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 five

Phenylmercury compounds

ECHA/RAC/RES-O-0000001362-83-02/S2

ECHA/SEAC/[reference code to be added after the adoption of the SEAC opinion]

SUBSTANCE NAME	IUPAC NAME	EC NUMBER	CAS NUMBER
Phenylmercury acetate	Phenylmercury acetate	200-532-5	62-38-4
Phenylmercury propionate	Phenylmercury propionate	203-094-3	103-27-5
Phenylmercury 2-ethylhexanoate	Phenylmercury 2-ethylhexanoate	236-326-7	13302-00-6
Phenylmercury octanoate	Phenylmercury octanoate	-	13864-38-5
Phenylmercury neodecanoate	Phenylmercury neodecanoate	247-783-7	26545-49-3

4 July 2011

Substances:
Phenylmercury acetate, EC number: **200-532-5** CAS number: **62-38-4**
Phenylmercury propionate, EC number: **203-094-3** CAS number: **103-27-5**
Phenylmercury 2-ethylhexanoate, EC number: **236-326-7** CAS number: **13302-00-6**
Phenylmercuric octanoate, CAS number: **13864-38-5**
Phenylmercury neodecanoate, EC number: **247-783-7** CAS number: **26545-49-3**

General comments

Ref	Att	Date	Country/ Organisation/ MSCA	Type	Comment[1]	Dossier Submitter (DS) Response	RAC Rapporteurs comments	SEAC Rapporteurs comments
113	N	2011/ 03/24 16:13	/ / Individual	(A) (B), (C), (F)	1. It is unclear why the restriction is proposed for the particular set of phenyl-mercury compounds. I am concerned that we could have a succession of separate proposals for restrictions on mercury compounds with a propensity to form methyl-Hg, when a more effective and efficient strategy may arise from a more comprehensive treatment. [Perhaps this needs to be done ahead of dossier submission, so is too late for the current restriction proposal. However, it remains relevant for future dossier submissions.]	Based on information in the report "Options for reducing mercury use in products and applications and the fate of mercury already circulating in society" (Cowi and Concorde East/West, 2008, also referred to as Lassen et. al (2008)) the uses of certain phenylmercury compounds as catalysts in polyurethane systems were identified as significant applications of mercury. It was stated that certain phenylmercury compounds are manufactured and used in extensive amounts and no other mercury compounds (except for mercury itself)	We have exactly the same concern. So in the RAC opinion an important consideration is added: "RAC considers that if the five substances mentioned above were to be replaced by other organomercury compounds this restriction could become ineffective. Therefore, in addition to the conditions	Agree with DS response. The restriction addresses five phenylmercury compounds which are considered as showing the same hazards to environment and health and, further, which are used extensively.

[1] Plese note that any page numbers or section numbers in the comment column refer to the annex XV report published on the ECHA website.

* (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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						were identified as being used in such large volumes in Europe. The extensive use of some of these phenylmercury compounds were confirmed during further consultations in connection with the elaboration of the Annex XV dossier. As a follow-up of initial comments regarding other organomercury compounds that may be used as alternatives more information has been collected and are included in the revised Background document (BD) (Part C). We agree that in principle a comprehensive treatment of mercury and mercury compounds with regard to restrictions on manufacture, use and mixtures and articles containing them would be desirable. At this stage also the legal aspect of a change in the scope must be taken into account.	mentioned above, RAC recommends considering necessary measures for verifying and controlling that other organomercury compounds are not used as alternative to the restricted substances."	
					2. It appears that the dossier does not address all uses of the phenyl-Hg compounds under consideration, noting comments by others about use in (e.g.) cosmetics. We are concerned not only about the risks that this may involve, but	The proposal is to prohibit manufacture, use of the substances as well as placing on the market of mixtures and articles containing the substances above a concentration limit of .0.01% of Hg. The consultations	The Cosmetic products entry is mentioned in our opinion. As indicated by DS the concentrations are below the limit	Agree with DS response + see other DS responses on the same issue.

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					also that a piece-meal treatment of chemicals may reduce the efficiency and effectiveness of the REACH legislation, e.g. requiring a series of restrictions to be worked on when one would do.	with industry did not reveal other uses of these compounds in Europe of significance. However, the use in eye cosmetics was indicated by UK in the early comments. Regulation 1223/2009 concerning eye cosmetics sets a condition of maximum 0.007 % (of Hg) in eye cosmetic products. Considering the different concentration limits it is evident that the proposal is not directly in conflict with the provisions in the cosmetics directive. However, it is recognised that the inclusion of manufacture, placing on the market and use would limit the availability of these phenyl mercury compounds for these kinds of products. The actual need for use in eye cosmetics today, and consequently the implications in this area has not yet been investigated further.	concentration proposed in this restriction.	
					3. A clear justification for the limit value of 0.01% Hg by weight is necessary. We assume that it links to a particular analytical method, in which case it would be useful to know why that is preferred over others with possibly different detection limits. Perhaps	A limit value of 0.01% Hg was chosen as all identified analytical methods (both field and laboratory instruments) have detection limits below 0.01%. As the phenylmercury compounds included in this restriction proposal are	In our opinion, we underline that this 0.01% limit is sufficient regarding the concentrations needed to obtain the catalytic	RAC issue.

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					agreement is needed on ways of standardizing the reporting of limit value setting in restriction dossiers in order to improve consistency.	primarily used as catalysts in the polyurethane production, and the mercury concentrations in polyurethane articles normally are more than 10 times higher than the proposed limit value, the limit value is sufficiently low to prevent the use of the phenylmercury compounds as catalysts. The use of e.g. phenylmercury acetate in cosmetic products (the only other identified application area for these phenylmercury compounds) is regulated by Regulation 1223/2009 that allows at maximum 0.007 % (of Hg) in eye cosmetic products. A new appendix 10 "Analytical methods (mercury)" is added to the revised BD to include more information.	activity.	
					4. In places (e.g. Table B5.30) it is implied that DNEL and DMEL are equivalent terms. However, establishment of a 'minimal-effect' level implies a judgment on what constitutes 'minimal'. For example, risks may appear low, but this on its own is no indication of the outcome of the comparison of costs and benefits. 'DMEL' therefore	The headlines with DNEL/DMEL are remnants from the CSR template that has been filled in. This was commented on also in the eRCOM. Following that we have intentionally left both DNEL and DMEL in these tables, as well as introduced a paragraph in the revised BD (see paragraph below) that asks	RAC based its risk justification on a non-threshold approach because of the PBT, LRT, biomagnfication properties and neurodevelopmental effects of metabolites;	Please see the response from the RAC rapporteurs regarding the DNEL/DMEL in this specific dossier. In general, a restriction proposal

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					entails some socio-econo-political judgement and it is nto clear how RAC can reach this without SEAC input.	RAC to consider whether these effects have a threshold or not and which concept that should be applied, DNEL or DMEL. We agree that the derivation of a DMEL could have implications for SEAC as well as RAC. We also think that establishment of a DMEL is a societal and ethical issue that should not be left up to single MSCAs to decide. Reproduced from the BD, section B.5.11: "So far no apparent threshold has been identified for neurotoxicity in children exposed to me-Hg in utero (Castoldi et al., 2008; Rice 2004). The threshold for neurological effects from mercury vapour has also been questioned recently (Richardson et al., 2009). The concept of DNEL or DMEL for mercury was introduced in this report in order to mention previous assessment works; however the chosen approach is a non-threshold approach."	so a focus on DNEL/DMEL is not needed in this dossier.	has to demonstrate that there is an unacceptable risk to HH or the ENV that has to be addressed on a community-wide basis. As far as the unacceptable risk is concerned, SEAC has to rely on the input from RAC and considers this input further in its own evaluation of the restriction proposal.
					5. It is unclear whether organotins are considered as a technically viable alternative. If so, there should be more detailed consideration of the risks	The risks of organotin compounds in general are high and the use of several organotin compounds are regulated in the EU, this is stated in Section C.4.	RAC highlighted that – with reference to the updated annex XVII organostannic entry -	Agree. This has been addressed by RAC.

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					associated with their use.	Catalysts based on organotin compounds seems no longer to be specifically marketed as alternatives for the current uses of phenylmercury catalysts, cf. Section C.1 and C.1.2, C.1.2.4, C.1.2.6 and C.4. However, there is some conflicting information the BD concerning the actual use of organotin compounds as catalyst. The uses of these compounds as alternatives are clearly not desirable. Reference to REACH Annex XVII entry 20 (organostannic compounds) are included in the background document, and more detailed consideration of the risks of the use of organotins are included in section C.1.2.4, C.3.2 and C.4.	these compounds are not suitable alternatives.	
					6. In section F2.1 we are told that: "It is assumed that any reductions in MCPUE systems under the baseline scenario relate to those MCPUE systems where it is "relatively easy" to substitute with an alternative mercury free system. It is thought that around 30% of MCPUE systems available in 2007 (i.e. 75 systems) would be difficult to replace. It is	This assumption is based on what is considered to be the most likely behaviour. In practice some producers may choose to substitute their systems early even though the substitution is challenging. However we consider the assumption that the systems that are easiest to replace will be the first to be substituted as fairly robust.	We also were unsatisfied with the description of the difficulties to substitute. This is not a critic to DS, as we know the difficulties to request that kind of information from industry; and	Agree with DS response. Further, it was not possible to obtain information from industry on what a "difficult-to-replace" system might be.

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					considered reasonable to assume that any reductions in the absence of a restriction would relate to those MCPUE systems where it is easier and less costly to switch to an alternative. Therefore, it is assumed that the most difficult systems (totalling 75) will be last to be replaced." This leads to a question of what constitutes a 'difficult' system, and to what extent substitution has already occurred in such systems, noting the behavioural dynamics of environmental controls in various industries, where companies vary greatly in their willingness to adopt difference practices.		sometime even with good will industry is not able to produce such information. We thus build our opinion only on what is clearly known: 70% substitutions in 2-3 years, and we thus propose to shorten restriction to a 3-year delay before implementation. This is also justified by a scientific and political context which is at least 20 years old and which has thus let a lot of time to anticipate a way to avoid mercury in processes and products.	
					7. Section F2.2 deals with 'sunk costs'. From a social perspective these are not relevant – money spent cannot be unspent.	No sunk cost is expected to occur as the result of the proposed restriction.	/	Sunk costs are costs which have been incurred but which cannot be reversed. They are irreversible costs contrary to

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								other costs which may be recovered in some cases.
					8. Treatment of effects does not appear to have been done in a comprehensive way. Noting the statement: "The risk characterisation for consumers indicates that phenylmercury acetate release from articles in the indoor environment may cause adverse health effects to consumers" leaves open questions about the exposure of workers in production and transportation of the chemicals, and manufacturing and installation of the flooring. Although it may not be possible to quantify these effects they are still relevant to the proposal – even if it is considered for any reason that these risks are negligible, it would be useful to be told.	Following the early comments, risk characterisation of workers have been included in the revised BD. Risk assessment of the following occupational exposure scenarios now may be found in sections B.9.3.2.1-2.2.Open application of the PU systems for casting of PU parts (ECETOC-TRA Tool estimates), and Release from PU elastomer gym flooring (measurments). These mercury-catalyzed PU floors were laid in 1960-1980, so we assume that no workers are exposed today during the laying of new floors. However abatement workers and teachers in gymnasiums might be exposed and this is now described in the report.	We confirm the improvements regarding both consumer and occupational exposures. In our opinion we mention these possible risks as additional arguments beside all brought under the non-threshold approach.	RAC issue.
					Also, where reference is made to the results of Rice and Hammitt, comment should be provided that they did not considered ecological benefits at all and that quantification of the benefits through reducing IQ loss deals only with effects on	This is correct, however in the dossier we refer to Appendix 2 of the restriction dossier for mercury in measuring devices where this issue is highlighted. In the revised BD this reference is made more clearly and it is	/	Agree with DS response.

