



Committee for Risk Assessment (RAC)
Committee for Socio-economic Analysis (SEAC)

Response to comments document (RCOM)
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

1 July 2011

Substance: **Mercury**
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Comments and response to comments on Annex XV restriction report on **Mercury in measuring devices**
 Annex XV report submitted by ECHA on 15 June 2010.
 Public consultation on Annex XV report started on 24 September 2010.

General comments

Ref	Date Country/ Org./ MSCA Comment type	Comment	DS Response	RAC Rapporteurs comments	SEAC Rapporteurs comments
115	2011/03/24 23:42 Att. Ref115 Netherlands / International NGO /		<p>Thank for your comments in the attachment.</p> <p>We agree that the low collection rate of mercury measuring devices is of concern, and actually one of the main reasons to restrict the placing on the market of new devices. Addressing the waste issue for existing devices is as you also pointed out indeed not in the remit of ECHA, but the Commission and Member States.</p> <p>In line with your comment, the proposed derogation for epidemiological studies is indeed only for the studies which are ongoing at the entry into force.</p> <p>The derogation for validation is meant only for certified and specialised institutions. However we do not find it</p>	As SEAC Rapporteurs	<p>Thank you for sharing your views on the broader picture (low collection rates). In our view this broad perspective is essential and we included some paragraphs on this issue in the opinion.</p> <p>Regarding your remarks on epidemiological studies and calibration; we agree with DS response.</p>

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			useful to try to explicitly define these institutions in the entry.		
114	2011/03/24 18:07 United States / Company (C)	Hokanson manufactures and sells strain gauge plethysmographs that are used in medical research applications throughout the world, and have been since 1975. The majority of our strain gauges are mercury-type, where the mercury is contained in a small gauge silicone tube. The mercury is in its elemental form, and is not mixed to create a compound. We have never had a report of any person being harmed by the use of our mercury strain gauges. At the end of their useful life, we encourage customers to return mercury containing strain gauges to Hokanson so we can collect and recycle the mercury.	Thank you for the information.	As DS	As DS
112	2011/03/24 16:08 Belgium / International NGO / (A), (B), (C), (F)	1. EEB generally welcomes the proposal for restriction of mercury in measuring instruments, though would like to comment on the following issues: a. Waste from mercury-based measuring instruments that are already in circulation and (possibly) mercury use in porosimetry. There is a danger that it could be assumed that these problems are addressed by the restriction, or are negligible, unless the risks linked to these sources are explicitly and prominently recognised.	Thank you for your comments and support for the proposal. Please find the more detailed responses below.	Thank you for your comments.	Thank you for your comments.

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		<p>b. Derogations in the dossier. We agree with the time limited derogation for thermometers exclusively intended to perform tests according to standards that require the use of mercury thermometers. However, we do not believe that the proposed derogations for sphygmomanometers and thermometers reading over 200°C are necessary.</p> <p>c. The derivation of the benchmarks used in the dossier. It is currently implied that the benchmarks are more widely accepted than is the case.</p> <p>d. Inconsistencies in the dossier. It is possible to draw different conclusions on some issues from different parts of the dossier. More explanation would be useful to demonstrate why some sources are preferred to others. Reference to plethysmographs and mercury containing strain gauges needs to be corrected in the wording of the restriction.</p> <p>These issues are discussed in more depth below.</p> <p>Mercury in the waste stream, and mercury use in porosimetry</p>		<p>Agree, and the derogation is removed</p>	

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		<p>2. Part of the justification for the restriction is that the proper collection of wastes is not happening. In light of the proposed restriction there is a danger that readers could conclude that there is limited benefit from seeking to improve waste collection for Hg already in circulation, even though the effects of the restriction will take quite a number of years to have a significant impact. Therefore it still needs to be made clear that further to the proposed restriction, waste collection of such devices is absolutely necessary for devices already in circulation. The European Commission and Member States need to take appropriate action to that end as a matter of urgency.</p> <p>We recognise that this restriction is not going to be extended to the collection of waste mercury. We also recognise that a restriction may not be the most effective option for dealing with the problem of inadequate collection schemes for waste mercury that is already in circulation. However, it is important that information on the waste issue is not lost in the technical dossier, but is clearly recognised in both the wording of the restriction and the opinions of the committees. It may otherwise be wrongly concluded that the restriction deals with the existing waste problem when it does not.</p> <p>3. A major reason for the exclusion of porosimeters from the restriction may not be supported by information presented in the dossier on these instruments and seems to contradict reasons for the inclusion of other uses, specifically in relation to the statement:</p>	<p>The BD was updated to be clearer on the problems related to the collection of the mercury measuring devices as a hazardous waste, and on the fact that the proposal does not affect the existing devices that have been placed on the market before the proposed restriction applies.</p> <p>The restriction entries should be kept as clear and simple as possible. The entry is clear on the fact that it only covers placing on the market.</p> <p>The main reasons for the exclusion of porosimeters from the restriction are related to the technical feasibility of the alternatives. The</p>	<p>Agree, and the waste issue is addressed in the opinion</p> <p>As SEAC Rapporteurs</p> <p>The main reason for the exclusion of porosimeters from the restriction is the lack of technical alternatives.</p>	<p>We agree that proper waste collection is essential and that appropriate action should be taken. In the SEAC opinion, we addressed this issue.</p> <p>See above, we addressed the issue in the opinion. We agree with DS that the restriction entry should not be changed.</p> <p>The main reason for the exclusion of porosimeters from the restriction is the lack of technical feasible alternatives.</p>

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		<p>&quot;... for porosimetry, it appears that given the use of mercury porosimeters for essential professional uses and the rather high level of mercury recycling performed by their users, such mercury use may not pose an unacceptable risk to human health or the environment and therefore should remain possible in the EU.&quot;</p> <p>Annex 7 states that the amount of mercury bought annually by the users of porosimeters is estimated to be around 5-14 tonnes per year in the EU whilst the amount of mercury disposed of annually as hazardous waste is estimated to be around 1.2-3.4 tonnes. This could indicate that a significant amount of mercury could be lost to the environment outside of the hazardous waste treatment system. The essential question is, what happens to the difference between supply and hazardous waste disposal? The role of recycling is unclear from the information provided. It may account for all or a large part of the difference between the amount bought and the amount sent for waste, or it may not. The data given in Appendix 5 from the consultation of about 70 operators are different to those cited in Annex 7. However, again, they could indicate that a significant quantity of mercury is being lost from porosimetry, possibly much more than the amount from sphygmomanometers (for example).</p>	<p>quotation is from preliminary conclusions of the Commission (Appendix 5 of the BD). Furthermore, we do not see the contradiction mentioned in the comment.</p> <p>The high amounts of mercury used in porosimeters are also recognised in the BD and resources were allocated during the preparation of the report to better understand the potential risks related to the use of porosimeters. These results are reported in the Appendix 3 of the BD, and used to make the assessment in the Annex 7. We recognise the difficulties in interpreting the data collected by the Commission from the users of porosimeters (reported in Appendix 5 of the BD). However, based on the data from the users, and based on the</p>	As DS	As DS

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		<p>So, at best, the information provided about mercury loss from porosimeters seems inconclusive. At worst, it indicates that a significant quantity of mercury used for porosimetry is being lost to the environment. The final conclusion on the exclusion of porosimetry: “nevertheless, due to relatively high tonnages of mercury needed for measurements with porosimeters, further assessment of the feasibility of alternatives could be beneficial” should at the very least be strengthened and made far more visible. We believe that further action at Community level to eliminate mercury loss from these systems would be entirely justified, and necessary, ideally by the end of 2012, if porosimetry is to remain outside of the restriction. Further action could take the form of development of a best practice guide and a requirement that the fate of all mercury purchased is</p>	<p>interviews made by COWI as a part of the stakeholder consultation (see Appendix 3), it does not seem that the mercury used with porosimeters would not be recycled or not treated as hazardous waste according to the waste legislation. However, due to the high tonnages involved in the measurements, further investigation of this use could be beneficial.</p> <p>The DS recognises the potential for risks due to high tonnages of mercury used in porosimeters and resources were allocated to assess potential releases of mercury during the use. However, based on the screening of possibilities to set waste handling or use conditions for porosimeters in the Annex XVII to REACH, this was not seen appropriate. The reasons are related to existing</p>	As DS	As DS. .

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		<p>properly accounted for.</p> <p>4. Regarding the waste and porosimetry issues, we accept that inclusion of both issues would be a substantial extension of the scope of the proposed restriction and as such they are unlikely to be adopted here. However, we consider it essential that it is made clear that these issues are not covered by the restriction and that both may lead to significant releases of mercury in excess of what is controlled by the restriction. We suggest the following wording for both the restriction and the SEAC opinion: "The restriction does not apply to waste from measuring instruments that are currently in use or will be purchased ahead of the restriction coming into force, nor does it apply to the use of porosimeters. The waste problem certainly, and porosimetry possibly, are associated with significant releases of mercury to the environment and further consideration and action therefore seems both justified and urgent in both cases."</p>	<p>waste handling requirements and existing occupation exposure limit value. (See Annex 7 chapter 4.1.2 of the BD).</p> <p>We recognise the importance of both issues, i.e. the problems in collection of mercury measuring devices as hazardous waste and high tonnages used in conjunction with porosimeters. However, we do not think that the restriction entry itself is the right place to address the issues. The restriction entries should be kept as clear and simple as possible. The current proposed restriction and the summary of its justification are considered clear on the fact that the proposed restriction does not restrict porosimeters.</p>	<p>As DS, and the waste issue is addressed in the RAC opinion</p>	<p>As DS. The waste issue is also addressed in the SEAC opinion.</p>

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		<p>Derogations in the dossier</p> <p>5. The survey of the types of sphygmomanometer used in European hospitals demonstrates that the use of Hg-containing devices is unnecessary. This is highlighted by the German data which shows no Hg-containing instruments in the 29 hospitals surveyed. The SCENIHR conclusions back this up. It would therefore be inappropriate to adopt any derogation regarding these instruments should it be proposed in the final stages of consultation.</p> <p>6. Regarding SCENIHR conclusion 4:</p> <p>"4.Are mercury-containing sphygmomanometers essential as reference devices for validation of long-term clinical epidemiological studies enrolling patients with hypertension?</p> <p>"Yes. Mercury-containing sphygmomanometers are considered essential as reference devices for the clinical validation of the alternatives. 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."</p>	<p>The proposed derogations for sphygmomanometers have their basis in the SCENIHR opinion. Based on the public consultation comments, we do not see a need to have any additional derogation.</p>	<p>As DS, and the derogation covers only on-going and long-term epidemiological studies currently using mercury sphygmomanometers</p>	<p>As DS</p>

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		<p>EEB has published a significant amount of work in this field and questions the need for this to be accounted for in the restriction as an exemption. There are significant numbers of Hg sphygmomanometers already in circulation and available to researchers and the proposed restriction only concerns placing such devices on the market. Further to this, there is sufficient time available before the restriction comes into force for those running such studies to make the necessary arrangements to ensure that they have sufficient instruments for their purposes. There is thus no need for new devices to be placed on the market. At the very least, this derogation should be time limited.</p> <p>In addition, if this derogation is to be accepted:</p> <p>a) Any purchase of such a device should be accompanied by a certificate showing the purchaser and purpose of use; and</p> <p>b) A time limit should be proposed, or a qualitative limit such as “until clinical studies in place at the time of the restriction have been completed”.</p> <p>In addition, we would recommend that the Commission and Member States take necessary action to advance such research to develop mercury free standards for the validation clinical studies and of mercury-free sphygmomanometers</p>	<p>The proposed restriction for ongoing epidemiological studies will be needed only if the existing devices break during the ongoing studies. Furthermore, the proposed derogation is in reality time-limited, as it applies only to studies that are ongoing at the time of the entry into force, and thus the derogation ends with the end of such studies.</p> <p>We do not see a need for the suggested conditions or statements in the restriction entry.</p> <p>We do not have sufficient information to introduce /recommend any specific actions to develop mercury-free standards for the validation purposes in the BD.</p>	<p>As DS</p> <p>As DS, and the derogation covers only on-going and long-term epidemiological studies currently using mercury sphygmomanometers</p>	<p>As DS.</p> <p>As DS. The derogation only applies to on-going epidemiological studies.</p>

