available information on alternatives (Part C)

Alternatives using a gas replacement technique to measure the volume are available (Lassen et al., 2008). Inert gases such as helium or nitrogen are used as the replacement media. According to a producer of mercury porosimeters and non-mercury pycnometers, the alternatives have already substituted mercury in all the applications: "*As far as I know mercury is no more used in pycnometry as envelope or helium pycnometers have substituted mercury pycnometry in all the application.*" (Lassen et al., 2010).

The only identified producer of mercury pycnometers produces also the alternative, i.e. the gas pycnometer. According to a brochure of the producer, the application areas covered by the mercury pycnometer are also covered by gas pycnometers, and the brochure does not mention any specific advantages of mercury pycnometetry over the

alternatives. These application areas include battery separators, ceramic and fuel cells industries. In addition gas pycnometers can be applied in automotive, chemical, pharmaceuticals, powder metallurgy, nonwovens and construction industries. (Porous Materials, 2010)
This producer of mercury pycnometers (based in the USA) did not provide a response in the stakeholder consultation.

There are no derogations for pycnometers in the national restriction for mercury in Sweden. Sweden has not indicated any problems due to the restriction of these devices, which can be seen as an indication that the alternatives are technically feasible.

4. Justification why the proposed restriction is the most appropriate Community-wide measure (Part E)

4.1 Identification and description of potential risk management options

4.1.1 Risk to be addressed – the baseline

As discussed in Part B, the annual amount of mercury used in measuring devices is used as an indicator of potential release and exposure in this report. For mercury pycnometers, a way to describe the risk reduction capacity is the amount of mercury bought annually by the users, but there is no data available on that. Nevertheless this amount is assumed to be very small compared to porosimeters. Based on information received from a producer of porosimeters, the market of mercury pycnometers in the EU is very small if existing at all (Lassen et al., 2010). Thus, restricting the placing on the market of the mercury pycnometers can be seen as codifying the current situation.

4.1.2 Options for restrictions

Considering the evidence supporting the technical feasibility of alternatives and the low number of (if any) mercury pycnometers sold annually, only one restriction option is considered, i.e. a ban on placing on the market of mercury pycnometers after 18 months of the entry into force. This can be seen more or less as codifying the current situation.

4.2 Assessment of risk management options

The available data suggests that technically feasible alternatives for mercury pycnometers are available. Furthermore, the number of mercury pycnometers placed on the market annually is low (if any) and thus the risk reduction capacity is very small (if any). Accordingly the compliance costs related to the proposed restriction are small (if any) as only few users would need to move away from pycnometers after the end of their service life. The fact that replacement has already more or less happened, indicates that the alternatives should not be significantly more expensive than the mercury device.

4.3. The proposed restriction and summary of the justifications

Proposal:

The placing on the market of mercury pycnometers after 18 months of entry into force of the amendment of Annex XVII.

Summary of justification:

Technically feasible alternatives to mercury pycnometers are available. The available data suggest that the replacement has already taken place which supports the conclusion that alternatives are also economically feasible.

Annex 9: Mercury metering device for the softening point determination[131]

Content

[131] This mercury measuring device was identified in the very last stage of the preparation of Annex XV restriction report, and no questionnaire was sent to the producer in the stakeholder consultation. However the producer was contacted by phone to collect some information.

1. Technical description of mercury metering devices

The **softening point** is the temperature at which a material softens beyond some arbitrary softness (Wikipedia, 2010f). For a substance which does not have a definite melting point, it is the temperature at which viscous flow changes to plastic flow (answers.com, 2010).

For a bitumen it represents an index of its fluidity, the temperature at which a bitumen (used in roofing or road construction) softens or melts.

The softening point can be determined by several methods, depending on the type of the tested substance (carbonaceous substances, bitumen, resin, glass, foodstuff like cheese).

Mercury metering devices are used for measuring the softening point by the Kraemer-Sarnow method. The Kraemer-Sarnow softening point of a material is the lowest temperature at which a mercury load deforms a sample under standardized conditions.