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					earnings.	not referred to the Rice & Hammitt study explicitly.		
					9. It is hard to understand Table F6. In particular, why the benefit/kg changes from scenario 1 to scenario 2 if there is (as stated) no discounting. More significantly, though, the principal of direct adoption of estimates from other studies is of questionable value without consideration of the way that these estimates were derived, and whether the methods and assumptions used are consistent with those followed elsewhere in the dossier (e.g. on risk assessment) and in the available guidance.	The difference between the two scenarios is the amount of mercury released to the environment. This is explained in the footnotes below the table. This table is not included in the revised version of the BD. As stated in the document we do not consider the estimates from this study to be directly transferable to the restriction proposed. Therefore we do not calculate the net benefit of the proposed restriction. In the revised BD Table F.6 is replaced by a more general interval of potential benefits from Appendix 2 in the restriction dossier for mercury in measuring devices.	We had the same kind of comment and thus proposed some modifications in what we could call the "baseline" and how we can really compare the benefits of the different options in term of avoided emissions. This alternative approach is described in our opinion and the BD is amended accordingly.	Agree with DS response.
85	N	2010/ 12/22 15:53	/ / Germany MSCA	(B), (C), (F)	Comment for the German CA:	We would like to thank the German CA for useful comments.	/	
					• In the dossier it is not explicitly mentioned why the restriction aims for those particular five phenylmercury salts. Since the hazard assessment is mainly based on the reaction into methylmercury and mercury it would	Based on information in the report "Options for reducing mercury use in products and applications and the fate of mercury already circulating in society" (Cowi and Concorde	The grouping of these five phenylmercury compounds – based on usage and chemical breakdown similarities -	SEAC rapporteurs agree with DS response. The choice of the five phenylmercury

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					seem sensible to include further substances. The probable reason is economic relevance but this is not elaborated. Since the hazardous nature of mercury (and methylmercury) has already been agreed upon by several international (and EU) bodies it might be sufficient to rationalize the need for action with reference to the goals already agreed upon (e.g. EU-strategy on mercury, Global Mercury Assessment by UNEP, etc.). To assess the relevance of the problem it would be helpful to give some information of the production and usage scale of the phenylmercury compounds considered in relation to the overall mercury problem. For example Lassen et al. (2008) estimate a mercury production of roughly 370 tonnes in the EU. The overall production of Hg-chemicals amounts to 12% of this.	East/West, 2008, also referred to as Lassen et. al (2008)) the uses of certain phenylmercury compounds as catalysts in polyurethane systems were identified as significant applications of mercury. It was stated that the phenylmercury compounds are manufactured and used in extensive amounts in Europe and that no other mercury chemicals are used in such large volumes in Europe. 33 phenylmercury compounds or mixtures (reaction masses containing phenylmercury compound) were preregistered to ECHA in 2008, none of the preregistered phenylmercury compounds were registered in 2010. This information is included in Appendix 9. At this stage the legal aspect of a change in the scope must be taken into account. Environmental emissions from the manufacture and use of the five compounds that were identified has been estimated and compared to estimated or reported total emissions from anthropogenic sources, more information in this regard is included.	was further justified by DS. In addition, RAC is in favour of extending the scope to all other organomercury because on a long term the same metabolites will raise the same risks. As it isn't possible to widen the initial proposal, RAC has added an important consideration in their opinion: "RAC considers that if the five substances mentioned above were to be replaced by other organomercury compounds this restriction could become ineffective. Therefore, in addition to the conditions mentioned above, RAC recommends considering necessary measures for verifying and controlling that	compounds is justified and based (*inter alia*) on tonnages and industry's statements on their uses.

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							other organomercury compounds are not used as alternative to the restricted substances."	
					• Several times the impression is given that the overall production of phenylmercury salts may phase out by itself in a time-frame similar to the restriction proposal with a five year transition period (e.g. one comment in the Stakeholder consultation was "It is likely production will not continue beyond 2013"). This should be more prominently discussed (e.g. as an RMO of its own).	Without a restriction (proposal) we think that at least the use (and manufacture) of the phenylmercury compounds for certain areas where substitution is more difficult would probably not phase out by itself. Moreover, no quantitative data are available on imports of articles containing the substances but this may constitute a significant amount. It is expected that the decline in use in imported articles will be less pronounced than the assumed baseline for manufacture and use in EU + EFTA.	Calculations are provided to estimate the emissions that may occur if no restriction is applied and it should be notice that these estimations may be even underestimated if one considers that use decay rate may slow down because of the substitution difficulties for some applications.	This 'probable' spontaneous phase-out is based on industry's statements and on the (already observed) decreasing trend in phenylmercury compounds uses. However, as DS says, it might only concern the sectors where substitution is easy to implement. For the others, a restriction proposal is needed to impulse incentives to substitution.
84	N	2010/ 12/21 12:14	/ / Ireland MSCA	(A) (B), (C), (D) (E),	The Irish Competent Authority (IECA) would like to thank the Norwegian CA for the work it has undertaken to prepare this Annex XV dossier to propose a restriction on phenylmercury compounds.	We would like to thank the Irish CA for useful comments.	/	/

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Comments and response to comments on Annex XV restriction report
on **5 Phenylmercury compounds**
Annex XV report submitted by Norway on 15 June 2010.
Public consultation on Annex XV report started on 24 September 2010.

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				(F)				
					In general, we support the principle that a permanent EU restriction on phenylmercury compounds should be introduced to address the risk to the environment and humans via the environment.	Thank you for the support.	RAC rapporteurs acknowledge the support of The Irish Competent Authority.	/
					We would also like to contribute the following comments and observations in relation to the Annex XV restriction dossier under the specified headings:		/	/
					A. Suggested restriction		/	/
					A.1 Wording: We suggest one small text change to paragraph 1 and 2 (in bold), as follows:	Text of proposed restriction is amended.	Rapporteurs support these small modifications.	/
					Shall not be manufactured, placed on the market, or used, as a substance or in mixtures in concentrations greater than 0,01 % weight by weight (w/w) after [5 years of the entry into force].		Agree; Please notice that RAC is proposing an option-3 in which the implementation period is reduced to 3 years (instead of 5)	The final proposal is slightly different from both the original proposal by Norway and that proposed by the commenter. The wording proposed in SEAC's draft opinion follows the advice of the Forum.
					Articles, or homogenous parts of articles, containing the substance(s) in concentrations greater than 0,01 %		Agree; same note as above.	Please see the response above.

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					weight by weight (w/w) shall not be placed on the market [5 years of the entry into force].			
					A.2 Affect of other EU legislation on reducing the identified risk: We would like to suggest that the dossier would have benefited from inclusion of a section which discusses the aims of the current proposal in comparison to how the:		It's to note that DS included additional discussion on other legislations.	/
					• Regulation 1102/2008 on the banning of exports of metallic mercury and certain mercury compounds and mixtures and the safe storage of metallic mercury will contribute to reducing the risk associated with mercury compounds.	According to Regulation (EC) No 1102/2008 the export ban covers metallic mercury, cinnabar ore, mercury (I) chloride, mercury (II) chloride and mixtures of metallic mercury with other substances including alloys of mercury, with a concentration of at least 95 wt % Hg.	As answered by DS, the proposed restriction covers an area which isn't taken into account by Regulation EC/1102/2008.	We agree. This legislation has been extensively discussed in SEAC and it would have been appropriate to have it mentioned in the BD (although it does not cover the phenylmercury substances in its present version).
					• Other EU risk management instruments (e.g. establishing EU environmental emission/occupational limit values) will contribute to reducing the risk associated with phenylmercury compounds.	European indicative occupational limit value for mercury and divalent inorganic mercury compounds already in place (Commission Directive 2009/161/EU). The Scientific Committee on Occupational Exposure	We agree that focus is today rather on environmental emissions, and even with this concern in mind IPPC or WFD	Indeed, several RMOs which are relevant for the risks targeted in the proposal are described and

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						Limits (SCOEL) also proposed biological limit values (in SCOEL/SUM/84, 2007: 10 µg Hg/l blood; 30 µg Hg/g creatinine in urine), but these have so far not been implemented in European legislation. Establishment of an occupational limit value (indicative or binding) for the discussed phenylmercury substances would probably not contribute a lot to the risk management of these substances as the greatest concern regards emission to the environment, including from service life of articles and waste, and subsequent degradation to inorganic mercury. Other existing community wide risk management options like directive on integrated pollution prevention and control, water framework directive and their effect on reducing the identified risk are described in detail in part E1.	need to be completed by a direct restriction of manufacture and uses because of the PBT and LRT properties of breakdown products.	evaluated in section E.1, but of course more could have been mentioned.
					A.3 Limit value: We note that a justification for the choice of limit value of 0.01% Hg (w/w) for the restriction proposal is not included in the dossier. It would have been beneficial if the dossier had clarified	More information is included in the revised report.	It should here be said that expected concentrations (range of concentration needed to obtain the catalytic	Relevant and important question indeed. See DS response.

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					whether the choice of limit value was linked to the risk identified or the limit of detection of the analytical method?		function) in parts of articles are between 0.1 and 0.5%.	
					A.4 Scope and conditions of restriction: Paragraph 2 of the restriction states: 'articles or homogenous parts of articles containing the substance(s) in a concentration above 0.01 % Hg weight by weight (w/w) shall not be placed on the market after [5 years of the entry into force]'. In our opinion, this wording may result in some confusion as to whether the aim of the restriction is to restrict mercury content in articles or the phenylmercury content in articles. We would like to suggest that further consideration is given to this wording of the restriction.	The wording has been amended in order to clarify that the restriction aims to restrict the phenylmercury compounds, however, because of the current inadequacy of analytical methods to quantify the content of the phenylmercury compounds in PU-articles and the possibility that the compounds may be partly degraded in the articles, the concentration limit is proposed to relate to mercury.	Mercury quantification can be made by several methods and protocols for measuring in plastic samples are well known. For phenylmercury compounds quantification may be less standardised and possibly only semi-quantitative as degradations may occur during manufacture process or during service-life of articles. The more pragmatic solution would be to measure mercury and if necessary to confirm the presence of some phenylmercury compounds in a second step.	Agree with the possible confusion. For the reasons explained by the DS, the concentration limit proposed concerns mercury and not phenylmercury. This is clearer in the proposal presented in SEAC's draft opinion.

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					A.5 Pre-registrations: We suggest it would have been beneficial for the dossier to have included information on whether or not the substances have been pre registered and if so, by how many pre-registrants?	Easily available information on preregistration is included (the number of pre-registrants is not available). None of the organomercury substances are registered.	This subject is also bound to the grouping issue which is notably described in Tang and Nielsen, 2010; & appendix 12. Preregistration information are not clearly indentified in dossier, however following dialogue-2 it was decided to add some data which were prepared by DS on preregistrated mercury compounds which may be used as alternatives.	Information is available in Appendix 9.
					B – Information on hazard and risk		/	/
					B.1 Exposure Assessment: We suggest it would be useful if the Annex XV dossier gave some indication about what reductions have been seen in mercury exposure in ambient air as a result of the global measures to reduce mercury emissions by comparing ambient air monitoring data undertaken by Member States under Directive 2004/107/EC.	General information about mercury exposure in ambient air as a result of global measures would be of interest but is considered to be outside the scope for this restriction proposal.	As this restriction can be justified by the PBT and LRT properties of the breakdown products and exposure of man via environment, it can be acceptable not having occupational exposure data.	Agree with DS response.