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		<p>7. The following derogation is not adequately justified in the dossier: (b) Mercury-in-glass thermometers used in industrial applications for temperature measurements above 200°C as demonstrated by the reading scale. Affordable alternatives are already on the market. Indeed, it is surprising to be told that there remain high temperature operations still controlled using mercury in glass thermometers. Presumably, the market for these instruments is rather confined to replacements for broken instruments on existing industrial plant. We suggest that the derogation is removed, or otherwise that it should be time limited to account for possible short term difficulties that some operators may experience.</p> <p>8. The following derogation seems appropriate as it is time limited.: (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.</p> <p>Benchmarks</p>	<p>After reconsidering the available data, it was concluded in the BD that alternatives for these thermometers can be considered economically feasible, and the derogation for industrial thermometers measuring above 200°C was removed from the proposed restriction entry. This will also improve the enforceability of the restriction, as well as the clarity of the entry.</p>	<p>As DS and supported in the opinion</p>	

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		<p>9. Table 3 in Annex 2 should make it clear that the phrases ‘well established’ (etc.) are the dossier submitter’s own conclusion. This could improve the acceptance of the text amongst SEAC members. As currently presented it appears that the level of establishment of the costs per kg of mercury is subject to a much greater degree of consensus than is really the case.</p> <p>In setting the benchmarks, the use of the Rice and Hammitt data without considering the assumptions that went into their analysis (e.g. on risks, exposure and valuation) and its limitations (e.g. exclusion of ecological impacts, assuming that the effect of IQ loss is captured solely in terms of loss of earnings...) is not good practice. It could lead to inconsistency with other conclusions reached in the dossier and with the guidance on SEA provided by ECHA and the Commission. It should be possible to deconstruct Rice and Hammitt’s figures and recalculate using assumptions that are consistent with the views of RAC, EU valuation, etc.</p>	<p>After reconsidering the usefulness of the benchmarks to assess the proportionality of the proposed restriction, they were removed from the Appendix 2 of the BD.</p>		As DS

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		<p>Inconsistencies</p> <p>10. The dossier has different estimates of mercury use in measuring instruments in different places. For example, Section A2, Table 1 cites Lassen et al (2008) with an estimate of the amount of Hg placed on the market in barometers in Europe of 0.1 to 0.5 t/yr. Appendix 5 cites COWI (2008) with an estimate about 10 times higher (2 to 5 t/yr). Presumably this difference results from the restriction on Hg in measuring instruments for consumer use. Differences also apply in discussion of the amount of mercury purchased for use in porosimeters each year, and the amount sent for disposal from this route in different parts of the dossier. Discussion on these issues could be better structured to give readers a clearer understanding of which estimates are preferred and hence the scale of the problem.</p> <p>11. Different parts of the dossier come to different</p>	<p>The appendix 5 of the Annex XV report is a review prepared by the Commission before the preparation of the Annex XV restriction report by ECHA. During the preparation of the report, the information in Appendix 5 was updated to some extent, which may have lead to some inconsistencies. We have clarified these issues in the BD.</p>	As DS	As DS

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		conclusions on the use of mercury strain gauges in plethysmographs. Page 14 of appendix 5 concludes that there is currently no alternative for some health research, whilst Annex 4 in the main text concludes that technically and economically feasible alternatives are available and so supports the inclusion of the strain gauges under the Restriction. However, the inconsistency in the dossier makes it challenging to understand. There is also inconsistency in referring to what is proposed to be restricted – the preface refers to strain gauges used with plethysmographs, whilst Section A1.2 point 2 refers to plethysmographs designed to be used with mercury strain gauges. We believe that the version in the preface (focused on the strain gauges) is correct.	The BD is updated to describe the source of the appendices that are not prepared by ECHA. For the strain gauges, the restriction entry and the BD have been updated to propose a ban for the placing on the market of mercury strain gauges instead of plethysmographs designed to be used with mercury strain gauges.	As DS	As DS
111	2011/03/24 12:13 Hungary / Company / (B), (C), (F), (G)	<p>There are many specific techniques in the Annex XV, but there is a small but important technology which is missing. This is capacitance-voltage measurement technique performed with mercury electrodes. The technique plays a crucial role in the R&D and manufacturing process control activities of many important European semiconductor businesses and research institutions. Their willingness to use the tool in the future depends on the restrictions on mercury usage, and the missing information from the annex may prevent the sale and usage of such tools.</p> <p>As it is clearly shown the danger of such tools is minimal, the overall amount of mercury used for this purposes in Europe is 1 ... 5 kg per year, it would be reasonable to make</p>	<p>Thank you for the information provided on this specific technology. The application is described in the BD. Based on the provided and available information on the alternatives (see new Annex 10 of the BD), it does not seem appropriate to propose any restriction on this use, and consequently the proposed restriction is not amended.</p> <p>Furthermore, according to</p>	<p>Thank you for this new information. As the DS has mentioned the use might not fall under the REACH restrictions and besides the use is very small indeed.</p>	<p>Thank you for the information. The use of mercury electrodes in this technique is considered in the BD.</p>

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		the mercury CV systems exempt from restrictions.	REACH Regulation, restrictions do not apply to the manufacture, placing on the market or use of a substance in scientific research and development (SRD). The activities covered by the SRD exemption are those carried out under controlled conditions in a volume less than 1 tonne per year. The relevance of the SRD exemption is described in the BD in Section B.2 (Scope and approach).		
		<p>SPECIFIC COMMENT: Mercury CV systems are clearly not hazardous for the operators and the environment, as they use extremely small quantities of mercury and they are handled by skilled technical personnel. Also, the mercury is kept in a closed space with a very limited possibility of mercury vapor escaping. Alternatives do not provide all the measurement capabilities of a mercury CV system, thus a replacement could effectively double or triple the costs of the user because multiple tools are needed to replace all functionalities. Moreover, such tools are supplied by a significant European supplier and restricting the market would be a loss of revenue in the European semiconductor equipment sector.</p>	Thank you for the information provided on this specific technology. The application is described in the updated BD. Based on the provided and available information on the alternatives (see new annex 10 of the BD), it is not appropriate to propose any restriction on this use.	As DS	As DS. The use of mercury electrodes in this technique is considered in the BD.

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		The users of the tool need to be aware of the fact that the European regulatory bodies understand and accept the importance of mercury CV systems in the semiconductor industry.			
110	2011/03/16 12:15 / / Germany MSCA (F)	<p>SPECIFIC COMMENT: Comment on behalf of the German CA Comment on appendix 2 of the restriction dossier for mercury in measuring devices Estimating health and environmental benefits based on spill cleanup costs using the damage cost avoided method</p> <p>1. Background Based on the information included in the restriction dossier (in particular, appendix 2), it appears that there is at the moment relatively little data available to quantitatively assess the human health related and environmental benefits of reducing mercury in measurement devices. In order to be able to establish whether the proposed restriction can be considered proportionate, there seems to be a need for further analysis. Appendix 2 refers to various studies which present the following ranges regarding the benefits of reduced mercury emissions, including:</p> <ul style="list-style-type: none"> • €4,926 - €245,660 per kg (based on methyl mercury emissions from coal-fired power plants in the US, Rice Hammitt 2005) • €8,726 - €21,815 per kg (based on removing costs of mercury in Sweden, Hylander and Goodsite 2006) 	<p>Please see the actual comment and the responses below under the specific comments.</p> <p>We welcome your valuable input which offers one approach to assess the proportionality of the proposed restrictions. The provided information was summarised in the appendix 2 of the BD.</p>		<p>As DS. This is a good example of an other method for assessing the proportionality of the costs.</p>

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

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		<ul style="list-style-type: none"> • €9,424 - €11,256 per kg (based on mercury poisoning in Japan, Hylander and Goodsite 2006) <p>As noted in the dossier, it is unclear for several reasons whether these values can be transferred reliably to the case of mercury in measuring devices. Therefore, a different approach to estimate the benefit of the proposed restriction based on damage reduction costs of mercury emissions caused by spills of measuring devices is introduced below.</p> <p>2. The damage cost avoided method</p> <p>The argument to follow is loosely based on the damage cost avoided method which can be defined as below: “The damage cost avoided, replacement cost, and substitute cost methods are related methods that estimate values of ecosystem services based on either the costs of avoiding damages due to lost services, the cost of replacing ecosystem services, or the cost of providing substitute services. These methods do not provide strict measures of economic values, which are based on peoples’ willingness to pay for a product or service. Instead, they assume that the costs of avoiding damages or replacing ecosystems or their services provide useful estimates of the value of these ecosystems or services. This is based on the assumption that, if people incur costs to avoid damages caused by lost ecosystem services, or to replace the services of ecosystems, then those services must be worth at least what people paid to replace them. Thus, the methods are most appropriately applied in cases where damage avoidance or replacement expenditures have actually been, or will actually be, made.”</p> <p>Source: http://www.ecosystemvaluation.org/cost_avoided.htm</p>			

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		<p>3. US EPA data on spill cleanup costs A bulletin published by the US EPA in November 2002 entitled “Eliminating Mercury in Hospitals” contains data on costs associated with the use of mercury-containing sphygmomanometers and thermometers, and in particular on cleanup costs of mercury spills in hospitals. Mercury sphygmomanometers:</p> <ul style="list-style-type: none"> • The average cost to clean up a sphygmomanometer spill is \$1,539 (includes costs of spill kit, staff time, if applicable replacement of contaminated flooring and proper disposal of a waste bucket or drum). • Sphygmomanometers contain on average about 80g of mercury. <p>Mercury thermometers:</p> <ul style="list-style-type: none"> • The average cost to clean up a thermometer spill is \$270 (includes costs of spill kit, staff time, if applicable replacement of contaminated flooring and proper disposal of a waste bucket or drum). • Thermometers contain about 0.5g of mercury. <p>Source: http://www.epa.gov/region9/waste/p2/projects/hospital/mercury.pdf</p> <p>4. Avoided damage reduction costs in the case of measuring devices Based on the data presented above, the following may be considered. Mercury sphygmomanometers:</p> <ul style="list-style-type: none"> • 12.5 spills equal 1kg of mercury emissions. • The cost to clean up 1kg of mercury from sphygmomanometer spills is \$19,238 (12.5 x \$1,539). 			