By this method, the softening points of resins and fusible carbonaceous materials are determined according to DIN 53180 from 1996, Binders for paints and varnishes - Determination of the softening temperature of resins and DIN 52025 from 2004, Testing of carbonaceous materials -Determination of the Kraemer-Sarnow softening point.

The Kraemer-Sarnow is the oldest method and uses a small glass tube that is open at both ends and the load is a small mercury drop (5g). The mercury drop is placed on a small disk made of the test material contained in a metal ring fixed at the lower end of a tube. The ensemble is warmed on a bath at a constant rate. The softening point is obtained as the Kraemer-Sarnow temperature (TKS) at which the mercury drop breaks through the softening material and falls.

2. Description of release and exposure

As described in the approach to assess the risks related to measuring devices using mercury as described in Section B.4 of the main document, there is no single parameter to sufficiently describe the potential release and exposure from either the use or the waste phase. There is no data available on the number of mercury metering devices currently used in the Kraemer-Sarnow method in the EU. Only one producer of mercury metering devices for the Kraemer-Sarnow method was identified in Europe. According to the producer, no devices have been sold in the past three or four years[132]. This indicates that the number of mercury metering devices placed on the market in the EU annually is very small (if any).

According to this producer, the mercury is not included in the mercury metering devices during their production. The mercury used in measurements can be cleaned

[132] This information was indicated in preliminary screening of the device, but could not be verified before the submission date of this report, but should be further investigated during the processing of this Background document.

and dried and returned to the reservoir of the device. Thus, the production phase is not relevant for potential release and exposure. The mercury ends up mixed with the sample, indicating that potential emissions from waste phase exist.

3. Available information on alternatives (Part C)

Alternatives using other techniques to measure the softening point are available. According to Benedek and Feldstein (2009) and a producer of mercury metering devices (Petrotest, 2010), the alternatives have already substituted mercury in all the applications.

The softening point can be determined at least by the following methods:

The Ring and Ball method (R&B), carried out according to ASTM D 3461-76 and DIN ISO 4625; it is the most frequently used method to determine the softening point of resins (pavementinteractive.org). The sample of resin is melted into a metal ring and left to cool. The ring is placed in a special metallic device, which is placed into a water or glycerol bath. A steel ball of given diameter and mass is placed on the ring and the bath is heated at a given rate. The temperature at which the ball forces the softening resin downward is noted as the softening point.

Mettler Softening Point method, carried out according to ASTM D 3461-76; it is the most recent method used for resins and it has the advantage to be automatic. The method measures the temperature at which the resin flows out of a sample cup under its own weight; the temperature is recorded when the first drop crosses the light path of a photocell; the Mettler method is quite accurate and reproducible.

Plate-plate Stress Rheometer Test is another method used for resins; the resin is placed between the two steel plates of a stress-controlled rheometer, maintaining in between them a gap. The upper plate is oscillated at a given frequency, whereas the lower plate is heated. The variation of the storage and loss moduli as a function of the temperature is monitored. The softening temperature is estimated from the temperature at the cross-over between the two moduli.

Vicat method or **Vicat hardness** is used for polycarbonates. The apparatus used consists of a heated bath with a flat ended needle penetrator so mounted as to register its penetration on a gauge. The sample is placed with the needle resting on it. The Vicat softening point is the temperature at which the sample is penetrated to a depth of 1 mm by the needle when the bath is heated. The determination of the softening point with the Vicat methode can be carried out according to standards ASTM D 1525 and the equivalent ISO 306.

Although not widely used, other methods to determine the softening point exist, such as capillary method, the flow point, the drop point, and the Kofler method. In general, the R&B method provides the highest softening point, whereas the Mettler method provides the lowest softening point for a given resin. Therefore, always both methods should be given.

There are no known considerable risks related to the alternatives to the Kraemer-Sarnow devices, as they all have a composition similar to any other mechanical or electronic article used by consumers in the everyday life.

The alternative methods are widely used at least in petrochemical, chemical, building materials industry. There are no known problems related to economical feasibility of the alternatives to the Kraemer-Sarnow devices.

The only identified producer of mercury metering devices for the determination of the softening point also produces two other alternative devices. There are no known problems related to economical feasibility of the alternatives to the Kraemer-Sarnow devices.