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					B.2 Emissions: The environmental quantitative conclusion indicates that emissions to the environment "are below what is predicted to cause an effect". As phenyl mercury is only one source of mercury emissions to the environment, in order to justify the restriction of this particular fraction, we suggest it would have been beneficial for the dossier to include an estimate of the total emissions of mercury to the environment from all sources.	This would require collection of a lot of information and much work and is considered to be outside the scope of the restriction proposal for these specific compounds.	We agree that comparison with all other sources is important to understand the part of this restriction in global mercury reduction. However we also acknowledge the difficulties to collect information on all other sources which are numerous. We thus had suggested just further developing the discussion about the "4-7% contribution to European air emissions"; and this was made by DS.	This information would indeed have been interesting in order to understand the contribution of phenylmercury in mercury emissions to air but the SEAC rapporteurs also agree that this would have induced important and not necessary work. There is a difference between information which is "nice to know" and information that we "need to know"
					B.3 Emission factor: In Section B 9.2.2 we suggest that it would be beneficial to reference the data used to derive the air and waste water 0.0016% & 0.00015% emission factor.	Site specific information has been used to derive the emission factors for manufacture, details are confidential since there are < 4 manufacturers.	Manufacturing industry provided some data which justified decreasing these emission factors. However the quality of these data is not	RAC issue.

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							sufficient and cannot be considered as representative of the whole manufacture in Europe, therefore rapporteurs consider that there's a risk to underestimate these emissions and that this point should be taken into account when discussing the final estimation of the whole emissions in Europe from phenylmercury compounds life-cycle; this is particularly important as manufactured quantities are more than 4 times the quantity used in Europe (around 3/4 are exported). This was done by rapporteurs.	
					B.4 Indoor air concentrations: Section B.9.3.2.2 (Consumer exposure) of the dossier presents an exposure scenario for	We agree that based on the information we have been able to obtain it is not possible to conclude that this is a	On one side data were measured after a rather long time (so	Agree that the exposures might be overestimated for this

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					the use of phenylmercury catalysts in polyurethane flooring. The dossier states that "PU flooring with mercury catalysts has been previously widely used in school gyms and sport arenas in the USA (and probably also in Europe). Polyurethane flooring is widely applied in the EU today, but different non-mercury catalysts seem to be used for this application..." The dossier submitter considers this use of phenyl mercury compounds as a "worst case" exposure scenario. However, it is not clear from the information presented in the dossier whether phenyl mercury catalysts are still used in PU flooring in Europe. Therefore, while we agree that this scenario could be considered a worst case exposure scenario for consumers, it is not possible to conclude whether it represents a "realistic worst case" exposure scenario.	"realistic worst case". However, since only for this use actual measurements are available we consider them as being useful and relevant for consideration of a potential (and historical) use. However, it should be recognised that the measurements were made in gyms long time after they were new, exposures may be assumed to have been much higher in rooms with new floorings, this will be pointed out in the text.	underestimate when compared to a brand new article), and on the other side the surface/volume ratio and the frictions maybe very important for flooring (so overestimate when compared to an article). At the end, using as reference emissions from gym flooring appears as an interesting strategy to help estimates from articles.	use. . This is however more of a RAC issue.
					B.5 Minimum risk level (MRL): In Section B 9.3.2 we suggest that the dossier indicates whether the MRL figure of 200ng/m3 relates to elemental mercury.	ATSDR has established a chronic inhalation MRL of 0.2 µg/m3 for metallic mercury. This is specified in B.5.11.	DS precised the information.	RAC issue.
					B.6 2005 emission tonnage: In Section B 9.3.2.3 In order to quantify what 4% of European emissions in 2005 equates to we	This is further clarified in the revised report. More data and comparison with reported total air emissions from	DS provided additional data and discussion about the emissions	Acknowledged.

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					suggest it would be useful if the dossier indicated what the 2005 emission tonnage is.	anthropogenic sources in EU-27 for 2008 (and 2005) is now included in the revised report.	coming from phenylmercury compounds compared to the global air emissions.	
					B.7 EU consumption tonnage: In section B10.2 a figure of 16-31.5 tonnes per yr is quoted as the EU- EFTA consumption. In Appendix 1 'Predicted environmental concentrations' section a total consumption figure of 33 tonnes per year is reported. As both figures account for minor imports we suggest that it would have been beneficial if the dossier had included some clarification as to the differences in the two estimations.	We apologize for this confusion. The inconsistency was due to the fact that the figure of 16-31.5 tonnes covered only the use of phenylmercury neodecanoate in the EU + EFTA, whereas the figure 33 tons assumed some use of phenylmercury acetate and phenylmercury ethylhexanoate as well. The basis for the different calculations has been clarified in the revised report.	Inconsistency was clarified by DS.	Acknowledged.
					C – Information on alternatives		/	
					C.1 Catalysts based on organotins: Organotin based catalysts are suggested as alternatives to mercury catalysts in the Annex XV dossier. In our opinion, the dossier would have benefited from a discussion on how Regulation 276/2010 amending Annex XVII for Organotins will influence the future availability of organotin-based catalysts.	In our view such discussions is outside the scope of the restriction proposal. Catalysts based on organotin compounds are no longer specifically marketed as alternatives for the current uses of phenylmercury catalysts. However, the uses of these compounds as alternatives are clearly not desirable and more detailed consideration of the risks of the use of organotins are included in the background document	In RAC's opinion and in the revised BD was added a mention to the entry 20 of annex XVII and a statement that this is a clear signal that organostannics are not suitable alternatives.	Agree with DS response.

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						section C.1.2.4, C.3.2 and C4. Reference to REACH Annex XVII entry 20 (organostannic compounds) is included in the background document.		
					D – Justification for action at EU level		/	/
					D.1 Member states manufacturing, exporting, importing: In order to fully justify the restriction for community wide action, we suggest it would be useful to have a table indicating the Member States where each phenyl mercury compound is manufactured, exported, imported and used including an estimated tonnage.	We have not been able to obtain such detailed information. Industry contacts have pointed out that mercury catalysts are widely used in the UK, Spain and Italy; relatively little used in Germany, although the overall industrial output is very high; while France is somewhere in the middle. The information obtained indicates that formulation probably takes place by 50 to several hundred companies, processing may take place by hundreds to thousands of companies.	This information is not needed to build an opinion on this restriction: As users are several thousands in several European countries, it's justified to restrict at the European level.	Acknowledged.
					D.2 Restriction on manufacturing: We are of the opinion that the case for including manufacturing in the restriction proposal is not clear in the dossier. We believe the fact that inclusion or exclusion will have the same effect is not sufficient justification for inclusion. We feel that the dossier would have benefited from a more thorough justification for extending the restriction	Not including manufacture in the restriction, with a restriction in place on the other life cycle stages, would mean continued manufacture of the substances for export only. However, as a result of long range transport of mercury this would not remove the pollution problems associated with these substances. Moreover,	Rapporteurs fully agree with these DS' arguments to also include manufacture in this restriction. One could also add that emissions from the manufacture stage maybe underestimated	SEAC rapporteurs agree that the question of the inclusion of manufacturing is a question for which justification might not appear so clear as industry states that

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					conditions to manufacturing based on the identified risks.	considering the hazards and risks with mercury we think that export can not be justified on ethical grounds. We have included separate calculations of cost and benefits related to a ban on manufacture in the report.	(see rapporteurs comment for Irish's CA comment on environmental emission factors).	export would not continue with or without a restriction on manufacture. anyway. However, significant efforts have been made to better justify the restriction on manufacture. SEAC rapporteurs agree that the problem of LRT has to be taken into account in the examination of that question, which is now included in the new analysis presented in the BD.
					E – Why a restriction is the most appropriate EU-wide measure		/	/
					E.1 Enforcement of restriction: If documentary evidence (e.g. safety data sheets/supply chain lists/certificates of compliance from suppliers etc.) does not clarify whether or not phenylmercury compounds with a concentration limit of	This may be an option.		RAC issue.

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					0.01% (w/w) is 1) being used in mixtures/articles being produced in the EU or 2) contained in mixtures/articles imported from outside the EU, then an enforcement inspector would need to sample the articles and test them. We suggest that specific information about sampling, sample preparation and testing could be contained in the FAQs on the Restriction pages of the ECHA website.			
					E.2 Analytical method: Section E.1.2 of the Annex XV dossiers states: 'Any limit should take into account the ability to measure the substance in the article matrix (i.e. PU) at these concentrations for enforcement purposes. A limit of 0.01 % weight by weight (w/w) is proposed'. We suggest it is not clear from the Annex XV dossier whether an analytical method exists for measuring the phenylmercury substances in articles at concentrations greater than 0.01% (w/w).	For more information on analytical methods etc. see revised background document.	Availability and pertinence of the methods to extract and measure phenylmercury compounds versus mercury were further discussed with DS and forum. For rapporteurs it seems more appropriate to measure mercury content because of availability of the method, independency of any breakdown during the process or within the articles, and possibility	RAC issue.

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							to include other mercury compounds used as catalyst.	
					We would also suggest that any analytical method that is developed should be robust and have the capacity to test for the presence of the phenylmercury compounds covered by this restriction. IE suggests that perhaps a way around this issue could be provided by using a single test for either mercury (or organic mercury) as an initial 'screening' test for samples suspected of containing the phenylmercury compounds. A positive test would then indicate the need for further, more time consuming and expensive, sampling and testing for each of the phenylmercury compounds.	Availability of analytical methods to quantify the phenylmercury compounds as such in PU seems not to be adequate for the time being but may be developed in the future. However, analytical methods to quantify Hg in PU are available. If Hg is detected in quantities above the concentration limits, information about whether this relates to the use of the phenylmercury compounds will have to be obtained from the relevant company that will have to present relevant documentation. A new appendix 10 is included with information on analytical methods for measuring mercury in articles, including detection and quantification limits.	If necessary a two steps approach could be put in place: firstly measuring mercury and if concentration is above 0.01% as second step to confirm that some phenylmercury compounds are present. Alternately, the second step could be that the company provides the proof of other sources of mercury in the process.	RAC issue.
					F – Socio-economic assessment of the proposed restriction		/	/
					F.1 Non-mercury PU systems: We suggest that the dossier would have benefited from further information on the economic feasibility of replacing PU systems, so as to	Further information is always good. But we have contacted all identified manufacturers and formulators (i.e. formulator of catalyst) of these	No comment.	This information would indeed have been beneficial but is apparently not

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					be able to use non-mercury catalysts. The dossier states that there is no indication that non-mercury PU systems cost more or less. Further investigation on this point would have been useful, as we believe the necessity of changing to a non-phenylmercury system may have significant cost implications for the estimated 200-250 mercury containing PU systems in the EU.	compounds. They state that they expect that it will be possible to substitute use of phenylmercury within 5 years. The lack of other comments from industry on this point so far indicates support for our finding.		available. Information obtained was double checked by the DS and no additional comments have been received during public consultation. Rapporteurs agree with DS response.
					F.2 Emissions avoided each year: Table E.2 on p.197 illustrates the mercury emissions avoided under option 1 compared to option 2. We suggest it would have been beneficial if the dossier had included a column showing emissions avoided each year under the no-restriction scenario, as we feel this is a key piece of information for assessing the benefits of introducing the restriction.	The no restriction scenario is the baseline for the calculations. This table shows the emission reduction related to option 1 and 2 in addition to the reductions in the baseline.	Please note that some assumptions about the baseline could be worked out a little differently (e.g. see comment to German MSCA)	Agree with DS response.
					F.3 Imported articles containing phenylmercury compounds: We note the lack of data available on the impacts of restricting imported articles containing phenylmercury compounds. Without this information, we suggest it is difficult to understand the degree of possible impacts for distributors, users etc.	There is a general lack of data related to imports of articles in the EU. We agree that this is a problem. It has not been possible for us to solve this problem during this work.	This lack of information should be considered as an additional argument supporting restriction.	Agree that data on imported articles would have been beneficial but could not be obtained. DS highlighted in the dossier that there is a lack of such