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		<ul style="list-style-type: none"> • Converted to 2010 price level Euros (using the coefficient in end note 1 of appendix 2), the cost is equivalent to €22,684 per kg. Mercury thermometers: • 2000 spills equal 1kg of mercury emissions. • The cost to clean up 1kg of mercury from thermometer spills is \$540,000 (2000 x \$270). • Converted to 2010 price level Euros (using the coefficient in end note 1 of appendix 2), the cost is equivalent to €636,714 per kg. <p>In line with the logic of the damage cost avoided method, these data may be interpreted as follows. Assume a mercury spill has occurred and it would cost \$1,000 to properly remove and dispose of the mercury. A utility-maximizing actor will then perform the proper cleanup if and only if the cost of cleaning up is lower than the cost of not cleaning up. So in this example, the decision-maker must value any adverse consequences of not removing the mercury at or above \$1,000 in order to perform the cleanup. Some residual damage might still occur even if an attempt to clean up the spill is made. Regardless, the same rationale applies, i.e. if the damage cannot be fully avoided but only reduced, then the reduction in damages must be valued higher than the costs incurred to achieve the reduction .</p> <p>According to the US EPA data, society is willing to pay an average of \$1,539 (\$270) per case or \$19,238 (\$540,000) per kg of mercury to clean up spills from sphygmomanometers (thermometers). Therefore, society must place a value at least as high as these figures on the negative impacts resulting from the mercury not being removed and safely disposed of. These negative impacts</p>			

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		<p>would primarily consist of health and environmental risks following the exposure of human beings (e.g. by way of inhalation) or environmental compartments (e.g. by way of the substance entering the water supply) to the spilled mercury.</p> <p>To summarize, the analysis using the damage cost avoided method suggests the following:</p> <ul style="list-style-type: none"> • Based on the data for sphygmomanometers, the benefit of avoiding mercury emissions in hospitals must be equal to or greater than €22,684 per kg. • Based on the data for thermometers, the benefit of avoiding mercury emissions in hospitals must be equal to or greater than €636,714 per kg. <p>The rather large discrepancy between the numbers for sphygmomanometers and thermometers is explained by the dramatically higher mercury content of sphygmomanometers per device combined with expressing costs per kg. This does not mean that the benefit of 1 kg of mercury emissions avoided is in reality higher for thermometers than it is for sphygmomanometers.</p> <p>To avoid any confusion, it should be noted that the approach proposed here does not utilize information on spill cleanup costs to directly measure actual costs associated with mercury measuring devices (in fact, the restriction dossier already appears to include some costs related to waste treatment and spill response as part of the compliance cost calculations; these costs should clearly not be double-counted). Rather, spill cleanup costs are taken as indirect measures to derive economic values for health related and environmental resources put at risk by mercury emissions. Also, it should be stressed again that the damage cost</p>			

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		<p>avoided method can only be used to establish lower bound estimations for values placed on health related or environmental resources.</p> <p>5. Conclusion These thoughts obviously represent only a very rough and cursory sketch of a possible route of analysis. Nevertheless, the figures calculated above (€22,684 and €636,714 per kg) might be useful as an estimate of the benefits of the proposed restriction since they indicate a lower bound limit of the value placed by society on risk reductions specifically in connection with mercury-containing measurement devices. As part of one way to further assess the proportionality of the restriction, the figures could be compared to the compliance cost of the restriction per kg of mercury emissions avoided. It is important to emphasize that the approach described here deals with the benefits of avoided mercury emissions caused by breakage of measuring devices, not the benefit of avoided mercury as a substance on the whole.</p> <p>As the US EPA data set deals only with sphygmomanometers and thermometers used in US hospitals, the question arises whether a benefit transfer can be made to better fit the restriction proposal's scope. In particular, some adjustments of the values may be needed with regard to:</p> <ul style="list-style-type: none"> • transfer to other types of mercury measuring devices • transfer to uses in other settings (e.g. laboratories) • transfer to the EU region 			

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109	2011/02/18 14:30 // Ireland MSCA (A)	Please find below, comments received by the HSA from the National Standards Authority of Ireland (NSAI) in relation to the proposed restriction on mercury in measuring devices. The NSAI is now considering phasing out the calibration of Mercury in Glass thermometers by the end of 2012. We will notify our existing customers of this change and will advise them of alternatives. The NSAI maintains Ireland's Temperature Standards. We offer direct traceability to the SI Unit by measuring temperature at known fixed points. These points are listed on the International Temperature Scale of 1990 (ITS-90). They are Argon, Mercury, Water, Gallium, Indium, Tin, Zinc, Aluminium, Silver and Gold. These metals are found in a very pure state and they cover the range from -189°C to 1064°C with accuracies ranging from 0.0001°C to 0.002 °C. The Freezing point of mercury is at -38.8844°C. What is of concern to NSAI's National Metrology Laboratory is that it has a sealed Mercury Cell that is used for Primary Temperature Calibration work and provides the most accurate traceability to the International Temperature Scale of 1990 (ITS-90). One of the laboratory's clients would be The Irish Meteorological Service. The NSAI calibrates their thermometers at 3 Fixed Points Mercury, Water and Gallium over the range from -38°C to 30°C. The accuracy of such measurements is + 0.001°C. If the NSAI's National Metrology Laboratory were not permitted to use this cell it will have major implications to this work both nationally and internationally worldwide. Every National Metrology Laboratory would be affected and the International Temperature Scale would have to be revised. The laboratory sends this cell to our German colleagues every 5 years to be re calibrated. It is shipped overland.	Thank you for the valuable information confirming our assessment in the report (see Annex 5a, Part 4.4 of the BD), which suggests derogation for mercury triple point cells that are used for the calibration of platinum resistance thermometers (as prescribed in the 1990 International Temperature Scale, ITS-90). These aspects were also raised in comments made by BIPM, NPL UK, and HSL (Ireland).	As DS.	As DS.

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		. The NSAI would like to suggest that the restriction should state “shall not apply to mercury fixed point cells of the International Temperature Scale of 1990....”			
108	2011/02/18 14:08 / / Spain MSCA (A)	According to the information provided in the Annex XV, it is estimated that only 20% of the mercury in measuring devices, including sphygmomanometers, is collected as hazardous waste. Probably, that would mean a higher recovering rate than the thermometers’ recovering rate by consumers, which represent a higher number of users. So, it does not seem to be additional reasons of concern to restrict the use of mercury containing sphygmomanometers after 6.5 years. Considering the reasons provided in the Annex XV and also in coherence with the approach of the Directive 2007/51 regarding restrictions on the marketing of certain measuring devices containing mercury, we would agree the option 1 (Restriction on placing on the market) with the proposed limited derogations. Also economic considerations of the substitution, when considering the use restriction, are accounted. Measures to avoid hazardous wastes can also be considered.	Thank you for supporting our proposal. For the derogations regarding the sphygmomanometers we have also taken into consideration the opinion of SCENIHR and the information confirming that validated mercury-free alternatives based on the auscultatory technique are available and can replace mercury sphygmomanometers in all clinical applications.	As DS	As DS

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		Mercury-containing sphygmomanometers have been completely substituted in several countries. Nevertheless, in some Member States where substitution has not yet occurred, concerns remain on calibration, validation, and on the treatment of certain medical cases, which could at least in part be due to user-related preferences and habits, as well as lack of knowledge or training for using Hg-free sphygmomanometers. The fact that end-users have not replaced the mercury sphygmomanometers with possibly more economical alternatives, may indicate that certain characteristics of mercury devices are more valuable than perceived in the analysis of the Annex XV. Within the documents provided in the RMOA it was indicated that a recent study in a primary care setting has shown calibration errors in the aneroid devices. It should be assured that potential substitutes fulfil the requirements of the "EC-Mark" for medical devices assuring sufficient accuracy and stability. This is a legally binding statement by the manufacturer that their product has met all of the requirements of the Medical Devices Directive (Council Directive 93/42/EEC).	The CE-mark on a medical device indicates that the product complies with the essential requirements of Council Directive 93/42/EEC, but is not an indication of accuracy as such (although the limits of accuracy must be indicated by the manufacturer).		
107	2011/02/15 15:53 United Kingdom / National NGO / (E), (G)	If 50 years old is used as the limit for degogation for some instruments that contain mercury it will limit the ability of musuems to acquire objects for their collection. The Science Museum Collection policies includes items that are less that 50 years old. Will this proposed ban also restrict museums from passing such instruments between museum	Thank you for the information on the problems related to applying one age limit for all types of measuring devices. According to our understanding placing on	As DS	As DS

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		organisations as loans or transfers? If necessary could an extra derogation condition be added to allow museums to handle mercury containing items that are less than 50 years old. This idea would be supported by the Science Museum, London, where we have robust policies and procedures in place to manage hazardous materials in the Science Museum Collection.	the market includes the loans. To allow e.g. technical museums to obtain historically and culturally valuable devices for their exhibitions, a derogation is proposed for measuring devices which are to be displayed in exhibitions for cultural and historical purposes.		
106	2011/01/21 15:16 Germany / National authority / (A), (C)	A number of scientific endeavors and technical procedures rely on the very specific properties of the chemical species Mercury. By its very nature, due to fundamental physics/chemistry laws there is no substitute for these uses of mercury. A general exemption clause for scientific research and the trade in instruments needed for scientific research is therefore advisable. Specific examples where exemptions are absolutely essential are given below.	Thank you for the information. Responses to specific examples mentioned in the comment are given below under the heading "specific questions". According to REACH Regulation, restrictions do not apply to the manufacture, placing on the market or use of a substance in scientific research and development (SRD). However, activities covered by the SRD exemption are limited to those that are carried out under	As DS	As DS

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			controlled conditions in a volume less than 1 tonne per year. Furthermore, substances forming an integral part of a measuring 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. This is the case e.g. with barometers, manometers, sphygmomanometers, strain gauges and thermometers. The relevance of the SRD exemption is described in the BD in Section B.2 (Scope and approach).		
		SPECIFIC COMMENT: Two important exemptions are needed: (1) Mercury fix-point cells for the realization of the international temperature scale. These cells are used in the national metrology institutes worldwide to realize the international temperature scale and to perform high-level	(1) Thank you for the valuable information confirming our assessment in the report (see Annex 5a, Part 4.4), which suggests derogation	As SEAC Rapporteurs	As DS. From the information provided in Annex 1 and Appendix 5, we conclude that accurate alternatives are available and we see no need for a

¹ Chamois (2010), Website from Chamois, consulted on 3 November 2010. Available at http://www.chamois.net/_userfiles/pages/image/dpg10A.pdf

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		<p>calibrations of reference thermometers. Since the very definition of the temperature scale makes use of these element-specific properties of mercury, there is no alternative, and there cannot be due to fundamental laws of nature. As such fix-point cells are obtained from a manufacturer in the USA (Hart Scientific), international trade in these cells must remain allowed, as well. Suggested procedure: Add wording similar to this: "The restriction in paragraph ... shall not apply to trade and use of mercury fixed point cells of the International Temperature Scale..."</p> <p>(2) Special high-end/high-performance manometers/barometers used in national metrology laboratories for the realization of the international unit of pressure ("national standards"). In this application, only mercury barometers can provide the low measurement/realization uncertainty that is required by a large number of clients in industrial and consumer protection contexts. Note that these devices are NOT used to measure air pressure although they are called "barometers". In this sense, Lassen et al. (2008) are in error when they claim that there would be no barometer applications where mercury is indispensable. Suggested procedure: Add wording similar to this: "The restriction in paragraph ... shall not apply to trade and use of national-standard barometers for the realization of the international unit of pressure..."</p>	<p>for mercury triple point cells (i.e. fix-point cells) that are used for the calibration of platinum resistance thermometers. These aspects were also raised in comments made by BIPM, NPL UK, and HSL (Ireland).</p> <p>(2)According to Chamois¹ webpage, there are many modern devices available on the market designed for operation in both absolute & gauge pressure and are suitable for the calibration of high accuracy barometers and Air Data Test Sets. These devices are applicable for all pressure fields and we are not aware of any reasons why they would not be also applicable for all industrial and consumer protection contexts. Furthermore, certain types of barometers combine the metrological performance of pressure balance with</p>		derogation in this respect.

