

EEB comments on Restriction Proposal for Hg in measuring devices

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Proposed submission via the public consultation by EEB

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.
 - 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.
 - 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.
 - 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.

These issues are discussed in more depth below.

Mercury in the waste stream, and mercury use in porosimetry

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..

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

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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.

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:

*... 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.*

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 different¹. However, again, they could indicate that a significant quantity of mercury is being lost from porosimetry, possibly much more than the amount from sphygmomanometers.

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 properly accounted for.

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. 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

¹ Some data are excluded from totals and averages as they are said to be unrepresentative. The fact that they are unrepresentative (which we do not dispute) does not mean that they are wrong. These cases could provide useful insight on the variability of mercury use in porosimetry.

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.

Derogations in the dossier

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.
6. Regarding SCENIHR conclusion 4:
 4. *Are mercury-containing sphygmomanometers essential as reference devices for validation of long-term clinical epidemiological studies enrolling patients with hypertension?*

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.

EEB has published a significant amount of work in this field² 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.

In addition, if this derogation is to be accepted:

- a) Any purchase of such a device should be accompanied by a certificate showing the purchaser and purpose of use; and
- 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”.

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- [EEB-HCWH Letter to Commissioners 'Environmental and Health NGOs call for a rapid process to phase out of mercury-containing blood pressure devices in healthcare'](#), 13 November 2009,

- [Report from the conference 'EU Mercury phase out in Measuring and Control Equipment'](#) October 2009

- [EEB study: 'Turning up the pressure: Phasing out mercury sphygmomanometers for professional use'](#) Executive summary in [FR](#), 18 June 2009

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

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.
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.*

Benchmarks

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.

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.

Inconsistencies

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

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could be better structured to give readers a clearer understanding of which estimates are preferred and hence the scale of the problem.

11. Different parts of the dossier come to different 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.