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								information and that no solution can be found to address it.
66	N	2010/ 12/20 13:55	/ / United Kingdom MSCA	(A) (B), (C), (E), (F)	We agree with the broad policy commitment to reduce mercury emissions to the environment, but we are uncertain whether reference to 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.	We would like to thank UK for useful comments. We think it is useful to put the proposal in a wider context with reference to EU mercury strategy and UN activities. The demonstration of degradation of the phenylmercury compounds in the environment to elemental/inorganic mercury is an essential part of the work on this restriction proposal.	We agree with UK comments on strategy to demonstrate the concern and the necessity to further clarify it, notably by firstly analysing the European concern and context and separately add some considerations about the global concern and context. RAC's opinion also clearly states that a non-threshold approach is used to demonstrate risk.	Agree with DS on the usefulness of looking at the issue in a wider context by referring to UN and EU mercury strategy. The reference to this wider context strengthens, to some extent, the importance of taking measure to address the risks generated by the five phenylmercury compounds identified.
					From the information in the Annex XV	The information that all uses of the	Our understanding is	This information is

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					dossier it is not clear whether all uses for phenyl mercury catalysts based on these five compounds can be substituted within the proposed 5 year time frame. We consider that the option for authorisation with restrictions for imported articles should have been explored in more detail since this will allow Member States to evaluate uses where substitution cannot be achieved on a case-by-case basis. Alternatively the dossier needs to consider whether there are uses for which derogations would be required. At present there is not enough information to make this judgement.	catalysts can be substituted within 5 years is obtained from consultations with industry, a need for specific derogations after this time frame has not been indicated. During the public consultations by ECHA and consultations that may be undertaken by the Commission there will be new possibilities for industry to provide information if there are uses that would need derogations, such information could be considered in the final framing of the restriction. We think that two parallel processes, one with inclusion into the Candidate list and Annex XIV and subsequent procedures with applications and granting/refusal of Authorisations, in addition to a restriction proposal for imported articles would be very resource demanding.	that according to the consultation made by DS the unique figure is that 70% applications can be substituted within 2-3 years (BD section E.2.2.1.1 "Risk reduction capacity"). Data are NOT sufficient to guarantee that 100% may be substituted after 5 years, and it's NOT possible to say how much more may be substituted if implementation period is prolonged from 3 to 5 years.	based on industry consultation and should be relevant.. SEAC rapporteurs agree with DS response that elaborating on the one hand an SVHC dossier for the five phenylmercury compounds and on the other hand a restriction dossier only targeted on imported articles might be inefficient and time/resource consuming. Especially as regards the authorisation process, DS provided some justification in section E.1.2. An overview of RMOs is given in section E.1.
					We note that very little information is available on consumer exposure. We	We agree that more information on consumer exposure would be desirable.	As commented earlier it seems an acceptable	Agree with DS response.

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					consider that the uncertainties in the current consumer exposure assessment are too great to make a robust assessment of risk for this group. Better justification needs to be provided for the assumptions made in the exposure assessment for consumers. Also better information needs to be provided on consumer access to uncured phenyl mercury catalysed products (adhesives and moulding products are identified in the Annex XV dossier as possible sources of consumer exposure) since an exposure assessment based on the release of mercury from cured articles will not be relevant for these uses.	Actual measurements are available only for the use in gym floorings, this use is considered as a potential "worst case" for consumers. An exposure scenario for use in rollers on swivel chairs has been estimated. Consumer exposure from uncured articles like adhesives could be of concern, however, to develop additional scenarios based on model calculations only seems to be of limited utility for the present restriction proposal. Moreover, according to available information the current use in adhesives seems to be small. According to a major supplier of catalysts, elastomers take up about 90% of the market of mercury catalysts while about 10% is used for sealants, while for adhesives and coatings, the mercury use is today small while organotin or amine catalysts are the major catalysts for these applications. Other information indicates that the mercury catalysts are still widely used for coatings.	approach to use the gym flooring data to estimate releases from articles. It should also be kept in mind that PBT properties of degradation products combined with environmental exposures are sufficient to argue in favour of this restriction, and thus that occupational or consumer exposures are here only as additional arguments.	
					Although the main use for these five phenyl mercury compounds appears to be in	Regulation 1223/2009 sets a condition of maximum 0.007 % (of Hg) in eye	It's possible that although listed in the	Agree that the restriction proposal

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					catalysts for polyurethane systems, we are aware of other current uses e.g. phenyl mercury acetate can be used as a preservative in eye cosmetics (see Annex V/17 of regulation EU 1223/2009). The dossier has not explored other uses for these phenyl mercury compounds in any detail nor the impact that the proposal could have on these uses. This needs to be done in order to fully assess this proposal.	cosmetic products. It is recognised that the inclusion of manufacture and placing on the market would limit the availability of these phenyl mercury compounds for these products. Use in eye cosmetics has not been indicated by industry during the consultations and the actual need for use in eye cosmetics today, and consequently the implications in this area has not been investigated further. The implications of the proposed restriction for these products has not yet been further analysed.	cosmetic products regulation, phenylmercury compounds are not in fact used. It can also be noticed that no comments on any unmentioned uses were made during the public consultation. .	might have some indirect impacts on outside-REACH areas such as this specific use. However, given that this use is outside the scope of REACH and of this proposal, a possible impact can be recognised but SEAC rapporteurs have doubts about the proportionality of further investigations.

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Specific comments

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85	N	2010/12/22 15:53	/ / Germany MSCA	(B), (C), (F)	Comment for the German CA:		/	/
					• Section B5.11 (Page 96). From the text it is clear that DNELs are derived. However, the presentation of the data mentions "DNEL/DMEL" in a way that one may think these to be equivalent terms. However, the meaning of these terms is clearly different. So, in our opinion, reference to DMEL is incorrect in this case and may communicate an incorrect message.	So far no apparent threshold has been identified for neurotoxicity in children exposed to me-Hg in utero (Castoldi et al., 2008; Rice 2004). The threshold for neurological effects from mercury vapour has also been questioned recently (Richardson et al., 2009). The application of the concept of DNEL or DMEL for mercury should be discussed by RAC on this background. We have used the concept DNEL.	DMEL clearly is of societal concern and need policy guidance (R.8: Characterisation of dose [concentration]-response for human health, ECHA 2010). It's thus not the rule of one Member-State or of RAC to decide on one specific dossier of these rules that may then have to be applied in other dossiers. RAC stressed in its opinion that the mention of these	RAC issue.

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							values doesn't overcome the non-threshold approach which drives this restriction dossier.	
					• Section B9.3.2.1. (Page 142). In this section it is said that no worker exposure data is available. However, in Section B9.3.2.2.(P. 143) it is said that use of phenylmercury compounds in flooring may be the worst case exposure scenario for consumers. If this is true, should one not expect a high exposure for workers applying these floors (not just one, but continuously)? Even if no detailed data are available, worker exposure may be expected to be relevant. We regret this was not mentioned.	These mercury-catalyzed PU floors were laid in 1960-1980, so we assume that no workers are exposed today during the laying of new floors. However abatement workers and teachers in gymnasiums might be exposed and this is now described in the report.	We agree: as no use as flooring is listed in Europe, there's no need to describe this occupational exposure. Thank you to DS for additional consideration regarding workers in gymnasiums.	Agree with DS response. See new information in the BD.
					• Section C1. Concerning the chapter on alternatives there are some inconsistencies: Organotins are mentioned to be possible alternatives, but are not discussed in any detail later on (the risks concerning organotin compounds are not addressed, etc). Because of the wide spread use of such catalysts in PU curing chemistry, they may deserve a greater attention, including their	Catalysts based on organotin compounds are no longer specifically marketed as alternatives for the current uses of phenylmercury catalysts. Part C is restructured to make the text in each section more consistent. A table comparing available information on health and environmental related properties of phenylmercury	Organotins were mentioned but are within the actual context not substitution candidates. See also previous comment on this issue (Irish MSCA	Agree with DS response. See new information in the BD.

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					known potential safety problems (e.g. Dibutlytindilaurate which is toxic by inhalation and a suspected endocrine disruptor). Furthermore, Ti and Zr are at first not mentioned but later on. Also a final comparison would have been helpful.	compounds and alternative substances has been included in section C.4 and information on the properties of organotin substances and alos other mercury alternatives is included.	comment C1).	
					Section F. The following aspects in terms of cost calculations in the socio-economic analysis part should be revised: - calculation of the R&D investments - calculation of avoided emissions - reference to the study of Rice and Hammitt - cost evaluation in the Chapter „Loss of Export Revenue" - calculation referring to one kilogram of mercury	See response to the following comment.	SEA issue: No comment.	See response to the following comment.
					Calculation of R&D-Investments The costs that are connected to the change to mercury free products are calculated as an R&D Investment. The estimation seems to be too low. In the cited COWI report, 7-8 weeks working time of a developer are taken as € 10000-15000 (Personal resources+ Overhead). Simple calculation shows that this is very optimistic. This represents about 0,15 ManYear, meaning 1 ManYear would be € 65000 – 97000. In view of the fact one needs a qualified, experienced chemist this	We agree that the R & D costs may be underestimated. However, these are the numbers attained from industry and they have been double checked by an additional consultation during the work with the SEA, and no indications have been given to suggest the numbers are too low. As we agree that the estimates may be underestimated we have used the high cost estimates only when revising the document. In calculating costs to be used in	SEA issue: No comment.	Agree that R&D costs might be underestimated but these figures have been reported by industry. To face this possibility only the high estimate is used.

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					does hardly seem enough to cover salary alone (also taking into account social insurances, etc). For R&D there are also significant costs for a laboratory infrastructure that need to be taken into account. The exact amount depends very much on the internal accounting rules of a company. Anyhow, one also has to take into account that apart from R&D costs, there will also be costs related to product introduction, like marketing, customer trials, etc. To take the "lifetime" of the "R&D Investment" as 10 years and calculate the corresponding amortisation over these 10 years does not seem correct. Chemical companies would plan und calculate such projects with a very limited pay-back time (2-3 years). Of course the expectation would be that such a system would generate additional profit for a much longer time. In this respect the pay-back time significantly depends on the revenues or the cash flow that are achieved with such a product. Taken an assumed development time of 7-8 weeks for each system, it is to be expected that some alternatives would be marketed and generate revenue much sooner than the 2-3 years mentioned, which	investment decisions by private firms a short payback time would be more correct. However in a socio-economic analysis the assessment period would be the expected economic lifetime of the investment.		

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					is not reflected in the calculations. Thus an exact economic calculation is not present. In reverse reasoning, a pay-back time of 10 Years/System means that such a system would only yield € 1000 – 1500 of profit/year. This does not seem to be plausible			
					The calculation of avoided emissions In the chapter on SEA-Environmental Impacts avoided emissions are compared for the first 20 years after the restriction. The calculation that forms the basis of this is not shown. Also the basic data are not sufficiently presented. So, for large areas this cannot be checked. The used amount in the represented timeframe has decreased and the prediction for the future strongly depends on the fact how alternatives will develop in the coming years.	This is amended in the revised document.	We agree, the chosen timescale and other parameters of the baseline are very important to assess the impacts (in terms of emissions for the risk assessment side) of the different restriction options. Thank you to DS for amendments.	Acknowledged.
					Reference to the study of Rice and Hammitt The description of benefit for human health is not comprehensive enough. Here, only the qualitative statement is made that from the restriction a net-benefit for human health is to be expected. At the same time,	The estimates from Rice and Hammit are only presented as an indicative benchmark, but we see the point of discussing the uncertainties and assumptions better and have amended this accordingly.	SEA issue: no comment.	Uncertainties are now better addressed in the BD.