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			the convenience of digital instrumentation.		
103	2011/01/12 12:29 United Kingdom / National authority /	<p>The NHS European Office, in consultation with the UK MHRA and experts in the field of Blood Pressure measurement in the UK, presents the view that mercury sphygmomanometers should continue to be available for clinical validation purposes and for use by clinicians when oscillometric blood pressure monitors are inappropriate.</p> <p>While we support the principle of phasing out the use of mercury from an environmental perspective, this should not be at the expense of safe and effective healthcare delivery.</p>	<p>As described in the opinion of SCENIHR, there are validated mercury-free alternatives available that are based on the auscultatory technique, which are equivalent to mercury sphygmomanometers.</p> <p>The suggested restriction for the sphygmomanometers has derogations to devices on the basis of the opinion of SCENIHR. These derogations are: sphygmomanometers that are 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.</p>	<p>As DS</p> <p>As DS</p>	<p>As DS</p> <p>As DS</p>

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		<p>We believe that mercury manometers should continue to be used for clinical validation purposes (i.e. as a reference standard) as no suitable alternative currently exists. This is a view supported by the British Hypertension Society, the European Society of Hypertension, and the American Society of Hypertension and the American College of Cardiology.</p> <p>Furthermore on a clinical level, we maintain the view that patients with arrhythmias, pre-eclampsia and certain vascular diseases require blood pressure monitors with as high a level of accuracy as possible. Automated oscillometric blood pressure monitors have not yet been clinically proven as appropriate for such patients and as a result mercury sphygmomanometers should continue to be used. As soon as suitable alternatives have been scientifically proven to exist and have been validated for use with patients from special groups we would support a general phase out of mercury from measuring devices.</p>	<p>As described in the opinion of SCENIHR, there are validated mercury-free alternatives available that are based on the auscultatory technique, which are suitable also for specific groups of patients, including patients with arrhythmias and pre-eclampsia.</p>	<p>See above</p> <p>As DS</p>	<p>The restriction proposal contains a derogation for the use of sphygmomanometers as reference standards in clinical validation studies</p> <p>As DS</p>
102	2011/01/11 19:27 / / Individual	<p>Restricting mercury in the medical device is a good thing but I am wondering if the Energy-saving light bulbs should not also be regarded as problematic as their use is increasing, they have a lifetime<math>t</math>, medical device and how to treat this waste not well communicated. Moreover, the percentage of volume dedicated to this use is similar (3% instead of 4) to the medical devices.</p>	<p>The energy-saving bulbs are not in the scope of this restriction proposal.</p>	<p>As SEAC Rapporteurs</p>	<p>The use of mercury in light bulbs is outside the scope of this restriction proposal, in the context of the EU mercury strategy other measures are and will be discussed.</p>

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98	2010/12/25 00:58 United Kingdom / Company / (A), (D), (E), (F)	<p>We have manufacturing mercury thermometers since 1860 and mercury barometers since 1975. I am not a civil servant paid by the state, I am a craftsman who works on the bench and tries to keep 10 people(all craftsman) employed and keep their skills alive and for the future generations. I am filling this form in as I have been working until Christmas Eve to complete orders for our products to satisfy the demand of our customers all round the world including the EU but mainly out of the EU. In the last few months we have supplied mercury thermometers to Thailand, Fiji, Abu Dhabi, India, USA, Nigeria, Malta, Mauritius, West Indies to name a few. We also supply export houses in UK who export to other countries. Most of our products are used in the canning, meteorological and laboratory industries. Our customers want our accuracy. We have been asked to manufacture incubator thermometers for India for a project to save a certain type of Vulture which is will be extinct if the breeding programme fails. The alternatives that you say are available are not suitable for the processes and applications they require mainly for accuracy and cost.</p> <p>We have recently been advised that we are still allowed to blow new mercury thermometers to existing scales on antique barometers. Why were we not consulted when someone proposed this rule. Its cost a few of my colleagues and me a considerable of money to make the ruler makers see sense.</p> <p>Why can I go today to buy an new &quot;AGA&quot; cooker which costs some £5000 containing a mercury</p>	<p>Please note that the proposed restriction does not cover the export of the measuring devices.</p> <p>The background document takes into account all the available information regarding the risks and the technical and economic feasibility of the alternatives. Accuracy of alternatives is not considered an issue: electronic thermometers are generally more accurate than mercury-containing thermometers when properly calibrated (Lassen et al, 2008).</p> <p>If you are referring to this restriction proposal (rule), this public consultation is your opportunity to provide information. In addition, your company has been contacted and provided responses to the questionnaire of our</p>	As DS	As DS

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

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		<p>thermometer? I have been told if that thermometer gets broken that I can supply a new replacement to a trader but not a member of the public. The trader is not to supply to a member of the public so what is the use of that. A cooker that can not be controlled by the cook, madness. Think before you legislate in rules that you dont understand the knock on consequences in areas that you do not comprehend and why is it so dangerous to have mercury thermometers and mercury barometers when the public are allowed to buy and use millions of mercury vapour light bulbs?</p> <p>Double standards.</p>	<p>contractor (see Appendix 5 to the BD).</p> <p>According to AGA instruments, they are able to provide mercury-free heat indicator well before the restriction becomes effective (see section 3.3 of Annex 5a of the BD).</p> <p>The energy saving lamps are outside the scope of this restriction proposal.</p>		
89	<p>2010/12/21 12:44 Att. Ref89 Sweden/ Academic institution/</p>		<p>Please see the actual comments and the responses below under the specific question 4.</p>		
88	<p>2010/12/21 18:44 Germany/ Company/</p>	<p>Please see my confidential information in the attachment.</p>	<p>Thank you for the confidential information.</p>		

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87	2010/12/22 14:44 // Sweden MSCA	Swedish Chemicals Agency, our ref dnr 465-H10-00888 Comments in public consultation for Annex XV restriction dossier – Mercury We welcome the proposal for further restrictions on the use of mercury in measuring devices. Mercury is one of the most hazardous environmental toxins and is a threat to human health and the environment. Mercury cannot be broken down but accumulates in soil, water and living organisms. The more mercury is supplied to society the more the levels in the environment increase. It is therefore of great importance that the use and release of mercury should be eliminated. It should be emphasised that the current entry 18a in Reach Annex XVII stipulates that mercury in measuring devices should be phased out whenever technically and economically feasible. The national Swedish ban on the use of mercury also covers the industrial and professional use of measurement devices. Where those restrictions apply, substitution has been shown to be both technically and economically feasible and any relaxation of such restrictions would be unacceptable.	Thank you for the comment.	We agree with a need to clearly define limits of any exemption of Hg containing measuring device for SRD	Thanks for the supportive comment and agree with response DS.

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		The need for any exemptions in the proposed restriction should take into account the general exemption for the manufacture, placing on the market or use of a substance in scientific research and development (Reach article 67(1)), to ensure that the scope of any exemptions is clearly defined and as limited as possible.	The relevance of the scientific research and development exemption is clarified in the BD.		
85	2010/12/21 12:21 // Germany MSCA	<p>The dossier is a shortened version of a normal restriction dossier, as the proposed restriction is a review of an existing restriction. Given this special circumstances this approach is acceptable and sensible. Nevertheless, there are some special points that should be commented upon:</p> <p>In the dossier there is no new review clause proposed for the restriction even though some of the exemptions considered are solely based on current lack of feasible alternatives. As this lack of alternatives probably will change, especially if a restriction is in force, a new review clause should be considered.</p> <p>We believe it furthermore necessary to consider the restriction of the manufacture of measurement devices as well. The main reason for the proposed restriction is the general mercury strategy of the EU which must be considered in context with UN-initiatives to ban mercury. Therefore it is several times stated in the dossier that the problem is a global one. The logical conclusion is that exports should be restricted as well. This extension of the proposal could change the outcome of the SEA</p>	<p>The reasons for not proposing a new review clause is the legislative coherence and clarity of the entry (See Part E of the BD). A Member State or ECHA can propose a re-examination when deemed necessary.</p> <p>For the reasons explained in the Part B.2 of the report, the banning of export (or production) of mercury measuring devices is outside the scope of the dossier.</p>	<p>The justification of current restriction based on review clause is technical and economic feasibility of alternatives, and such clause may remain for other uses of mercury.</p> <p>Restriction dossier is not the only tool for executing EU policy, therefore it has to be focussed on tasks requested in the review clause. Restriction of export is not within the remit of this restriction.</p>	<p>Agree with DS</p> <p>We agree with the comment and the issue of export is considered in the opinion.</p>

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		<p>considerably.</p> <p>The authors of the dossier should furthermore consider discussing the problem of the RMM of Waste management more. In the dossier they are portrayed as very ineffective, while they are more effective in case of measuring devices using mercury. Since measuring devices using mercury are nowadays only employed in the professional sector (e.g. hospitals or laboratories) the installation of a more effective recycling system should in principle easily possible.</p> <p>Some comments related to the effectiveness of the proposal:</p> <p>1. In the overall consideration of the mercury issue, it can be expected that by the proposed restriction on several measuring devices, only a small part of the mercury emission sources in the waste could be reduced.</p>	<p>Concerning waste management: we have no information supporting that the separate collection rate of mercury containing devices from the professional sector is sufficiently high. On the contrary, Lassen et al. (2008)² estimated (although with high uncertainty) a collection rate of only 20%. Low separate collection rates are also indicated in the report from Cowi and Concorde East/West³. Taking into account the relatively high awareness with regard to the environmental and human health risks related to mercury (compared to many other hazardous</p>	<p>We agree that better management of mercury containing wastes is important and plausible issue, but it is outside of the remit of a review clause and scope of this restriction proposal</p> <p>We agree with first comment.</p> <p>Restriction of energy saving lamps (ESLs) may be possible when economically and technically feasible alternatives will be available. It is a good candidate for next review clause.</p> <p>This does not weaken a need for better</p>	<p>Thanks for the supportive comment to address the waste issue in the SEAC opinion. In our view the opportunity to improve the recycling rates is right now.</p> <p>Your expectation is correct.</p>

² 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

³ COWI and Concorde East/West. (2009), *Turning up the pressure: Phasing out mercury sphygmomanometers for professional use*". Available at http://www.eeb.org/publication/2009/SphygReport_EEB_Final-A5_11Jun2009.pdf

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			<p>wastes) and the fact that the requirements have been in place for a relatively long time, and keeping in mind the problems that are in general encountered with respect to implementation of Community waste legislation, it does not seem plausible to rely on better enforcement of waste legislation as a measure that would be sufficient to address the issue. Moreover, it should be noted that restriction is an important waste prevention instrument, thus satisfying to the top priority in the waste hierarchy .</p> <p>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</p>	<p>management of Hg cont. waste.</p>	

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		2. In (Part B, p.16, Figure 1), the data show that mercury is used almost in the same amount in measuring devices (4%) than in light sources – energy saving lamps (3%). The likelihood that energy savings lamps are not able to be properly disposed by the consumers is much higher than in case of measuring instruments containing mercury by the especially qualified staff. Besides, for proper disposal of the energy savings lamps the infrastructure is absent in most cases. The emission rate after breakage of a ESL is higher than the mercury emission limit of 0,05 mg/m ³ in waste incineration Directive (Directive 2000/76/EC) and	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 remit of our restriction proposal under REACH, 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. The energy-saving bulbs are not in the scope of this restriction proposal.	As SEAC Rapporteurs	Energy saving lamps are not covered in the restriction proposal. Your observation regarding the 4% share of mercury in measuring devices as part of the whole 'mercury pool' is correct.

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		occupational exposure limit of 0.02 mg/m ³ (Directive 98/24/EC). The highest mercury concentrations after breakage of a ESL are: 0.05 mg/m ³ up to 0.1 mg/m ³ http://www.bfr.bund.de/cm/232/gefahr_durch_quecksilber_in_energiesparlampen.pdf 3. In the light of these aspects it may be questioned why, on one hand, the EU promotes the use of ESL (each containing 5 mg of mercury), while on the other hand, it aims for reduction of mercury use in measure devices by professionals.			Agreeing with DS response
85	2010/12/21 12:21 // Germany MSCA	SPECIFIC COMMENT 1. Section B4.1 (Page 17ff): The assumption for the estimate of the accumulated pool of mercury is not well understandable (Part B, p. 17, Table 5). Furthermore, it is not understandable, how the data from the source of the year 2008 were transferred to 2010. 2. The assumption that all mercury present in measuring devices will end up as emission to the environment is questionable. On p. 19 it is already indicated that 20% of mercury will be properly collected. Moreover, many of those measuring devices are used at laboratories or research institutes that may be expected to have an effective disposal procedure. We agree that specific data are difficult to come by, but the authors could have tried a high/low recycling scenario. Because they will have an influence on the calculated costs & benefits per kg of mercury, different recycle scenarios have a large impact.	1. Both the assumption and unclear updating of data are clarified in the BD. 2. We describe the fact that we do not assume that all mercury present in the devices will be emitted to the environment (it is a maximum <i>potential</i> for emissions) in the BD. We have no information supporting that the separate collection rate of mercury containing devices from the	Thank you for comments. See response DS.	See response DS. Thank you for this remark. The 'waste issue' including collection rates and recycling is addressed in our opinion.