4. Justification why the proposed restriction is the most appropriate Community-wide measure (Part E)

4.1 Identification and description of potential risk management options

4.1.1 Risk to be addressed – the baseline

As discussed in Part B, the annual amount of mercury used in measuring devices is used as an indicator of potential release and exposure in this report. For mercury metering devices, a way to describe the risk reduction capacity is the amount of mercury bought annually by the users, but there is no data available on that. Nevertheless this amount is assumed to be very small compared to porosimeters. Based on the available information, the market of mercury metering devices for this specific use in the EU is very small if existing at all. Thus, restricting the placing on the market of the mercury metering devices can be seen as codifying the current situation.

4.1.2 Options for restrictions

Considering the evidence supporting the technical feasibility of alternatives and the low number of (if any) mercury metering devices sold annually, only one restriction option is considered, i.e. a ban on placing on the market of the mercury metering devices for the determination of the softening point after 18 months of the entry into force. This can be seen more or less as codifying the current situation.

4.2 Assessment of risk management options

The available data suggests that technically feasible alternatives for mercury metering devices are available. Furthermore, the number of mercury metering devices for the determination of the softening point, placed on the market annually is low (if any) and thus the risk reduction capacity is very small (if any). Accordingly the compliance costs related to the proposed restriction are small (if any) as only few users would need to move away from mercury metering devices after the end of their service life.

The fact that the alternatives, available from the same producer are preferred due to their accuracy, indicates that the alternatives should not be significantly more expensive than the mercury device.

4.3. The proposed restriction and summary of the justifications

Proposal:

The placing on the market of mercury metering devices for the determination of the softening point after 18 months of entry into force of the amendment of Annex XVII.

Summary of justification:

Technically feasible alternatives to mercury metering devices for the determination of the softening point are available. The available data suggest that the replacement has already taken place which supports the conclusion that alternatives are also economically feasible.

Annex 10: Mercury probes used for capacitance-voltage determinations[133]

Content

[133] This Annex 10 of the BD was not included in the original Annex XV restriction report and consequently subject to the public consultation of the restriction report. The mercury probes used for capacitance-voltage determinations were recognized as a mercury measuring device based on the information received in the last day of the public consultation on the Annex XV restriction report.

1. Technical description of mercury probes

The mercury probe, also called mercury probe contact, is an electrical junction device (Schroder, D.K.). Mercury creates the front side contact in a mercury capacitance–voltage (MCV) and in a current–voltage (IV) measurement. The mercury in the probe is used since its density allows to form non-destructive contacts of well-defined areas. Mercury probes may be connected to different devices such as capacitance–voltage (CV) plotters, computerized semiconductor measurement systems, curve tracers, and doping profilers (MDC, 2011).

There are two types of probes, depending on the configuration of the mercury contacts (MDC, 2011):

- Standard: mercury forms a concentric dot and a ring to allow contact in both front-back and front-front modes, for measurements on semi-insulating substances. The ring contact can be configured as a guard ring for special applications.
- Mapping versions, with 3 contacts: allow for repeatable contacts over a wafer using two manual positioning controls. They use a 300 mm diameter platform.

The probes are used to measure several parameters related to the sample such as permittivity, doping, oxide charge and dielectric strength. The method requires that the analysed material does not react with mercury (Wikipedia, 2011b, Mercuryprobe, 2011, Semilab, 2011b, MDC, 2011). The measurements with MCV tools are applicable for materials such as metals, semiconductors, oxides and chemical coatings (Wikipedia, 2011b). The samples need to be thinly sliced as wafers or disposed as thin films (mercuryprobe.com).

The mercury probes are used for e.g. in following applications:

- Doping profiles of bulk and epitaxial layers of SiC, GaAs, 2DEG, GaN, InP, CdS and InSb
- Mercury-oxide-semiconductor (MOS) structure characterisation
- Permittivity and thickness of dielectrics
- Detection of residual films on conducting substrates
- Current-voltage testing of photovoltaic devices
- Ferroelectric sample investigations
- Poly silicon characterization

The functioning of the MCV tool and mercury probes is described in the Box 1.