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					one tries to quantify the benefits for human health via the amount of mercury, by referring to the study of Rice and Hammitt (2005). Also here, the basic assumptions that have been used in that study are absent. For example it is not clear how many people will be adversely affected by 1 kg of mercury On top of that, it is not clear if the follow-up cost of an illness (like loss of production, but also changes of quality in life, possible lost years of life or costs for "repairing the environment") are taken into account.			
					Cost calculations in Chapter „Loss of Export Revenue Also in relation to the „Loss of export revenue", the calculated costs do not seem transparent. For the calculation of socio-economic costs at the introduction of the restriction, indications are made that do not take into account other loss of revenue that originates in the value chain because of the restriction. (Suppliers (sales of raw materials), Labourers (wages), state (e.g. tax revenues), etc). On the other hand it is not clear on which assumptions the derivation of 50% profit margin is based. On top of that, in the calculation of	In our view it is plausible that the production of alternative catalysts will replace the production of mercury-containing catalysts in the EU. We therefore assume that the cost of lost revenue from mercury-containing catalysts will be offset by increased revenue from mercury-free catalysts. In terms of lost export we find it more plausible that this production will be replaced by mercury-containing catalysts produced outside the EU. Therefore we have assumed that there will be no increase in the export of	SEA issue: no comment.	Agree with the comment made by DE. Concerning the fact that "*the cost of lost revenue from mercury-containing catalysts will be offset by increased revenue from mercury-free catalysts*", it may be of course a disputable assumption, such as the assumption on the

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					„Loss of export revenue“, future revenues by the sales of alternatives should be taken into account.	alternatives in our calculations. This has been addressed qualitatively when revising the document. Due to no information on the cost structure we have assumed a linear 45 degree marginal cost curve in order to calculate the value added in production for export. This is of course a highly uncertain assumption.		marginal curve. In the SEAC rapporteurs' view, the most important is to be transparent and very clear on the assumptions made (as well as about the weaknesses of calculations and analyses). Some issues have been addressed qualitatively in the revised BD.
					The calculation based on one kilogram of mercury For the estimation of the total benefit it is necessary to compare the total value in € represented by avoided annual emissions in kg and benchmarks in €/kg Hg (€/kg * total kg, for each option) to the total annual costs by the industry. In the dossier the comparison has been done on the basis of costs per kg of mercury. In our view, such a representation obscures the total costs and is seen as not very helpful. In total, we state that a branch-overview,	In the revised document we will present the net present value of the total cost compared to the total reduction in kg Hg.	SEA issue: no comment.	Agree with DS response.

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					listing which companies would be concerned by the restriction, would be helpful for the evaluation and to estimate the distributional effects. In terms of safety and health protection of employees, some calculations are not transparent and many aspects are not taken into account. As a consequence this leads to the impression that the estimated costs of the proposed restriction are too low.			
66	N	2010/12/20 13:55	/ / United Kingdom MSCA	(A) (B), (C), (D) (E), (F)			/	/
					Section A.1.2 Scope of restriction		/	/
					The placing of a limit value for total mercury would prevent substitution of the phenylmercury compounds with other mercury-containing substances, which is logical. However, confusion is caused by referring only to the five phenylmercury compounds. We think it would be better if the restriction refers to any mercury compound for use in the specific applications that phenylmercury compounds	The scope of the present restriction proposal is not limited to specific applications but covers specific phenylmercury compounds. At this stage the legal aspect of a change in the scope must be taken into account.	We agree with this UK MSCA comment: a limit value for total mercury would prevent substitution with other mercury substances. As on a legal point of view, RAC cannot	We agree with DS response. The scope of the present restriction proposal is limited to specific Phenylmercury compounds and not to specific applications.

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					are used for. This would then avoid confusion about the need to develop any substance-specific analytical method.		propose a widening of the scope, RAC instead included this issue as an important consideration in their opinion.	
					The limit value proposed for mixtures or articles is 0.01% mercury w/w, although no scientific argument is provided to justify this value. However analysis for mercury content alone would not be sufficient to determine whether the mercury is present as one of the five restricted substances. Analysis for each of the phenyl mercury compounds would be required and this may not be technically feasible.	The wording is amended in order to clarify that the restriction aims to restrict the phenylmercury compounds, however, because of the current inadequacy of analytical methods to quantify the content of the phenylmercury compounds in PU-articles and the possibility that the compounds may be partly degraded in the articles, the concentration limit is proposed to be related to mercury.	See also the proposed 2-step approach discussed for the comment made by Irish MSCA.	The wording has been amended to increase clarity.
					What is the current detection limit for mercury in articles?	See new Appendix 10.	Can be around 10 times lower than the 0.01% proposed in this restriction.	Agree with DS response.
					Section A.2.1 Identified hazard and risk		/	/
					We recommend that this section is re-written and simplified, with references provided as appropriate. At the moment, it	More detailed information on the PBT properties of methylmercury is included in order to substantiate its	The risk approach is that there is no safe threshold and	RAC issue.

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					presents a range of information on problems associated with release of mercury compounds in general. Instead, we think it should concentrate on concisely expressing the identified hazards of elemental mercury and methylmercury, with a justification for their identification as SVHCs (or being of equivalent concern). This is important because the general premise of the proposal appears to be that there is no safe threshold for the observed effects (although we note that the dossier does mention "internationally accepted safe levels of methylmercury" in this section, which is then not referred to later). We understand that the dossier submitter is considering this, and we encourage them to strengthen the dossier in this regard.	hazard and its PBT like properties. It is clarified that there is no safe threshold for effects from methylmercury .	we thus also had encouraged DS to rewrite somewhat this section. This was well done with also the inclusion of additional information; we thus thank DS.	
					Once the SVHC status and relevance of the transformation products has been established, the risk assessment depends solely on the emission pattern of the phenylmercury compounds, in comparison with other sources of mercury. A quantitative risk assessment based on the properties of the phenylmercury compounds themselves is not relevant in our view,	We agree that a quantitative risk assessment of PMA is not as relevant as the risk from the transformation products. Therefore the quantitative risk assessment has been moved to appendix I and should be regarded more as supplemental information.	We agree that assessment should rather focus on the emissions of the transformation products. This was done by DS (e.g. Table B.60 shows the estimated	RAC issue.

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					because this is not the basis for the concern.		emissions' prediction).	
					The reference to 'wide dispersive' use of the catalysts (p. 10) needs clarification. How many sites actually use the catalysts? Use in industrial settings is not always considered to be a wide dispersive use pattern. We agree that the use of the final polymers and their presence in consumer products that can be considered as wide dispersive.	The exact number of sites using the catalyst is not known, but the information obtained indicates that formulation probably takes place by 50 to several hundred companies, processing may take place by hundreds to thousands of companies. We realise that use in industrial settings is not always considered as wide dispersive use. However, according to the draft document from ECHA concerning "General approach for Prioritisation of Substances of Very High Concern (SVHC) for inclusion in the List of Substances subject to Authorisation", it is stated that: "In general, comsumer use can be considered as wide-dispersive if it can be reasonably assumed that this use result in non-negligible releases. Professional use can be wide-dispresive as well if it takes place at many sites and is carried out by many workers and if it cannot be excluded that releases are negligible." It seems justified to consider the use of	We agree with DS' arguments: 1) number of users on one hand and significant release during service life on the other hand are in favour of a wide dispersive use. 2) as far as no proof is brought that professional uses are not wide dispersive, it should be rather considered that exposure can be at least similar to the ones foreseen for consumers.	Agree with DS response. Further, the estimation of sites is given in the dossier in B.9.5.1.

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						the phenylmercury substances as wide-dipersive.		
					Section A2.3 Justification that restriction is the most appropriate option		/	/
					The restriction appears to target up to approximately 4% of known anthropogenic mercury emissions to the environment, which seems relatively low. Based on our following comments, the contribution might even be lower. As mentioned below, authorisation might have been an alternative approach but this does not seem to have been thoroughly considered.	Environmental emissions have been estimated and compared to estimated or reported total emissions from anthropogenic sources, more information in this regard is included. Authorisation as an alternative RMO has been considered in Part E.	In the updated version, it was precised that emissions to air were estimated around 4% of the estimated European emissions of mercury in 2005 and around 7% of the reported emissions to air for EU-27 in 2008. It should be noted that DS clearly stressed that these are only rough estimations that should be used only as an indication. Moreover, as other mercury uses are	Authorisation is indeed examined as an alternative RMO but is considered as less effective and less practical (see Table E.3).

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							decreasing very quickly now, it could be that the phenylmercury contribution may in proportion even increase during the coming years.	
					Section B.1 Identity and physico-chemical properties		/	/
					(p14-24) Very little information is available, even for phenyl mercury acetate, so it is difficult to assess the justification for grouping of these five compounds on the grounds of similar chemical properties. In the table for phenyl mercury acetate there is nothing against flash point, is there information available or not?	Flash point for phenylmercury acetate is included. Aqueous dissociation constants have been estimated for the compounds based on theoretical calculations and are included in the revised document	We found sufficient information for grouping, especially with the added study on degradation in air and water predictions.	RAC issue.
					The dossier does not give validity markings for any of the physico-chemical data, nor robust study summaries. Have original study reports been assessed?	Original study reports have been assessed as far as possible for available literature on phenylmercury compounds. In the conformity check the technical dossier (including RSS) was concluded to be sufficient	Again, based on the study mentioned above + the EPISUITE estimations + some real data notably for phenylmercury-acetate, it seems	RAC issue.

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							possible to draw the physicochemical properties which are important for this risk assessment.	
					Is the reported vapour pressure for phenylmercury acetate likely to be caused by the substance or an impurity (e.g. acetic acid – we note that no information on impurities is provided)? Is it possible to say something about the likely vapour pressure of the other substances? This information is relevant for considering volatility during different parts of the life cycle.	According to new information three substances manufactured in EU are produced as pure substances (>99% purity). No data are available from manufacturers on any impurities. No data on vapour pressure for the other compounds have been found.	This information would of course be welcomed for reasoning on the life-cycle. Volatility may also come from the metabolites. DS highlighted well the limits of the description of the life-cycle.	RAC issue.
					Section B.1.6 Justification for grouping		/	/
					The grouping approach based on use pattern and structural similarity appears to be acceptable for the purposes of the dossier, but should additional substances be considered? For example, could other phenylmercury carboxylates (e.g. C4- to C7-carboxylates) or arylmercury	The possibility of using other mercury compounds has been further investigated and is now considered under "Alternatives" (part C). At this stage the legal aspect of a change in the scope must be taken into account. Mercury release from use of phenyl	We acknowledge the support for grouping these five substances and the mention of the possible pertinence to extend to other	RAC issue.

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					compounds be used as alternatives? We understand that the dossier submitter is considering this, and we think it is important for the final decision. Also, other compounds e.g. phenyl mercury nitrate (which is listed as an excipient in currently licensed eye drop formulations and injectable products in the UK at a concentration of up to 0.002%) or phenyl mercury benzoate (listed in EU 1223/2009 as a permitted preservative for eye cosmetics at a concentration of up to 0.007%) also have the potential to contribute to global mercury release.	mercury nitrate in eye drops and phenylmercury benzoate for eye cosmetics is considered to be out of the scope for this assessment.	phenylmercury carboxylates and arylmercury compounds. DS has pointed out that according to their survey and public consultation, this cosmetic application seems not to be used.	
					Section B.2.1 Manufacture and import		/	/
					Only article import is discussed - is it possible that polyurethanes containing these substances are imported for processing? Is all of the polyurethane made using these substances in Europe used there, or is some of it exported? This uncertainty could be reflected in the summary of emissions later.	The import of catalyst formulations containing the substances is indicated to be < 5 tonnes. The information from the consultations has not revealed any import of polyurethane formulations (two component systems) containing these substances for processing in Europe, however, this cannot be excluded. The information obtained concerning export covers export of the substances and of catalyst formulations containing the substances only. These	DS made the improvements in order to underline some uncertainties bound to the small volumes which may be imported in formulations.	Agree with the comment and agree with DS that the uncertainties are now better reflected in the Background Document.