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		<p>3. Similarly, there are no data/information/estimation about the mercury amount which is fed to landfill and incineration installations.</p> <p>4. B6. (p. 28 – “Summary of hazards and risks”) There is lack on data about mercury emissions in the environment and on worker exposure, and also about the mercury level in waste samples.</p>	<p>professional sector is sufficiently high(er). On the contrary, Lassen et al. (2008)² estimated (although with high uncertainty) a collection rate of only 20%. Also the report from Cowi and Concorde 2009³ indicates low separate collection rates.</p> <p>3. See above response 2 on collection rates. We have no good data on the shares of the <u>measuring devices</u> fed to the landfills or to the incineration.</p> <p>4. We consider the mercury estimated to be placed on the market in the EU in mercury containing measuring devices to be an adequate figure to describe the maximum potential for emissions to the environment that might ultimately occur. Clearly this is a <u>potential</u> and not</p>		<p>We appreciate if the MSCA could provide data of the situation in his country.</p> <p>See above.</p>

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65	2010/12/20 13:50 // United Kingdom MSCA	<p>We agree with the broad policy commitment to reduce mercury emissions to the environment, but we are uncertain whether reference to the UN activities and the EU mercury strategy is applicable in a REACH context, where controls depend on a specific risk being identified. The dossiers for both phenylmercury compounds and mercury in measuring devices are based on the same generic concern. This is that any release of a mercury compound to the environment will eventually lead to the formation of elemental mercury and methylmercury, which are either SVHCs or an equivalent level of concern, presumably with no thresholds for their effects. By reducing the available mercury pool, the potential for formation of significant quantities of methylmercury is reduced (even if this cannot be quantified as such). It would be helpful if the two dossiers were consistent in the way this generic issue is expressed.</p> <p>SPECIFIC COMMENT Section B - Hazard and Risk The argument for the restriction is clearly presented. Our main comments are that:</p> <p>i) The 'risk' is taken for granted. However, from the information presented in this dossier, it is actually rather unclear what proportion of mercury in the environment will be in the form of methylmercury, for which a threshold is assumed not to hold. We have suggested that some further attention is paid to this aspect in our comments for</p>	<p>a figure of actual emissions. We amended part B.6 to clarify that there is occupational exposure as well. Thank you for the comment.</p> <p>i) It is indeed unclear what proportion of Hg in the environment will be in the form of MeHg. For that reason, and because of the extremely complex</p>	<p>We agree with the proposed general justification of restriction of Hg containing measuring devices and phenyl mercury. Reference to UN activities only shows that other bodies also undertake activities to reduce emission of mercury into environment.</p> <p>Thank you for the comments and questions i-vii. We agree that more data and information on the proportion of mercury</p>	<p>Thank you for sharing your views on the broader picture. In our view the restriction proposal fits in the EU mercury strategy and the UN activities.</p> <p>Agreeing with DS's response.</p>

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		<p>phenylmercury compounds.</p> <p>ii) The contribution of the measuring devices to the overall emissions of mercury appears to be small. Whilst it is true that the total amount of mercury used in measuring devices may be available for release at some point during the life cycle, it should be recognised that the actual releases may be rather lower. It would be helpful to discuss natural emissions to provide additional context.</p>	<p>geochemical cycling and ecological interactions in general (including re-emissions, ‘hops’, and bioaccumulation and biomagnification), it was concluded that it is not possible to make a quantitative exposure estimation.</p> <p>ii) The BD is updated to reflect the relevance of unintentional anthropogenic and natural sources of mercury in comparison to potential releases from measuring devices. Note that we consider the amount of mercury estimated to be placed on the market in the EU in mercury containing measuring devices to be an adequate figure to describe the maximum potential for emissions to the environment that might ultimately occur. Clearly this is a potential and not</p>	<p>released converted to methylmercury would improve justification, but it is not a condition for restriction.</p>	<p>As DS</p>

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		<p>iii) The reasons for the low collection rates for the measuring devices are not very clear. Better enforcement is dismissed as ‘implausible’, but if this equipment is only now used by professional users, presumably the scope for improved recycling (e.g. through manufacturers’ take-back schemes and awareness raising by professional bodies) could actually be quite good. Has this been discussed with the equipment suppliers? We think it would be helpful to discuss this aspect more in the dossier.</p>	<p>a figure of the actual emissions.</p> <p>iii) Lassen et al. (2008)² estimated (although with high uncertainty) a collection rate of only 20%. Also the report “Turning up the pressure”³ indicates low separate collection rates. 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, and keeping in mind the problems that are in general encountered with respect to implementation of Community waste legislation as a measure that would be sufficient to address the issue. Moreover, it should be</p>	<p>The issue of better management of waste containing mercury is addressed in the RAC opinion, , but it is not an alternative for restriction. Please note that the restriction is proposed whenever it may be demonstrated that technical and economically feasible alternatives exists to HG measuring devices.</p>	<p>We agree that the reasons for the low rates are not clear. Further we thank you for your suggestions how to improve this. Although outside the scope of REACH, we pay special attention in our opinion to this aspect.</p>

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			<p>noted that restriction is an important waste prevention instrument, thus satisfying to the top priority in the waste hierarchy .</p> <p>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 our restriction proposal under REACH, but can be considered by the Commission and Member States in the appropriate fora under e.g. the</p>		

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		<p>iv) There is an implication that current waste legislation (including collection) is incapable of adequately controlling emissions. This is a concern, especially as the dossier acknowledges that the restriction will only affect a very small proportion of the mercury that is currently released from human use. Although somewhat outside the scope of this proposal, it might be helpful to describe what steps the Commission is taking to address the waste issue.</p> <p>v) Page 1 of the summary document does not correlate with page 16 of the main restriction dossier in that, the summary document states that the restriction would count for 1.5% of the current mercury use, whereas the main dossier on page 16 states measuring devices account for 4% of mercury use in the EU. Please clarify the actual reduction in mercury use expected by the proposed restriction?</p>	<p>framework of waste legislation and the Community Strategy Concerning Mercury. This has been clarified further in part E of the BD. Public consultation might deliver additional information (see specific public consultation question 5)</p> <p>iv) A paragraph has been added under part E of the BD (together with a reference to a Commission report on the implementation of the Community waste legislation - COM(2009) 633 final).</p> <p>v) The mercury in measuring devices represents around 4% of the mercury use in the EU. As the report does not suggest to ban all the measuring devices (e.g. mercury porosimeters), the suggested restriction</p>		<p>We agree with the comment</p> <p>As DS</p>

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		<p>vi) Although this restriction will prohibit placing mercury containing measuring devices on the EU market, it will still allow manufacture within the EU, for export for use outside the EU. To reduce the mercury pool effectively and address the issue on a community-wide level and to address the adverse effects at worldwide level (page 33) should the restriction include prohibiting manufacture within the EU?</p> <p>vii) The continued production of devices for sale outside the EU will also lead to continued workplace exposure within the community. Although reference is made to existing legislation and occupational exposure limits in place this dossier does not appear to include the exposure or potential addition to the mercury pool as an issue, merely focusing on the environmental issue of use of devices within the EU.</p>	<p>covers about 1,5% of the intentional mercury use in EU.</p> <p>vi) For the reasons explained in the Part B.2 of the report, the banning of export (or production) of mercury measuring devices is outside the scope of the dossier.</p> <p>vii) Indeed, the main concern is considered to be emissions to the environment from the waste stage. However, it is acknowledged that in fact there are emissions during all stages of the life-cycle, and although not the primary concern, more emphasis has been given in the BD to direct exposure of workers occurring during production, professional/industrial use of the devices and during waste management operations.</p>	<p>The issue of export is in our understanding outside of the proposed restriction due to legal constraints.</p> <p>The population occupationally exposed to mercury will certainly be reduced as a result of the proposed restriction. In addition the level of mercury exposure in the workplaces is controlled by requirements of health and safety following from work legislation.</p>	<p>Thank you for this useful comment. We address the issue of export in the context of the relevant EU legislation outside the scope of REACH in our opinion.</p> <p>See above.</p>

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		<p>Section E We accept that there is a global strategy regarding the reduction in use of mercury due to associated risks, therefore due to the nature of this particular use of mercury this review has had to be written a certain way. We appreciate the reasons why in this case the document didn't follow the standard format.</p> <p>Section F As requested in section B clarification is required as to whether the restriction will produce a 1.5% or 4% reduction in mercury use and whether the restriction is considered cost effective against the actual cost to impose and regulate this restriction. It would be useful if the dossier could identify the fate of devices which are less than 50 years old at the end of their service life. In particular, and although there is some information about low separate collection, the fate of mercury in devices that have not been collected is unclear. Any attempt at quantification of Health and Environmental impacts has not been undertaken in the dossier on the grounds of proportionality. Where costs are imposed as a result of a restriction it seems reasonable and appropriate to compare those costs with benefits in order to justify the restriction. Since this is not done then the proportionality of the restriction can only be determined in those cases where there are cost savings arising from the restriction. Could you explain if the alternative mercury devices result in any trade-offs between their technical quality and cost as</p>	<p>Section E Thank you for the support.</p> <p>Section F: The suggested restriction accounts for 1,5% of the mercury use in the EU. It is concluded that the suggested restriction is a cost-effective measure to tackle the problem as part of the overall mercury emissions and the Community Strategy Concerning Mercury addressing this problem of Hg emissions.</p> <p>The fate of the mercury in the measuring devices (regardless of the age) is described in Section B.4 (See also the Figure 2) of the BD.</p>	<p>Thank you for your understanding of the need to modify the format of the Annex XV report.</p>	<p>Thank you for the support of the chosen approach.</p> <p>Your observations are sharp and recognized and the Appendix 2 has been improved by the DS..</p>

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		<p>compared to the mercury devices. The concept of economic feasibility does not seem to be related to any cross-comparator or benchmark. It is unclear then at what point any alternatives cease to be economic feasible and become economically infeasible. The benchmarks for proportionality are useful but lack any theoretical (or other basis). It would have been useful for the dossier submitter to have openly discussed this issue and consulted with stakeholders on a way forward in determining what is essentially a measure of societal acceptability of risks and costs.</p>	<p>We chose alternatives which are as similar from the technical point of view as possible for the assessment. When differences in technical quality have been identified, they have either been considered in the compliance cost calculations (e.g. different life-times) or have been qualitatively described (e.g. possibility to remote reading). The problems around establishing the economic feasibility and proportionality have been recognised by the dossier submitter. Based on the comments received in public consultation and discussions in the SEA Committee, the Appendix 2 to BD has been revised. The benchmarks were removed as they were not considered sufficiently grounded..</p>		

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		Section H If we accept that there may be concern regarding compliance with certain aspects of this restriction in that mercury containing equipment may continue to be used, are there proposals/ideas as to how this issue is this likely to be addressed?	Concerning your comment on compliance (note that there is no section H in the report). Member States which have implemented national bans have not reported problems on enforcement. In addition, we are not aware of significant problems in enforcing the existing restriction entry 18a. We have not identified any major problems for the enforceability of the suggested restriction either. We of course acknowledge that - as always - specific cases might cause some difficulties, and might require case-by-case decisions by enforcement authorities. For the above reasons, we have concluded that the proposed restriction is enforceable. We recognise the importance of ensuring		As DS.