Box 1: The functioning of the MCV tool
In a MCV tool, the mercury probe has either a stainless steel cylinder or a capillary which holds mercury, a small vacuum pump and a support platform. When the probe head is lowered on the wafer to form a contact, mercury is pressurized and lowers through the capillary to form the contact. A hole bored into the underside of the platform, to which the pump is attached, allows the wafer to be held in place through the negative pressure of the vacuum. A measuring voltage is applied via a metal wire to the mercury, which is the contact itself. After the measurement is done, the mercury is sucked up into the glass capillary and the probe lifts up. The created mercury contact contains a few microns (<37 µl) of mercury. The mercury has to be changed once a week leading to 2 cm^3 of mercury used per year per device.
Source: Semilab 2011, mercuryprobe.com 2011.

2. Description of release and exposure

There is no data available on the number of mercury probes currently used in the EU. Only two producers of mercury probes located in the US have been identified. According to the information received in the public consultation, the device seems to be used mainly for R&D and quality monitoring in the semiconductors industry. Only around 1 to 5 kg of mercury is used annually in the EU in mercury probes for capacitance-voltage determination and the mercury is kept in a closed space with a very limited possibility of mercury vapour releases. (Semilab, 2011a)

The mercury is not included in the mercury probe during their production, and consequently, the production phase is not relevant for potential release and exposure. The mercury used in measurements is purified and returned to the reservoir of the device. Some of the mercury ends up mixed with the sample wafer, indicating some potential for emissions during the waste phase. (Semilab, 2011a)

3. Available information on alternatives (Part C)

A good quality contact has to be created between a probe and the front surface of the semiconductor wafer to perform the capacitance- or current-voltage measurement.
The alternatives used to perform the same measurements, are normally time consuming processes (usually a few hours for a measurement), such as metallization or photolithographic processing. As described below, these alternatives usually lack one or two key features needed by the users or they do not deliver the expected precision and repeatability, or the handling of the sample or the measurement cannot be performed automatically.

Potential alternatives include:

<u>Metallization or photolithographic processing</u>
The contact can be made by evaporating a metal, but the process is lengthy and the heat during the process may change wafer properties and the wafer may not be used anymore.

Airgap CV method

This technique uses a non-contact electrode placed at a 500nm distance from the sample. The non-contact nature makes IV measurements and generally measurements made on dielectric layers impossible. The tool is only available in fully automated versions for high-end semiconductor lines at a price of about 1 million USD. (Semilab, 2011a)

Surface charge analyzer

The technique is used mostly for dielectric measurements, has a generally weaker performance and it is not suitable for epitaxial layers. (Semilab, 2011a)

Non-contact corona charge –voltage (VQ) tools

This is a non-contact technique, suitable for dielectric layer characterization. Corona chargers are used to charge dielectric layers, and a Kelvin probe to measure the resulting change in potential. The technique has limitations or no applicability to leakage current and epitaxial layers measurements. (Semilab, 2011a)

Surface charge profiling

The method is based on the surface photo-voltage technique. It enables epitaxial layer resistivity measurements, but it does not allow dopant concentration profile. (Semilab, 2011a)

Spreading resistance profiling

The technique is applicable to epitaxial layers measurements, but not to dielectric layers. It is a destructive method and requires a lengthy sample preparation procedure which cannot be automated. (Semilab, 2011a)

Elastic metal CV

In this technique, a contact is formed by a very small sized elastic metal probe placed on the sample. This system may perform the whole range of MCV measurements, however the probe is technically difficult to produce, and different types of measurements require different probes. The technique is fully automatic and fast, and constitutes a reliable alternative, but it is much more expensive. (Semilab, 2011a and b)

The systems described above are available from the same supplier as the MCV tools but none of them is completely capable of replacing the mercury CV systems in all the applications (or in case of the elastic metal CV requires a set of different kind of probes). In most of the cases, the replacement of a mercury probe would require several other devices for purely technical reasons, and consequently the alternatives seem not to be economically feasible. This is supported by the information received in the public consultation stating that “a replacement could effectively double or triple the costs of the user because multiple tools are needed to replace all functionalities”(Semilab, 2011b).