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						uncertainties are reflected in the text.		
					Editorial: What are the units for Table B.2.1?	Tonnes	More exactly: tpa We added it in BD.	Acknowledged.
					Section B.2.2 Uses		/	
					It would be helpful to briefly indicate how the catalyst works – presumably it is not chemically bound into the polymer matrix? The text gives a maximum concentration of phenylmercury neodecanoate in polymers of 0.6% - presumably this should be 0.8% (given that the upper limit quoted for Thorcat 535 is 78%)?	Some description of how the catalyst works is included. It is not assumed to be chemically bound into the polymer. More information about the chemical form of the catalyst in the finished article is not available, based on well documented elevated levels of mercury vapour in gym floorings it can be assumed that they are (at least partly) converted to elemental mercury, either before or after release from the PU.	DS clarified description of catalyst. It's to note that the behaviour of phenylmercury catalysts during the process and the service-life of articles are unknown and that this is a difficulty in standardising a monitoring method based on phenylmercury compounds.	No further comments.
					The last sentence of the first paragraph on p. 28 says that 71 tonnes of phenylmercury compounds is equivalent to 33 tonnes of mercury. It would be helpful to indicate how this was calculated (we note that the mercury content of the various substances is mentioned in Section B.9.6.1 on p. 155, and	This is corrected and clarified. The amount of 31.3 tonnes mercury (70 *0,447 =31,29), based on the maximum figure of 70 tonnes phenylmercury neodecanoate for use in the EU + EFTA, are used for the calculations of emissions in EU+EFTA. The figure 71	We acknowledge that the estimated mercury content was based on neodecanoate form.	This has been corrected and clarified.

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					a cross-reference could be added). If the vast majority of the phenylmercury is in the form of neodecanoate, then this should be closer to 31.5 tonnes (the correct figure seems to be mentioned in Figure B2.1 – the text and figure need to be consistent). This has minor implications for the subsequent release estimates.	tonnes phenylmercury compounds and 33 tonnes mercury assumed some use of phenylmercury acetate and phenylmercury ethylhexanoate in EU + EFTA as well. Information about the total European PU market for CASE applications has not been obtained.		
					There is no information on the scale of use of the polyurethane made using phenylmercury compounds. Assuming a phenylmercury neodecanoate content in polymers of 0.1 – 0.78% w/w and a total amount of 70 tonnes, this would be equivalent to 9,000 – 70,000 tonnes of polyurethane as a worst case. It would be helpful to know how this compares with the total European polyurethane market for CASE applications.	Information about the total European PU market for CASE applications has not been obtained.	Rapporteur agree that knowing the total polyurethane use would have been useful especially for understanding how far substitution is already in place or how important the waste issue can be.	We agree that this is desirable (but not available) information.
					It might be helpful if ECHA could indicate the registration deadline for these substances, and how many companies have pre-registered them.	A new appendix (9) with information about pre-registrations and envisaged deadlines for the substances have been compiled. For 3 of the substances the envisaged deadline was 2010, however, there are no registrations for the compounds.	It's to note that if these compounds maybe classified for Reprotoxicity category 2 they should have been registered before 1st Dec. 2010.	See the new Appendix 9.

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					Section B.4.1 Degradation		/	/
					We appreciate that most of the studies in this section have been given a validity marking. However, in some case a 'range' is given for a study (e.g. Klimisch code 1-2) – in our view only one marking should be given. Also, occasionally the marking is missing (e.g. Baughman et al., 1973).	We agree that a range of Klimisch codes is unfortunate, but since different people were involved in this report this kind of divergency might appear. Klimisch code for study from Baugman is included.	We found acceptable the use of a Klimisch code range rather than a unique code.	RAC issue.
					Section B4.1.1.1 Hydrolysis		/	/
					The information presented in this section appears to conflict with that given in Section B.4.1.2.1, where it says that the substances easily dissociate in water to form phenylmercury ions. If this is the case, it calls into question the relevance of the log Kow/BCF estimates presented elsewhere in the report.	The section B4.1.1.1 is revised. New information is provided that explains dissociation and hydrolysis of all compounds. Furthermore, dissociation of the compounds is also taken into account when calculating BCFs in the revised version.	We confirm the revision of the BCF calculations.	RAC issue.
					There is an expectation that the other substances will behave similarly to phenylmercury acetate. Presumably the rate of hydrolysis could depend on the water solubility, adsorption potential, etc.? This could be briefly discussed, since it is relevant to the subsequent biodegradation discussion.	This is further discussed based on the new information obtained.	Prediction of degradation pathway is well documented in appendix-12.	RAC issue.
					Section B4.1.1.2.1 Phototransformation in air		/	/

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					Is this a relevant fate process given the vapour pressure of the various substances? Some comment should be added.	The relevance of this fate process is discussed. Additionally, new data on the phototransformation is provided that is based on quantum chemical calculations.	We agree that some differences may occur in the short first period after emission as solubility, vapour pressure and adsorption may be different; however as degradation may occur in a relative short time (usually around 1 day); the fate and behaviour of degradation products will much more drive partition, exposures and finally risks.	RAC issue.
					Section B4.1.1.2.2 Phototransformation in water		/	/
					Given the limited light exposure of substances in freshwater bodies, how relevant is this fate process?	A comment is added to this section dealing with the relevance of this fate process.	Regarding the reversible pathways, all movement between environmental compartments are	RAC issue.

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							possible; so phototransformation in water is not a key issue.	
					Section B4.1.2.2 Biodegradation in sediments		/	/
					Editorial: The discussion of diphenylmercury bioaccumulation should be moved from this section to Section B4.3.	The discussion of diphenylmercury bioaccumulation is moved to section B 4.3.	We confirm that this was done.	RAC issue.
					Section B4.1.2.3 Biodegradation in soil		/	/
					Is it likely that the different substances will degrade at different rates (e.g. due to differing bioavailability caused by different solubilities and sorption potential)?	The section is revised emphasizing the fact that all phenylmercury compounds are initially transformed to a common degradation product (phenyl mercury hydroxide) that is further degraded. Therefore minor differences in bioavailability are expected.	Of course the first fate & behaviour stages may vary among the different phenylmercury compounds, but as degradation may occur relatively quickly, reasoning can focus on metabolites.	RAC issue.
					Editorial: There seems to be a word missing in the second sentence “The presence of noticeably concentrations….”	The sentence is as follows: "The presence of noticeably concentrations of methylmercury in soil is restricted …"	/	Acknowledged.
					Section B4.1.3 Summary of degradation		/	/
					The second paragraph refers to chemical	The sentence regarding chemical	/	RAC issue.

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					degradation in soils under basic conditions, but this is not referenced, and there is no discussion of this in the preceding sections (presumably it is linked to the brief mention of alkaline hydrolysis in Section B4.1.1.1?).	degradation in basic soil is not relating to the remaining content of the paragraph and is deleted.		
					We note there is no mention of formation of mercury sulphide – is this a possible removal process in anaerobic sediments? The reported half-lives for biodegradation tend to refer to cultures of mercury tolerant micro-organisms: presumably half-lives will be longer in more typical environments? Nevertheless, we agree that the ultimate degradation product will be mercury.	We have included information on the fate of phenylmercury compounds in landfills in section B.4.1.2.3, the formation of mercury sulphide is mentioned. Additionally, the section about the biochemical pathway of mercury (B.4.1.3) includes information about the role of mercury sulphide in the methylation of mercury.	One knows that pathways can be different according to the environmental conditions and it can thus be supposed that in some cases half-life may be longer. One also considers that the sulphide forms are more stable, however it's stills possible under some conditions (e.g. sediments movements) to observe the return of mercury in the water column. Of	RAC issue.

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							course some refinements may demonstrate that all mercury emissions will not immediately represent exposures, however on a long time scale – which is pertinent for these non degradable substances, it's justified to make estimations based on all mercury content.	
					We realise that the data set is limited, but it is difficult to get a clear picture of the overall levels of the various SVHCs/substances of equivalent concern that may be formed from the release of these substances under normal conditions. Although the fact that they can be formed is a serious concern, and the contribution to the pool of mercury is perhaps the more	For the purpose of a quantification of the likely amounts of e.g. methylmercury from the release of the substances we need more data.	This input could be of interest, but should be used very carefully regarding the appropriated long time scale that should be used for assessment (see	RAC issue.

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					relevant factor, we think it is important to present an analysis (even if only crude) of the likely amounts, if possible. Do any of the existing reviews attempt to estimate the amount of methylmercury present in the environment relative to the total pool of mercury? The Environment Agency in the UK has a report in press that summarises the ratio of mercury to methylmercury concentrations in aquatic systems collected from the literature. We will provide this when it is available since it might provide supporting information.		comment just above).	
					Section B.4.2 Environmental distribution		/	/
					In this and subsequent sections there is no indication of study validity. This should be given for the key studies at least.	Study validity in form of Klimish codes is included for the key studies	Very well.	RAC issue.
					Section B.4.2.1 Adsorption/desorption		/	/
					Editorial: Presumably the reference to methylmercury acetate in seawater (study of Dalland et al., 1986) should be phenylmercury acetate?	The text is amended accordingly.	/	Acknowledged.
					Section B.4.2.3 Distribution modelling		/	/
					It is usual practice with level III fugacity models to model 100% emissions to air, water, land separately, and then all three equally, otherwise the picture on	We used Kow for phenylmercury acetate in the level III fugacity model. Even if the compound dissociates, the log Kow of 0.71 does not seem	UK MSCA comment is pertinent but DS' choices are	RAC issue.

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					distribution might be misleading. This could be done for comparative purposes, although our query about the relevance of the log Kow values might make this less relevant.	unreasonable. We also think that the actual emission that is estimated in the document is a better emission estimate than to model 100% emissions to air, water and land, separately. However, we have corrected the numbers in the revised document as we found a mistake in the model entry.	justified as more representative of what could really happen. Rapporteurs agree to keep the choices of DS as that.	
					Section B.4.2.4 Aquatic bioaccumulation		/	/
					It would be helpful to indicate whether the various species listed are invertebrates or fish. However, in terms of the overall aim of the dossier, information on bioaccumulation of the substances themselves does not seem to be especially relevant. Much more relevant are data on mercury and methylmercury, but only very brief details are provided. Are the cited studies reliable? Is there an existing compilation of quality assured data on this substance that could be referenced? For example, later on in Section B8.1.2 there is a mention of fish BCF data for methylmercury from a Water Framework Directive fact sheet, as well as an unreferenced SCHER document. All this information should be in the same section.	The species described in the bioaccumulation study by Fang 1973 are fish, snail and aquatic plants. More data on methylmercury are included, among others from the substance data sheet for mercury for WFD. The WFR substance data sheet is assumed to present a compilation of quality assured data.	We agree that description of methylmercury BCF is important in the context of this dossier and thus thank DS for improvements.	RAC issue.

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					Editorial: Salmo gairdneri is now Oncorhynchus mykiss. PMA is mentioned as an acronym – is this phenylmercury acetate? There is inconsistent use of this throughout the document.	The text is amended accordingly.	Very well	Acknowledged.
					B.5 (Human health hazard assessment)		/	/
					The toxicity of mercury is pivotal to this dossier and it would be helpful to include a summary of the toxicity of mercury (and methyl mercury) as an introduction to this section.	Such a summary is given in Part A.	We also had requested such data; however we accept now the argument of DS that this information is well accepted and has just to be recalled in section A.	RAC issue.
					Of the five substances, data are only available for phenyl mercury acetate (PMA) and for a number of endpoints the data on this substance are either inadequate or lacking. It is not clear whether the data generated on PMA is to be read-across to the other substances (as appears to be implied in the Justification for Grouping, B.1.6). If read-across is proposed, we feel that a more thorough justification is required.	Text amended.	We confirm improvements by DS.	RAC issue.