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			the compliance on the restriction. To this end the obligations have to be clearly expressed and enforceable. The assessment of practicality of the proposed restriction (including enforceability) is reported in Part E of the report, as well as in the device specific Annexes. It is noted that the Member States are responsible for the enforcement of the REACH Regulation including restrictions. The If needed later on, e.g. joint enforcement programmes can be initiated in the EU.		
51	2010/12/13 18:48 United Kingdom / National authority /	The National Physical Laboratory is the National Metrology Institute in the UK, and is responsible for establishing standards for the measurement of physical quantities, such as mass, length, time, temperature, electricity, ionising radiations, etc, for the benefit of industry, science, technology, medicine and the quality of life. In the field of temperature metrology, we are required to establish the UK realisation of the International Temperature Scale of 1990, ITS-90, and to disseminate it through calibrations to our customers in the UK and abroad.	Thank you for the valuable information confirming our assessment in the report (see Annex 5a, Part 4.4), which suggests derogation for mercury triple point cells that are used for the calibration of platinum resistance thermometers.	As DS response.	As DS response.

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		It is important that we do this with low uncertainties in order that the UK can be competitive in international markets (and of course, other NMIs in Europe are in a similar situation).	These aspects were raised also in a comment by BIPM (see below).		
		<p>SPECIFIC COMMENT</p> <p>As the Restriction Report notes, in several places, the ITS-90 specifies that the triple point of mercury, at -38.8344 °C, is used as a fixed point for the calibration of Standard Platinum Resistance Thermometers, for any application below 0 °C. It provides no alternatives. Any European solution not involving the use of the mercury point would not comply with the standard and would have significantly increased measurement uncertainties. This would place us, and UK/European manufacturers of mercury cells (and fixed point cells generally) which are sold world-wide, at a distinct disadvantage. Note there is no technical alternative currently available, nor foreseeable, to the use of the mercury triple point.</p> <p>The mercury in a fixed point cell is contained in a cylindrical stainless steel body about 200 mm high, 35 mm in diameter and 1.65 mm wall thickness, with a stainless steel axial re-entrant tube into which the thermometer is inserted for calibration. The structure is welded and robust, and we have had no instances of rupture (and are not aware of any in other NMIs), but in any case the cell is used and kept in a holder which would contain any spillage. Note that mercury does not expand on freezing, so there is no analogy with water pipes bursting in cold weather.</p>	Thank you for the valuable information confirming our assessment in the report (see Annex 5a, Part 4.4), which sets derogation for mercury triple point cells that are used for the calibration of platinum resistance thermometers. These aspects were raised also in a comment by BIPM (see below).	Thank you for the valuable information confirming our assessment in the report (see Annex 5a, Part 4.4), which sets derogation for mercury triple point cells that are used for the calibration of platinum resistance thermometers. These aspects were raised also in a comment by BIPM (see below).	Concurring with DS's response.

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		<p>Each cell contains about 3 kg of mercury, and we estimate that there may be 30-50 cells in use in the EU. The cells remain serviceable for many years (ours are more than 20 years old), but on eventual disposal mercury is designated as hazardous waste.</p> <p>I strongly support the indefinite derogation of mercury triple point cells as envisaged in the Restriction Report, and refer also to the case submitted by the International Bureau of Weights and Measures.</p>			
50	2010/12/02 11:57 Ireland / Company /	Mercury sulphate is a constituent of a COD test kit that is used on-site. It is a requirement of our IPPC licence to monitor COD and I'm not aware of other test kits. Also I'm not sure if this would be included in the ban.	Thank you for information on the use of mercury sulphate in the COD test kits. However, mercury sulphate is a reagent of the COD kit and not included in any (measuring) device. In addition, mercury sulphate is a different substance than mercury, and thus, the COD test kit is not in the scope of the restriction report.	We agree with DS	Agreeing with DS response.
48	2010/10/28 16:21 France / International organisation /	The BIPM was created as an Intergovernmental Organization in 1875 by governments through their accession to the Metre Convention. Over 80 Governments and States now support the BIPM's work. Its mission is worldwide uniformity of measurement in all areas of activity: science, trade, and society. Its work covers	Thank you for the valuable information confirming our assessment in the report (see Annex 5a, Part 4.4), which sets derogation for	Thank you for information. We support derogation for mercury triple point cells that are used for the calibration of	Thanks for this valuable contribution and understand your concerns about mercury triple point cells. As you know there is a derogation for these

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		<p>applications which range from physics, engineering, and chemistry and their applications in manufacturing, climate change, hospital medicine and many more.</p> <p>Two particular aspects of the BIPM's work would be damaged significantly by a ban on mercury-based standards and we, speaking on behalf of our 54 States Parties to the Metre Convention and 31 Associates of the General Conference on Weights and Measures strongly support the proposed derogations for mercury triple point cells as suggested in the various documents associated with this issue. This community represents about 150 National Metrology and related Institutes which maintain and improve national measurement standards.</p> <p>There are two main reasons for our position.</p> <p>First, the BIPM is responsible for the International System of Units (the SI), created and supported by Governments through the General Conference of Weights and Measures in 1960. All measurable quantities used throughout science and industry can be derived from seven "base units". The unit of temperature, the kelvin, is one of these "base unit" of the SI and is realized through an internationally defined and accepted temperature scale, ITS90. The triple point of mercury is an extremely important defining fixed point within the scale and is used to calibrate platinum resistance thermometers (PRTs) at - 38.8344 degrees Celsius in carefully controlled conditions in many National Metrology Institutes and high level calibration laboratories, not just the VSL in the Netherlands that is mentioned on page 119 of the Annex XV restriction report.. This is a key fixed point, and the range of temperatures covered between it and the melting point of gallium at 29.7646 degrees Celsius are</p>	mercury triple point cells that are used for the calibration of platinum resistance thermometers.	platinum resistance thermometers from the proposed restriction. It is clearly expressed in Part A of Annex 1 in section A.1.2 point 2. of the BD.	devices in the proposal.

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		<p>amongst the most important and covers, for example, much of the area of interest for climate change monitoring and measurement. It is also applicable to many medical measurements. Without an ability to make these measurements using mercury triple point cells, large parts of the ITS could not be realised and, as a result, disseminated to users. If there were to be a ban on the production and use of this material for triple point cells, then the parts of the world covered by the ban could be legally unable to realize the ITS which has been adopted by Governments world-wide. Restrictions would bring enormous consequences for the calibration of PRTs which then routinely support many millions of temperature measurements in industrial medical and other areas of precise measurement. In relation to health issues, the production and use of these cells is carefully controlled, almost always under relevant ISO/IEC quality standards and the personnel are thoroughly trained and aware of the effects of mercury on health and the environment. At the moment, and despite significant efforts, an alternative has yet to be identified.</p> <p>Secondly, the BIPM operates a Mutual Recognition Arrangement between some 200 laboratories worldwide that have the responsibility, allocated by Governments, to realize, maintain and disseminate the SI. The MRA demonstrates, inter alia, the equivalence of these realizations as there can be small but significant differences in the way in which laboratories realize the definitions and make their measurements. Some 22 000 “calibration and measurement capabilities” (CMCs) of these laboratories are peer reviewed and listed in a data base maintained by the</p>			

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		<p>BIPM. Accreditors, legislators and regulators use these data to minimize technical barriers to trade and if European laboratories could not provide calibrations in these key ranges and can declare their CMCs to the rest of the world, then many thousands of European companies would be severely disadvantaged as they would have no way in which to demonstrate the traceability of their measurements to the world-accepted references of the SI. Additionally, if use of triple point cells was restricted or banned in the EU, then European measurement scientists would have to rely on calibrations and traceability to ITS as realized elsewhere in the world. This would lead to larger uncertainties in the measurements which would be damaging to those European enterprises which require the highest possible accuracy, and lowest uncertainty, of measurement.</p> <p>I hope, therefore, you can see why I and my colleagues in the metrology community are gravely disturbed by any proposals for restrictions. They would have a highly negative effect for the reasons stated above. We therefore fully support the proposed derogation as an essential element in metrological uniformity and in ensuring accurate measurements- paradoxically many of which are in the field of human health and safety.</p>			
47	2010/10/27 17:42 Att. Ref47 Netherlands / Academic institution /		Please see the actual comment and the response below under the heading specific question 3.	Thank you for demonstration of the safer laboratory practice.	As DS
46	2010/10/25 12:17		Please see the actual		As DS

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43	2010/10/13 20:35 Att. Ref43 United States /.../	<p>need to be calibrated against the true pressure. This is normally done by reference to a mercury filled tube that shows the real pressure. Without a mercury barometer, many manufacturers and repairers will be unable to calibrate an aneroid or other non-mercury movement correctly. A tube filled with water could be used, but this would have to be around 36ft tall, making it unsuitable in most situations.</p> <p>The European Commission, Directorate-General for Health & Consumers has released it's report :Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR), Mercury Sphygmomanometers in Healthcare and the feasibility of Alternatives, 23 September 2009. This multinational collaborative study included 17 committee members and an additional 6 External Experts, from 5 E.U. member countries. Amongst the key conclusions they found: “ It is recommended that mercury sphygmomanometers remain available as a reference standard for clinical validation of existing mercury-free blood-pressure measurement devices. Therefore, the mercury sphygmomanometer should remain available as a reference standard until an alternative device is recognized as such.” “For certain patient groups, blood pressure measurement by a trained observer, using mercury sphygmomanometers or a validated auscultatory alternative, remains the most</p>	<p>available on the market designed for operation in both absolute & gauge pressure and are suitable for the calibration of high accuracy barometers and Air Data Test Sets. Certain types of barometers combine the metrological performance of pressure balance with the convenience of digital instrumentation.</p> <p>The suggested restriction for the sphygmomanometers has derogations to devices on the basis of the opinion of SCENIHR that the commenter refers to. These derogations are: 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. There are validated</p>	We agree and support the response of DS.	Thank you for the comments and we agree with DS's response.

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		<p>accurate and reliable form of indirect blood pressure measurement.”</p> <p>“Blood pressure measurement is vital for the prevention and treatment of blood pressure related diseases, and for monitoring of cardiovascular homeostasis. Based on long-term experience, blood pressure measurement using a mercury sphygmomanometer is currently regarded as the gold standard for indirect measurement of blood pressure.”</p> <p>“There are a number of physiological and pathological states that may influence the ability of an oscillometric (automated) device to obtain and equivalent reading to a mercury sphygmomanometer. Oscillometric measurements are dependant on movement, and changes in amplitude of this movement, in the artery, and therefore maybe altered. Oscillometric measurements cannot be relied on it patients with arrhythmias, some valvuar heart disease such as aortic incompetence. Other patients with altered vascular compliance, such as diabetics, or the elderly, could have less accurate blood pressure readings using oscillometric measurement. Changes in vascular compliance may also be confounded by oedema, intravascular volume, hyperdynamic circulation and by changes in cardiac output such as pre-eclampsia, in which oscillometric (automated) readings frequently underestimate the blood pressure.”</p>	<p>mercury-free alternatives available that are based on the auscultatory technique, which can replace mercury sphygmomanometers in all applications.</p> <p>Oscillometric devices are described in the report, but they are not seen as fully technically feasible substitutes for mercury sphygmomanometers.</p> <p>Thus, the suggested restriction is in line with the opinion of SCENIHR.</p>		
		<p>SPECIFIC COMMENT</p> <p>Clinical sphygmomanometers must be exempt from this ban or restriction as their benefit out weighs any risks.</p>	<p>According to Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR), the mercury</p>	<p>We support opinion presented by DS.</p>	<p>The comment is a statement without any arguments. We agree with the DS’s response.</p>

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			<p>sphygmomanometers are needed to be used (i) in long-term, epidemiological studies which are on-going on entry into force and (ii) as reference standards in clinical validation studies of mercury-free sphygmomanometers.</p> <p>According to our assessment, for all other applications of mercury sphygmomanometers, the alternatives are both technically and economically feasible, and the potential health and environmental benefits are higher than the costs. For details, see Annex 3a and 3b of the report.</p>		
42	2010/10/07 14:16 United Kingdom / Industry or trade association /	<p>The imposition of a ban on the selling, buying of mercury containing pycnometers and metering devices of less than 50 years of age may have a deleterious effect on the heritage industry.</p> <p>The relevant definition currently in REACH is Placing on the Market.</p> <p>Placing on the market: means supplying or making available, whether in return for payment or free of charge,</p>	<p>Thank you for the information on the problems related to applying one age limit for all types of measuring devices. To allow e.g. technical museums to obtain historically and</p>	As DS.	<p>Your interpretation of the definitions in REACH concerning the ‘placing on the market’ and ‘use’ is correct. As responded by DS, a derogation is proposed for measuring devices which are to be</p>