4. Justification why the proposed restriction is the most appropriate Community-wide measure (Part E)

Identification and description of potential risk management options

Risk to be addressed – the baseline

As discussed in Part B, the annual amount of mercury used in measuring devices is used as an indicator of potential release and exposure in this report. Around 1 to 5 kg of mercury is used annually in mercury probes for capacitance-voltage determination (Semilab, 2011a).

According to the information received in the public consultation (Semilab, 2011a) the risks related to both use and waste phase seem to be very low in the modern devices as a result of the minimization of the mercury used (around 30 µl for one measurement, around 2 cm^3 mercury used/year). There is no information available to assess the trend in the amount of mercury used, or in the number of mercury probes placed on the market annually.

Assessment of risk management options

As a result of the low quantities of mercury used in capacitance–voltage and current–voltage measurements, only one restriction option is assessed: *Restriction on the placing on the market of mercury to be used as mercury probes in capacitance–voltage and current–voltage measurements*.

The maximum risk reduction capacity of this option is estimated to be less than 5 kg annually. As described in Part B.2 (Scope and approach), the restrictions do not apply to the manufacture, placing on the market or use of a substance for scientific research and development provided that the conditions in Article 3(23) of REACH are achieved. Article 3(23) of REACH defines scientific research and development as "*any scientific experimentation, analysis or chemical research carried out under controlled conditions in a volume less than 1 tonne per year*". It is possible that some of mercury probes used in capacitance- or current-voltage measurements fulfil the above mentioned requirements, namely mercury is used under controlled conditions in a volume less than 1 tonne per year, and consequently benefit from this exemption. If this is the case, the risk reduction capacity would be reduced accordingly, i.e. it would be lower than estimated above.

As described in Section 3, the alternatives for mercury probes have limitations related to both technical and economic feasibility. None of the alternatives are both economically and technically feasible. Thus, no restriction on the placing on the market of mercury used in mercury probes used in capacitance- or current-voltage determination is proposed.

The proposed restriction and summary of the justifications

Proposal:
No restriction proposed.

Summary of justification:
None of the alternatives for mercury probes used in capacitance-voltage or current-voltage measurements are both technically and economically feasible. This is mainly because in most of the cases the replacement of a mercury probe used for capacitance-voltage determinations would require several other measuring devices.

Appendices

All the following appendices are attached as separate documents:

Appendix 1: Classification and labelling

Appendix 2: Review of literature estimating the compliance costs, human health benefits and restoration costs of reduced mercury emissions to support assessment of the cost-effectiveness

Appendix 3: Services to support preparing an Annex XV restriction report on mercury containing measuring devices: Working notes based on stakeholder consultation[134]

Appendix 4: Restriction of mercury in measuring devices under Regulation (EC) No 1907/2006 (REACH) in relation to restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS)

Appendix 5: Review on the availability of technically and economically feasible alternatives for mercury containing sphygmomanometers and other measuring devices for professional and industrial uses[135]

[134] This appendix is prepared by Cowi consulting company, together with ENTEC and IOM as a part of the stakeholder consultation during the preparation of the original restriction report. The consultation took place between January and May 2010. The objective was mainly to collect input data to assess the proportionality of the restriction options and for socioeconomic analysis – in particular on costs of alternatives as well as technical and economic feasibility of replacement. This BD has been updated to take into account the comments received in the public consultation (September 2010-March 2011), and consequently there might be some inconcistancies between the information in the BD and and in the appendix.

[135] This appendix reports the results of consultation by DG-Enterprise & Industry that was launched in summer 2008 before the preparation of the original Annex XV restriction report. Questionnaires were prepared and circulated to the Members of the Commission Experts Working Group on Limitation of Chemicals (LWG) and to the Experts Working Group on Medical Devices (MDEG). This BD takes into account the additional information collected during the stakeholder consultation (see appendix 3) and also the comments received during the public consultation (September 2010-March 2011), and consequently there might be some inconsistencies between the information in the BD and in the appendix.