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					We note that although data on the Hg-related metabolites/degradation products has been provided, no consideration has been given to the potential toxicity of the side-chains of these substances. For example, if ethylhexanoic acid is formed from phenylmercury 2-ethylhexanoate (a substance with no data to support it) there will be a concern for developmental toxicity. In addition, information on metabolites, etc., has been provided in each section, but no attempt has been made to relate the effects observed in these studies to the likely toxicity of the five substances of interest.	We assume that all the five phenylmercury substances are metabolized into inorganic mercury and organic components. However information on the presence of the side-chains after metabolism and the rate of further metabolism is not available. Hence further speculations on the toxicity from the side-chains would not be recommended. The text in the introduction of B.5 has been revised to relate the effects observed in the available studies to the toxicity of the other phenylmercury substances.	It's true that the side-chain could also be of concern. However, information on the phenylmercury part and its degradation products seems largely sufficient to argue for this restriction. Rapporteurs thus don't think that it's necessary to also assess the potential concern of the side-chain part.	RAC issue.
					As a general comment, for each endpoint, it would be beneficial to the reader if the authors could provide an overall conclusion on the hazard/adequacy of the data. For example, do the data allow a conclusion to be reached on the skin sensitisation potential of PMA.	Conclusion inserted.	Very well.	Agree with comment.
					The following specific points are noted:		/	/
					B.5.2.2 (Acute toxicity)		/	/
					A minor point, in the acute toxicity	Thank you. You are correct. The value	Very well.	RAC issue.

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					summary you state that the classification is based upon an LD50 of 60 mg/kg bw in mice. According to table 5.17, the LD50 for the mouse study was 70 mg/kg bw.	in the summary is amended accordingly.		
					B.5.3.1. (Skin irritation)		/	/
					Given that PMA is corrosive, we question the relevance of including the human information in this section, particularly as the dose levels employed were very low and it is not clear whether the irritation observed in the Morris (1960) study was true irritation or sensitisation.	We agree. The two studies have been deleted and are vaguely touched upon in the summary and discussion of irritation.	Very well.	RAC issue.
					B.5.3.2. (Eye irritation)		/	/
					Since the corrosive classification covers both skin and eye irritation, it would be useful if the reader were referred to the corrosive section.	We agree, the text is amended accordingly.	Very well.	RAC issue.
					B.5.5.1. (Skin sensitisation)		/	/
					No animal data is available to assess the skin sensitisation potential of PMA or any of the other phenyl mercury compounds.		/	
					Data from human patch tests are available; however, the usefulness of the data is limited. It is unclear whether the responses observed were due to irritation or were, in fact, true sensitisation responses. It is also unclear on what basis the volunteers were	We agree. In the summary and discussion of this effect, this has now been clarified according to the comment. More information concerning selection of volunteers has been included in the text. Reference	Very well.	RAC issue.

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					selected – did they have an underlying skin response? Lastly, if these reactions are sensitisation responses, it is unclear whether they are a result of sensitisation to PMA or a similar substance (cross-reactivity). Overall, limited conclusions can be drawn from this information.	and link to the database IVDK is given. Cross-reactivity is now included in the summary and discussion of sensitisation (B.5.5.3).		
					B.5.6.2.2 (Repeated dose toxicity)		/	/
					Most of the data on the hazards associated with PMA are taken from poorly reported repeat dose studies, toxicokinetic studies or studies investigating the distribution of mercury and, therefore, afford limited information on the repeat dose toxicity of PMA.	That is correct.	These weaknesses should be discussed a little bit by DS, would it be only to say that these studies are provided as a general description and the focus is rather on neuro-developmental effects. We acknowledge the efforts of DS to come back in the study, as also the limits of the study (no histology provided). Let's	RAC issue.

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							recall again that risks are mainly related to the transformation products mercury and methylmercury.	
					The best information comes from a chronic study. However, it is not clear from the study summary whether the examinations conducted were as extensive as the examinations that would be performed for a guideline study. Please can you provide additional details about the scope of the histological investigations in this study to help assess the robustness of the DNEL.	More information on the histological investigations is included.	Summary description of histological investigations was included.	RAC issue.
					B5.10.1 Neurotoxicity		/	/
					In this section you state that no information is available. However, neurological symptoms were noted in the FAO meeting report No. PL/1965/10/1 WHO/Food Add./27.65 (page 81) and for completeness it would be useful to make some comment about the relevance of this information in the neurotoxicity section.	The text is amended and the original study is now discussed instead of the FAO-report. We question the neurological findings, in line with the authors own uncertainties concerning the findings.	We appreciated the effort. In fact there's a link in section B.5.10.1 towards the repeated dose toxicity section where additional description of the neurological effects	RAC issue.

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							can be found.	
					B.5.11. (Derivation of DNEL/DMEL)		/	/
					Please check the values that have been applied for absorption and the way they have been used to calculate the corrected inhalation NOAEC. As the dossier stands, the written form of the equation does not correspond with the figures., i.e. Abs oral rat/Abs inhalation human should be 100/50 and not 50/100. If there has been an error this may increase the NOAEC 4-fold, resulting in a higher NOAEC for PMA than mercury and methyl mercury.	The editorial mistake has been corrected. The calculations are correct.	Very well.	RAC issue.
					Exposure estimation		/	/
					B.9.3.2 (p 142) – Very little information is available on human exposure to mercury as a result of the use of phenyl mercury catalysts. The examples that have been provided consider exposure to mercury volatilised from gym flooring (this is the only scenario for which measured data are available) and from castors on chairs. The dossier does not properly consider how representative these sources of exposure are for other sources e.g. other article types and whether these exposure assessments reflect worst case or typical conditions. Also on	We agree that exposure from consumer use of uncured products may be different. See response to general comments above. Consumer exposure from uncured articles like adhesives could be of concern, however, to develop additional scenarios based on model calculations only seems to be of limited utility for the present restriction proposal.	Our comment is similar to the one made about this issue raised also by the UK MSCA but for section A. We agree with DS that this additional work may not be necessary to argue this proposal.	Agree with DS response (+ see other DS responses above on the same issue).

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					p145 the dossier states that consumers may use adhesives or moulding products containing phenyl mercury. It is likely that the exposures from the use of uncured products will be very different to the exposures received from hardened articles and the exposure values that have been reported in the Annex XV dossier will not be appropriate for use of uncured products.			
					P143 – Although the data on exposure to elemental mercury released from polyurethane flooring is the only measured data available, the relevance of this information needs to be evaluated. For example, the ambient mercury concentrations are spot samples not time weighted averages for personal exposure and the variations in concentrations reported in the ATSDR 2006 and 2008 papers represent samples taken in different locations and under different circumstances. In both reports, the highest values were measured under conditions of limited ventilation. The assessment has not considered the evidence in ATSDR 2008 for a temperature dependence on release. It is therefore difficult to relate these values to	It is true that most of the sampling has been done with Lumex instruments which can only give an understanding of exposure that may occur during a snapshot-in-time. The limitations of this method are described further in the report. Beaulieu et al. (2008) reports mercury sampled by Lumex (average ~0.51 microgram/m3)as well as by NIOSH 6009 method (average ~0.20 microgram/m3, ~8 hours).	We acknowledge the limits of mercury emission estimations from flooring (case does not exist in Europe, measurements were made late in service-life, some measurements are punctual …); however these estimations maybe sufficient to alert about other potential exposures than via food.	RAC issue.

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					the typical or even worst case exposures that an individual using or working in the gym may experience.			
					In the risk characterisation for exposure to elemental mercury from gym flooring on p259 the exposure values based on spot samples are compared to a DNEL adjusted from occupational data to represent 24 hour exposure, 7 days per week. This is an inappropriate DNEL to use for this exposure situation. The worst case exposure situation is for a gym instructor who may spend 8 hours per day at work and therefore it would seem more appropriate to use a worker DNEL for this risk characterisation. We note an inconsistency in the dossier here where the first paragraph on p259 indicates that the highest measured value will be used but in fact the calculation is based on the lowest measured value.	We are concerned about the children and students as well as the teachers. The 24 hours DNEL is now commented on in the text. A DNEL for workers is now derived. Both the highest and the lowest measured values have been used in the calculations. This is now made clear by editorial changes.	Very well.	RAC issue.
					Additional exposure calculations based on the release of phenyl mercury from castors are presented in Appendix 1 p256-258. In the refined calculation, it is assumed that all of the phenyl mercury content in the castors is released over a 15 or 30 year period but there is no evidence to indicate that this	As already stated in the report the half life for mercury from the PU floorings has been estimated to be 16 years (ATSDR, 2008). Therefore, it is likely that the assumption of 15 years for release of all the PMA is an overestimation of the exposure	DS' approach seems realistic regarding the timescale and the room size, and also the fact that multiple sources	Agree with DS response. The values taken for the calculation of exposure assessment are extracted from EU guidelines and

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					level of emission will occur in practice. If the majority of the phenyl mercury remains encapsulated in the article this assumption will result in an unrealistically high exposure assessment. The calculations are based on a 16 m3 room with 24-hour exposure. This represents an extreme worst case situation. It would be helpful to consider typical exposure as well. Also, it is not clear if the values calculated for castors are representative for other article types. Additional justification for the assumptions in the dossier would be helpful.	compared with in real life. Because of this we also estimated RCR when the emission time was 30 years. The default size of the sleeping room is taken from the guidance document on consumer exposure Table R.15.17/ Consexpo fact sheet (Bremmer et al., 2006).	may be present at the same time.	can thus be considered as relevant.
					Given the lack of data on consumer exposure it is challenging to make a robust assessment of the risks to consumers and it may be better to focus on risk to the environment instead. We note that the ATSDR (2008) report determined a rate of release of elemental mercury from a 24 year old polyurethane floor at around 24 °C of 17.4 ng/ft2/min (11.2 micrograms/m2/hr). It may be possible to use this rate of release as an alternative basis to determine potential exposures from phenyl mercury in polyurethane flooring.	The mentioned release rate refers to a calculation in a single gymnasium in Minnesota and is a theoretical calculation based on the values measured with the Lumex Mercury Analyzer, the area of the gym and the ventilation rates of the fans in that gymnasium. We believe that it is more rational to use the measured values directly, and give more information on conditions. This is included in the revised report.	We support DS' approach. Elsewhere we acknowledge here the UK MSCA conclusion that focus should be made on risk to the environment (and probably also human via the environment).	Agree with comment and DS' response.
					B.9.3.2.3 (p146) – We agree that it is not	More information is included.	We confirm	Acknowledged.

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					possible to carry out a quantitative risk assessment of indirect exposure via the environment. Is it possible to provide supporting evidence for the statement that 4% of EU mercury emissions arise from these 5 phenyl mercury compounds?	Comparison with reported total air emissions from anthropogenic sources in EU-27 for 2008 (and 2005) is now included in the revised report.	addition of further discussions about this contribution to global air emissions.	
					B.9.3.2.4 (p148) – Please clarify which life cycle stage is covered by "formulation" in the first paragraph on this page. The number of entities engaged in formulation is not consistent with the number of formulators given in earlier sections.	This is clarified in the revised report. The apparent inconsistency is due to the fact that there are two formulation steps, the manufacture of the catalyst (the substances are formulated into catalysts by the manufacturers manufacturing the substances) and the manufacture of the PUR elastomer system.	We also had some difficulties with these two types of formulators which were not separated in all calculations through the report. Thanks to DS for improvements.	Please see response by DS.
					B.10 (p165) – Given that there is no information on the time course of release of phenyl mercury compounds from articles and it is not clear whether phenyl mercury compounds convert to elemental mercury prior to volatilising from articles (see p140) there is considerable uncertainty in the consumer exposure calculations that have been performed. This is compounded by the uncertainties due to the assumptions that have been made in order to perform a quantitative risk characterisation. The	A further refinement is considered to be of limited utility for the present restriction proposal. (The main basis for this restriction proposal concern the transformation products of phenylmercury substances). The uncertainties are stated in the revised report.	We acknowledge the uncertainties of consumer exposure estimations but consider information sufficient as consumers' exposures from articles are only a secondary argument.	Agree with DS response.