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		<p>to a third party. Import shall be deemed to be placing on the market;</p> <p>The practical impact of this ban would mean museums would not be able pass on objects from their collections to other heritage institutions.</p> <p>Existing health and safety legislation deems storage and display of historic items as “use”.</p> <p>Few museums would seek to “use” the pycnometers and metering devices of less than 50 years of age in their collections for practical or industrial application. However, they do “use” them.</p> <p>The existing definition of use includes storage and display.</p> <p>Museums that store and display historic scientific, engineering and medical objects may have hundreds of pycnometers and metering devices of less than 50 years of age in their collections.</p> <p>By dint of them being either in storage or on display, they are being used.</p> <p>A complete ban on the sale, purchase of these historically recent objects would lead to a loss of objects of significant historic and scientific value.</p> <p>We are seeking a clarified definition of the word “use” for the REACH regulations to take into account its application in the heritage (museums and galleries) industry.</p> <p>We are seeking a blanket exemption for historic object storage and display activities for all REACH duties.</p> <p>We are seeking that sale and purchase of pycnometers and metering devices of less than 50 years of age be allowed.</p> <p>Please do not hesitate to contact me if you require any further information.</p>	<p>culturally valuable devices for their exhibitions, a derogation is proposed for measuring devices which are to be displayed in exhibitions for cultural and historical purposes.</p>		<p>displayed in exhibitions for cultural and historical purposes.</p>

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41	2010/10/05 14:12 United Kingdom / Industry or trade association /	Does the restriction apply to the supply of new instruments within the EU or does it also restrict the use of existing instruments for which no alternative method is available?	The suggested restriction would apply only to the placing on the market of the mercury devices, not to the use of existing devices. These existing instruments can be used until the end of their service life. However, existing devices are not allowed to be placed on the market anymore. It is also stressed that when the devices reach the end of their service-life, they have to be disposed of in accordance with the waste legislation i.e. as mercury containing hazardous waste.	We support response of DS.	As DS.
		SPECIFIC COMMENT My company operates two ISO17025 accredited Schvien mercury manometers within a controlled laboratory environment for high accuracy pressure metrology purposes, predominantly the calibration of aircraft altimeter, Rate of Climb and airspeed instrumentation. There does not exist on the market an alternative method that can generate the same absolute pressures down to 1.7 kPa absolute with the same level of uncertainty or ability to apply gradual	Thank you for bringing out the concern on technical feasibility of mercury free alternatives for specific applications of mercury manometers. However, according to two independent	We support view presented by DS	We concur with the response of the DS.

* (A) The proposal; (B) Information on hazard and risk; (C) Available information on alternatives; (D) Justification for action on a Community-wide basis; (E) Why a restriction is the most appropriate Community-wide measure; (F) Socio-economic Assessment of Proposed Restriction; (G) Stakeholder consultation; (H) Other information

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

Comments and response to comments on Annex XV restriction report on **Mercury in measuring devices**
 Annex XV report submitted by ECHA on 15 June 2010.
 Public consultation on Annex XV report started on 24 September 2010.

Ref	Date Country/ Org./ MSCA Comment type	Comment	DS Response	RAC Rapporteurs comments	SEAC Rapporteurs comments
		analogous pressures in a rising and falling direction in order to determine transducer micro-hysteresis and repeatability. To restrict the use of these particular manometers would seriously impact on the traceability of pressure calibrations within the UK and European aerospace industry and be detrimental to the economic performance of our company.	laboratories, the mercury-free alternative devices are suitable for performing the mentioned calibrations. Please see attached document for details. R to COM Ref.41 The mercury containing devices can be used until their service life, as it is not proposed to restrict the use of existing devices. The proposal is also suggesting 18 months transitional period before restriction becomes effective. This will give time to industry and service providers to adapt to the regulation.		
40	2010/09/24 14:07 / / Individual	I welcome the fact that the original proposal to ban the use of mercury electrodes for polarography has been changed and that no restriction on this use is now proposed (Table 3 in Annex XV). There is no substitute for mercury in polarography and it is a very important technique in chemistry.	Thank you for the supporting comment. Please note that there has not been any “original proposal” suggesting restrictions on mercury electrodes for polarography.	Thank you for comment.	So far no alternatives are available, so there is no restriction proposed.

* (A) The proposal; (B) Information on hazard and risk; (C) Available information on alternatives; (D) Justification for action on a Community-wide basis; (E) Why a restriction is the most appropriate Community-wide measure; (F) Socio-economic Assessment of Proposed Restriction; (G) Stakeholder consultation; (H) Other information

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Specific question 1: Thermometers exclusively intended to perform tests according to analytical standards (ISO, ASTM, etc.) that require the use of mercury thermometer are suggested to be derogated from the proposed restriction until 5 years after the date of adoption of the restriction (the exemption might thus expire somewhere around 2018).

Please provide information in support of the derogation, or information that indicates that a derogation is not needed. Do you foresee any problems with the expiring of the derogation?

See Annex 5a, pages 131-133 of the dossier for a description of the issue.

Ref	Date Country/ Organisation/ MSCA	Comment	DS Response	RAC Rapporteurs comments	SEAC Rapporteurs comments
107	2011/02/15 15:53 United Kingdom / National NGO / (E), (G)	Museums would like to be able to acquire, and transfer items containing mercury between museum organisations with all necessary precautions in place to manage the hazard due to mercury. This would include objects of all ages up to the present.	To allow e.g. technical museums to obtain historically and culturally valuable devices for their exhibitions, a derogation	As DS	As DS

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			is proposed for measuring devices which are to be displayed in exhibitions for cultural and historical purposes.		
98	2010/12/25 00:58 United Kingdom / Company / (A) (D) (E), (F)	The alternatives are just not accurate enough and do not comply with the specifications of IP and ASTM.	Electronic thermometers are generally more accurate than mercury-containing thermometers when properly calibrated (Lassen et al, 2008,). Although traditionally many standards have prescribed mercury thermometers in analysis, many standards now allow for the use of alternatives (Lassen et al., 2010). There seems to be a need to amend standards that would not yet allow for alternatives to be used. In order to allow sufficient time to amend the standards, it is proposed to have a time-limited derogation (until 5 years after the date of adoption of the restriction) for	As DS	As DS

* (A) The proposal; (B) Information on hazard and risk; (C) Available information on alternatives; (D) Justification for action on a Community-wide basis; (E) Why a restriction is the most appropriate Community-wide measure; (F) Socio-economic Assessment of Proposed Restriction; (G) Stakeholder consultation; (H) Other information

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			thermometers exclusively intended to perform tests according to analytical standards (ISO, ASTM, etc.) that require the use of mercury thermometers.		
86	2010/12/21 12:44 / / Individual	I think that in 5 years, the problem will remain for technical reasons as there are no alternative to reimplace mercury for thermometers. Several manufacturers are looking for other solutions since years.	We have no indications that there would be essential uses. We came to the conclusion that there are alternatives for all applications of mercury thermometers. The question was related to the concern that time is needed to amend certain analysis standards (ISO, ASTM, etc.).	In our opinion there are feasible technical alternatives for all types of mercury containing thermometers	As DS
85	2010/12/21 12:21 / / Germany MSCA	The given 5 year deadline for the restriction of mercury thermometers which are need to perform tests according to analytical standards is to insufficient. Due to the norm for the determination of the flash point the amount of work is very high. First the norms have to be revised in which mercury thermometers have to be used. Afterwards the updated norms have to be implicated into EU-directives no. 1272/2008 and no. 440/2008 in order to get legal force. Further an adaption of the transportation directive has to be	Firstly, according to our information, currently many (if not all) standards for flash point determination allow for the use of electronic devices with similar temperature response as the mercury thermometers. Secondly, the Test	There is a need to justify more precisely a time-table for updating analytical standards requiring use of mercury thermometers as well as a list of such standards.	Agreeing with DS's response.

* (A) The proposal; (B) Information on hazard and risk; (C) Available information on alternatives; (D) Justification for action on a Community-wide basis; (E) Why a restriction is the most appropriate Community-wide measure; (F) Socio-economic Assessment of Proposed Restriction; (G) Stakeholder consultation; (H) Other information

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		done.	<p>Method Regulation (Regulation (EC) No 440/2008) does not seem to require the use of a mercury thermometer. There are several methods, and for each method there are several standards. Importantly, the Regulation mentions that deviations to the methods are possible (“the method used should be stated as well as any possible deviations”). Concerning Regulation (EC) 1031/2008 it seems sufficient that 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. Amendments to the Annex I to this Regulation</p>		

* (A) The proposal; (B) Information on hazard and risk; (C) Available information on alternatives; (D) Justification for action on a Community-wide basis; (E) Why a restriction is the most appropriate Community-wide measure; (F) Socio-economic Assessment of Proposed Restriction; (G) Stakeholder consultation; (H) Other information

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Ref	Date Country/ Organisation/ MSCA	Comment	DS Response	RAC Rapporteurs comments	SEAC Rapporteurs comments
			occur several times a year ⁵ . 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. On this basis there appears not to be need to prolong the timelimited derogation related to standards.		
50	2010/12/02 11:57 Ireland /	No			Thanks for your confirming answer.
43	2010/10/13 20:35 United States /.. /	no			Thanks for your confirming answer.

⁵ [1] <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31987R2658:en:NOT>

* (A) The proposal; (B) Information on hazard and risk; (C) Available information on alternatives; (D) Justification for action on a Community-wide basis; (E) Why a restriction is the most appropriate Community-wide measure; (F) Socio-economic Assessment of Proposed Restriction; (G) Stakeholder consultation; (H) Other information

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Specific question 2: A derogation to restriction is proposed for industrial mercury-in-glass thermometers used in industrial applications for temperature measurements above 200°C as demonstrated by the reading scale. The reasons for proposing this derogation is the high estimated costs of replacing with alternatives.

Please provide additional information on average device prices, lifetime, mercury content per device, calibration frequency, and calibration costs of both industrial mercury-in-glass thermometers and their alternatives. Do you foresee changes in this information in the next 5 years?

Please provide information on the savings (e.g., labour cost savings) arising from the use of automated electronic alternatives compared to the use of manual mercury thermometers in industry.

Are you aware of any reasons for users to buy industrial mercury-in-glass thermometers that can measure temperature above 200°C, even though they have no need to measure temperature above 200°C?

Ref	Date Country/ Organisation/ MSCA	Comment	DS Response	RAC Rapporteurs comments	SEAC Rapporteurs comments
107	2011/02/15 15:53 United Kingdom / National NGO / (E), (G)	See answer 1	See the response above.		
98	2010/12/25 00:58 United Kingdom / Company / (A (D) (E), (F)	Certain IP and ASTM tests require thermometers to be used above 200C. No one needs a thermometer to measure above 200C if they are not going to use it above 200C, its rather obvious.	There are technically feasible mercury-free alternatives available also for measurements at temperatures above 200°C. In order to allow sufficient time to amend the analytical standards, it is proposed to have a time-limited derogation (until 5 years after the date of adoption of the restriction) for thermometers exclusively	As SEAC Rapporteurs	As DS. We would like to note that the derogation for thermometers above 200°C in the original proposal has been removed.

* (A) The proposal; (B) Information on hazard and risk; (C) Available information on alternatives; (D) Justification for action on a Community-wide basis; (E) Why a restriction is the most appropriate Community-wide measure; (F) Socio-economic Assessment of Proposed Restriction; (G) Stakeholder consultation; (H) Other information

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Ref	Date Country/ Organisation/ MSCA	Comment	DS Response	RAC Rapporteurs comments	SEAC Rapporteurs comments
			intended to perform tests according to analytical standards (ISO, ASTM, etc.) that require the use of mercury thermometers.		
86	2010/12/21 12:44 / / Individual	the derogation should be applied not only for thermometers above 200°C. Because there is also the question about accuracy. Some thermometers need an accuracy till 0.05°C and 0.01°C. Only mercury can provide a such accuracy, also for thermometers under 200°C. (refer to astm standards)	According to our information accuracy for industrial mercury-in-glass thermometers is not an issue. In addition electronic thermometers are generally more accurate than mercury-containing thermometers when properly calibrated (Lassen et al, 2008, see footnote 1).	We support the view of the DS and find no reasons for exempting the mercury-in-glass thermometers used in industrial applications for temperature measurements above 200°C	As DS
50	2010/12/02 11:57 Ireland / Company /	N/A			Thanks.
43	2010/10/13 20:35 United States /.. /	no			Thanks.

* (A) The proposal; (B) Information on hazard and risk; (C) Available information on alternatives; (D) Justification for action on a Community-wide basis; (E) Why a restriction is the most appropriate Community-wide measure; (F) Socio-economic Assessment of Proposed Restriction; (G) Stakeholder consultation; (H) Other information

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Specific questions 3: Mercury porosimeters are not suggested to be restricted in the restriction report

Please provide information on technical and economic feasibility of alternatives for mercury porosimeters. Please specify the application area in question, and the measured parameters.

Please provide information on releases or exposure of mercury (based on monitoring or modeling) during the use or waste handling phase (including recycling/in-house purification).

Ref	Date Country/ Organisation/ MSCA	Comment	DS Response	RAC Rapporteurs comments	SEAC Rapporteurs comments
112	2011/03/24 16:08 Belgium / International NGO (A) (B), (C), (F)	See comments on porosimeters in our general comments.	See the responses above.		
50	2010/12/02 11:57 Ireland / Company /	N/A			Thanks.
47	2010/10/27 17:42 Netherlands / Academic institution /	I work on tables that have a stand-up edge. The area I work in with mercury has a tresshold, separating it from the rest of the lab. In my opinion working in a fumehood is not the best option as the vapours are very heavy. I have designed a table with a suction under the working area. Some photo's Iwill include. Considering the use of a filter: a good filter will create some pressure drop over the filter, so it will lower the suction rate.	Even though no restriction is proposed for the use of mercury in porosimetry, any information on measures to reduce the risks posed by mercury to the human health and the environment are most appreciated. The provided information is presented in the BD.	This suggestion may only be used in recommendations on technical reduction of emission and occupational exposure to mercury due to use of non-restricted Hg containing measuring devices.	Thank you for your information and the illustrative photos.
46	2010/10/25 12:17 / / Individual	We use a mercury porosimeter to characterise porous polymeric materials with pore sizes in the range 0.01 to 100	Thank you for the information supporting	Thank you for the information	Thank you for your valuable information.

* (A) The proposal; (B) Information on hazard and risk; (C) Available information on alternatives; (D) Justification for action on a Community-wide basis; (E) Why a restriction is the most appropriate Community-wide measure; (F) Socio-economic Assessment of Proposed Restriction; (G) Stakeholder consultation; (H) Other information

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Ref	Date Country/ Organisation/ MSCA	Comment	DS Response	RAC Rapporteurs comments	SEAC Rapporteurs comments
		microns. The materials can be either hydrophobic or hydrophilic. The data from these characterisation experiments is vital for research work in a range of areas, including biomedical science, chemical technology and materials science. This work is funded by UK national funding agencies, the EU and industry. As is highlighted in the report (Annex 7: Porosimeters), there is no single validated technique that can replace mercury porosimetry for these materials. A ban on the use of mercury in porosimeters would have a significant negative impact on our research into porous polymeric materials. For this reason we are pleased that no such ban is currently proposed. Of the two risk management options proposed, we would favour Option 2: Information gathering with further assessment of the technical and economic feasibility. Further evaluation and validation of the various proposed replacement techniques could be conducted.	our assessment on the current status in technical feasibility of alternatives for mercury porosimeters. We would like to encourage all the relevant stakeholders (including producers and users) to actively participate in future efforts to assess and develop the mercury free alternatives.		Further we agree with the response by the DS.
43	2010/10/13 20:35 United States /.. /	no			Thanks.

* (A) The proposal; (B) Information on hazard and risk; (C) Available information on alternatives; (D) Justification for action on a Community-wide basis; (E) Why a restriction is the most appropriate Community-wide measure; (F) Socio-economic Assessment of Proposed Restriction; (G) Stakeholder consultation; (H) Other information

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Specific questions 4: Plethysmographs designed to be used with mercury strain gauges are suggested to be restricted in the restriction report.

Please provide information on the technical and economic feasibility of alternatives to mercury strain gauges, in particular indium-gallium strain gauges, used with plethysmographs.

Ref	Date Country/ Organisation/ MSCA	Comment	DS Response	RAC Rapporteurs comments	SEAC Rapporteurs comments
114	2011/03/24 18:07 United States / Company / (C)	For some strain gauge plethysmograph applications, indium-gallium is an alternative strain gauge material. There are limitations in the size of indium-gallium gauges, and the temperatures that they may be used at. It is true that we can manufacture a strain gauge made with indium-gallium in sizes smaller than 6 cm. However, the resistance of indium-gallium is much lower and our plethysmograph cannot make measurements from such a small indium-gallium strain gauge. The resistance of mercury is higher, so our plethysmographs can make measurements with the small mercury-type gauges. Indium-gallium is also substantially more expensive than mercury. The price difference of the finished strain gauge is 30% more for the Indium-Gallium type gauge. The cost difference is much greater, however. We use the product by volume: Mercury: US\$ 0.90 per cubic cm Indium-Gallium: US\$ 14.95 per cubic cm The indium-gallium is 117% more expensive than mercury.	Thank you for the valuable information. According to our understanding, there are other alternatives available for measurements where small strain gauges are needed, including laser-Doppler and ultrasound equipment. Based on the prices available on a webpage of one supplier of strain gauges, the price difference of mercury and indium-gallium strain gauges are around 17%, somewhat lower than your estimate.	As DS	
89	2010/12/21 12:44 Sweden/ Academic institution/	Concerning Annex XV restriction report: Mercury in measuring devices part Annex 4: Strain gauges (used with plethysmography). Paragraph 3: Strain-gauges with Indium-Gallium are available as an alternative to mercury strain-	Thank you for the very useful information confirming the information in the	Thank you for the suggestion to slightly modify the scope of the restrictions: restrict	Thank you for this relevant information. Your research project comparing these devices

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		gauges in existing as well as new plethysmography devices. Thus the electronics and physical properties of the measuring devices are identical regardless of the actual alloy used in the rubber tubes/strain gauges. Currently in Sweden, to our knowledge, one ongoing research project will compare indium-gallium and mercury gauges during 2011 and there are no methodological research studies documented in the international research community. "The mercury-free products are fully competitive in terms of quality"; The currently most promising alternative Indium-Gallium is not yet independently validated for research. "...no information available if specific mercury-free strain-gauges..."; Strain-gauges with Indium-Gallium alloy can be used in existing and new plethysmographs. 4.1.2 Options for restrictions: section 1. Ban on placing on the market new plethysmographs: A ban of plethysmographs is not realistic because research in arterial/endothelial function is since long time depending on strain-gauge plethysmography (note that the plethysmographs as of 2010 may be equipped with possibly equivalent indium-gallium strain-gauges). 4.2 paragraph 2; In Sweden we estimate a need for additional time for validation of indium-gallium techniques in comparison with mercury until December 2012. "...the restriction option is targeted only to new devices..."; Again, the plethysmographic technique with strain-gauges is well established in circulation research and a ban of the technique would severely affect European clinical circulation research. 4.3 paragraph 1: same comment as above 4.2 paragraph 2 – we suggest the ban is placed on mercury filled strain-gauges in a timely manner	footnote of Annex 4 of the report, reporting that indium-gallium strain gauges can be used with existing plethysmographs. We have accordingly revised the restriction proposal to restrict the mercury strain gauges instead of plethysmographs. However, it is good to note that the proposed entry was intended to restrict only those plethysmographs, which relies on the mercury strain gauges.	mercury strain gauges instead of plethysmographs. We took this into account The time table for introducing this restriction should be considered having in mind that the technical alternative might be available only in December 2012.	this year looks promising, and the outcome (report) might be too late for our considerations. Further we concur with DS's response.

* (A) The proposal; (B) Information on hazard and risk; (C) Available information on alternatives; (D) Justification for action on a Community-wide basis; (E) Why a restriction is the most appropriate Community-wide measure; (F) Socio-economic Assessment of Proposed Restriction; (G) Stakeholder consultation; (H) Other information

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		allowing for proper validation. Proposal paragraph: because plethysmographs for use with indium-gallium strain gauges are technically identical with devices for mercury strain-gauges we suggest that the proposal is revised.			
50	2010/12/02 11:57 Ireland / Company /	N/A			Thanks.

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Specific question 5: Please provide any information on occupational exposure to mercury (e.g. exposure levels and duration, number of persons exposed) from mercury containing devices. Please provide information on costs of preventing and reducing such exposure. Please provide information on any collection systems (e.g. take-back systems, separate collection) for mercury measuring devices, including possible economic incentives (e.g. fees, financial stimulation).

Ref	Date Country/ Organisation/ MSCA	Comment	DS Response	RAC Rapporteurs comments	SEAC Rapporteurs comments
114	2011/03/24 18:07 United States / Company / (C)	The sale of Hokanson strain gauges into Europe brings in only very small quantity of mercury, nearly all of which can be cleaned and reused. We encourage all Hokanson customers to send their spent strain gauges back to Hokanson so we can recycle (cleaned for re-use) the mercury in the gauges. Indium-gallium cannot currently be recycled.	Thank you for the information, The possibility of the customers to return the mercury strain gauges to you is mentioned in the BD.	As DS	As DS
111	2011/03/24 12:13 Hungary / Company / (B), (C), (F), (G)	For the mercury CV systems, detailed measurements prove that there is no operational exposure during normal operation, and even in worst case system malfunctions exposure is only possible for a very limited time and does not exceed the respective limitations.	Thank you for the information provided on this specific technology. The application is described in the BD. Based on the provided and available information on the alternatives (see new annex 10 of the BD), it does not seem appropriate to propose any restriction on this use, and consequently the proposed restriction is not amended.	As DS	As DS
98	2010/12/25 00:58	Costs are not available for "fees and financial stimulation"	Thank you for the information.		As DS

* (A) The proposal; (B) Information on hazard and risk; (C) Available information on alternatives; (D) Justification for action on a Community-wide basis; (E) Why a restriction is the most appropriate Community-wide measure; (F) Socio-economic Assessment of Proposed Restriction; (G) Stakeholder consultation; (H) Other information

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	United Kingdom / Company / (A) (D)(E), (F)				
86	2010/12/21 12:44 / / Individual	We propose a "depollution kit" for mercury in case of breakage of thermometers. We also propose a take back system with an agreed company for re-shipment.	Thank you for your comment.	Thank you for your comment.	Thank you for the information.
50	2010/12/02 11:57 Ireland / Company /	1 person exposed for approximately 10mins per day	The COD test kit is not in the scope of the restriction report.	We agree with the DS	As DS
46	2010/10/25 12:17 / / Individual	We use a mercury spill tray to contain stray mercury during sample clean up, which is conducted in a fume cupboard. Waste mercury is recycled using a commercial service.	Thank you for the information on handling and recycling practices for mercury used in porosimetry. Similar practices have also been reported and described in the Annex 7 and Appendix 3 of the report.	Thank you for suggestion to strengthen a description of the safer handling mercury while using porosimeters.	As DS.

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