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					calculations that have been made seem to represent worst case situations and it would be useful to conduct a risk characterisation based on typical values to put these worst case values into context. It would be useful to state the uncertainties associated with the exposure assessment in the risk characterisation.			
					B.10.1.3 - The risk characterisation for man via the environment has been based on consumption of fish contaminated by methyl mercury. There needs to be a clear reference in the dossier that methyl mercury is obtainable from several sources so the stated risk is not totally due to phenyl mercury acetate.	It is clarified in the revised report that methylmercury may be generated from other sources than phenylmercury compounds.	Very well.	RAC issue.
					Section B6 – Human health hazard assessment of physico-chemical properties (p 100). Statements that the substances are not explosive, flammable or have no oxidising properties cannot be made given that in B1 it is stated that no data were available for these endpoints.	You are correct. The text is amended accordingly.	Very well.	RAC issue.
					Section B.7 Environmental hazard assessment		/	/
					In our view, the risks that form the basis for this restriction proposal concern the	The environmental hazard assessment of the phenylmercury substances is	We agree that PNECs and other	RAC issue.

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					transformation products of phenylmercury substances. Therefore the ecotoxicity data (and PNECs) for the substances themselves are not relevant, and distract from the main argument. We have therefore not reviewed these data, and would prefer to just see a summary of (validated) data for mercury and methyl mercury in this section.	included in the main document of the revised report since these data are of relevance for the PBT assessment of the phenylmercury substances itself.	characteristics of the main transformation products, mercury and methylmercury are central in this assessment.	
					Section B.8 PBT assessment		/	/
					Similar to the last section, we think that the primary focus of this section should be the transformation products. It seems clear that (subject to some text clarifications as indicated in our preceding comments) methylmercury should be considered to be very bioaccumulative and also highly toxic (the avian data should also be mentioned in this context). In fact, the human health classification seems to provide a solid basis for identification as an SVHC, regardless of the discussion of persistence.	We agree that the PBT assessment should mainly focus on the transformation products of the phenylmercury substances. The PBT assessment of the phenylmercuy compounds is done for sake of completeness.	We would have wished more discussion on why the authorisation route was rejected. We confirm substantial improvements in the PBT properties discussions.	RAC issue.
					In terms of persistence, we are sympathetic towards the case presented, which is based on the differing rates of methylation and demethylation – however, the dossier does not present any detailed data on these aspects so it is difficult to make any	We have elaborated more on the PBT like properties of methylmercury. In addition monitoring studies are added demonstrating increasing trends of mercury levels in biota, which are of concern.	Our conclusion is also that there's an equivalent concern to a PBT substance and thus that no-threshold should be	RAC issue.

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					judgment about this issue. We think this should be discussed more explicitly. In addition, evidence from monitoring studies (currently summarised in Section B.9.7) should be mentioned, together with an argument based on the fact that the cycling of mercury means that the source of this transformation product is always present once released. Given the high accumulation and toxicity, we think this would provide a very good argument for 'equivalent concern' to a PBT substance, and therefore non-threshold effect, which then forms the basis for the restriction. We do note, however, that the dossier mentions "internationally accepted safe levels of methylmercury" in the opening section. This should be briefly discussed here in our view.		foreseen. This is all the more a strong argument as the cycling of mercury means that these transformation products are always present once released.	
					We have some concerns about the lack of quantification of the overall level of formation of SVHCs from release of the phenylmercury substances, though we also recognise the difficulties. The restriction is based on a presumption of harm, even though the actual amounts of relevant transformation products might be very small	Additional information is provided in the paragraph "The biogeochemical pathway of mercury" in section B.4.1.3. Generally, about 1-1.5% of the mercury in anaerobic sediments is methylmercury. It is recognised that REACH allows the emissions of PBT substances provided	We agree that discussion about methylmercury to mercury ratio could be of interest. However, as stated in our previous comments, this	RAC issue.

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					indeed. REACH allows the emissions of PBT substances provided they are below a minimal level. This is an important principle for all substances in which transformation to PBT substances is the key issue, and if not addressed, might form the basis for a legal challenge from the affected industry. The Environment Agency has a report in press that summarises the ratio of mercury to methylmercury concentrations in aquatic systems collected from the literature. We will provide this when it is available since it might provide supporting information.	they are below a minimal level, this is discussed in the report (B.8.2). Consideration of the total volume and the fact that the use is wide dispersive is of relevance as well when considering the need for legal action. The environmental degradation of the substances to inorganic mercury is further substantiated in the revised version (on a theoretical basis). More information concerning the ratio of mercury to methylmercury would be of interest. Quantification would probably also require more detailed information on possible regional-specific differences in the use and releases.	approach should be used carefully as transfer notably in the food chain makes these environmental levels not really representative of risks.	
					Section B.8.2 Emission characterisation		/	
					As a general remark, there appear to be major uncertainties in the exposure estimates, not least the unclear leaching/volatilisation potential of phenylmercury compounds from different types of polyurethane articles. This uncertainty is not discussed in the document at all.	This is discussed further in B.9.5.2 (releases from service life)	Thank you to DS for this additional work.	RAC issue.
					Section B.9.1 Exposure assessment		/	/
					Table B9.1: Why is there no ERC number	See response to UK general comment	We agree that some	Agree with DS

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					for use of PU adhesives, sealants and elastomers in industrial settings? Is there any way of estimating a split between indoor and outdoor uses? Would different release factors be likely? We hope that better information will be provided by industry during the public consultation.	on the same issue: We agree that more information on consumer exposure would be desirable. Actual measurements are available only for the use in gym floorings, this use is considered as a potential "worst case" for consumers. An exposure scenario for use in rollers on swivel chairs has been estimated. Consumer exposure from uncured articles like adhesives could be of concern, however, to develop additional scenarios based on model calculations only seems to be of limited utility for the present restriction proposal. Moreover, according to available information the current use in adhesives seems to be small. According to a major supplier of catalysts, elastomers take up about 90% of the market of mercury catalysts while about 10% is used for sealants, while for adhesives and coatings, the mercury use is today small while organotin or amine catalysts are the major catalysts for these applications. Other information indicates that the mercury catalysts are still widely used for coatings.	clarifications about the 10% applications that are not for PU systems would be nice; but as we said previously it seems acceptable to deal only with the gym flooring data.	response + see other DS responses above on the same issue.

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					Editorial: Chemical forms released from articles (p. 143): the word "Lumex" is not explained at this point in the document.	Thank you, the text is amended accordingly.	Very well.	RAC issue.
					Section B.9.2 Manufacturing		/	/
					There is no discussion of the efficiency or appropriateness of the abatement measures in place at the main site. What happens to the captured mercury? In addition, no release information has been provided by two of the three EU manufacturers, so the representivity of the reported data is unknown. Are the risk management measures in place at the main site likely to be standard within the industry? Perhaps the national competent authorities might be contacted to assist in the data gathering process for those companies that did not respond?	More information from industry is included in the report. The representativeness of the information is further clarified, see table G.1.	We are also not totally convinced by such very low release factors. Our concern is for example on the few monitoring data and the absence of a mass balance approach; we thus have proposed an adjustment. See also our comments on B3 and D2 Irish MSCA comments.	This information is indeed desirable. Please see response from DS.
					The maximum air emission estimate of 0.3 kg/year for the whole of Europe appears to be a mistake: 0.0016% of 120 tonnes is 1.92 kg. The amount per site will of course be lower.	Thank you for the control calculation, the value is corrected accordingly	Very well	Correction has been made.
					Is the 'total mercury' concentration in the wastewater a mean or maximum value? What sort of 'treatment' is in place at the	The total mercury concentration in waste water is a single measured value, which is representative for	Our position is similar as for the previous comment	RAC issue.

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					major site before discharge – could it be improved?	measurements in 2008 according to the manufacturers. No further information on waste water treatment before discharge is available	and we have proposed also here an adjustment.	
					It is not clear whether the formulation of catalysts takes place at a separate location from the substance manufacturing site – could this be confirmed? This stage of the life cycle appears to be missing from the release estimates.	More information from industry is included in the report.	It's to note regarding the low number of manufacturers, that information was considered as confidential.	Acknowledged.
					Section B.9.3.1 General information on use as a catalyst in PU elastomer systems		/	
					The percentage content of the substances in two-component systems (0.2-0.8%) appears to be different from that reported in Section B2.2 on p. 27 (0.1-0.6%).	A percentage in the order of 0.1-0.6% is taken to be a typical concentration range in the polyurethane material in finished articles. The concentration range may also be wider, cf. revised report Section B.2.2	We observed that the range was modified into 0.1-0.6 in B.9.3.1. A discussion about the 0.8% would however have been welcomed as it could better reflect the concentration in known products.	Acknowledged.
					Section B.9.3.2.2 Consumer exposure		/	
					Editorial: The discussion of some types of article being considered hazardous waste	The statement regarding hazardous waste refers to the USA (ref. MPCA,	It's in section B.9.5.3.	Acknowledged.

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					requires some context – are the same criteria applied in the EU as in the USA? (Also mentioned in other sections, e.g. B.9.4.)	2008). The classification of the material with regard to EU hazardous waste criteria is discussed in section B.9.5.3, in the paragraph with the heading; "Hazardous waste incineration and landfilling".		
					Are the same types of flooring used in the EU as those in the US studies?	No information on current use of phenylmercury in flooring in Europe has been obtained during this study (B.9.3.2.2), but information on possible former use has been indicated and the text is thus amended. As proposed in the evaluation of the EU mercury strategy, a potential action to protect against human exposure to mercury via products is to investigate whether mercury containing PU has been used in public buildings in the member states and identify if there is a risk of adverse health effects from old floors. This is not within the scope of the restriction proposal. According to a company consulted by personal communication mercury-containing PU floors were produced in Europe and exported, but it is also possible that it was marketed in Europe. This could not be confirmed,	Very well.	Acknowledged.

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						however.		
					Section B.9.2.3 Indirect exposure of humans via the environment		/	/
					Most of this section discusses overall intakes of methylmercury from all sources. It is perhaps therefore better presented as an annex, since it is not related solely to the substances under consideration. In addition, we note that the levels of mercury in Norwegian fish appear to be increasing, while the use of these substances is declining. This would suggest that there are other much more important sources of mercury, and this restriction may make little overall difference to the reduction of risk. There could be some discussion of this. If these substances are only contributing about 4% (which might be an over-estimate – see comments below), then the 'added risk' from their contribution might be very small.	Agree, most of this section is moved to Appendix 1, since there are several sources for Hg-emissions and this text is therefore not only related to the substances under consideration. Some possible explanations for the increase in fish in Norway and Sweden are discussed in the relevant publications, see Appendix 8, "Mercury monitoring data". For instance in the publication of Åkerblom and Johansson, 2008, it is stated that "although the atmospheric depositions has declined, the depositions are still high and they contribute to a slowly increasing level in soil. This in turn implies an increasing run-off and load on aquatic systems. Climate changes might also be a contributing factor". According to Fjeld and Rognerud (2009b) "factors stimulating the mercury methylation, such as a warmer and wetter climate and also forestry and lumbering, may have contributed to the	Increase in mercury found in fish is a complex issue, for example the digging of sediments can remobilize old sources of mercury. This information only means that any source of mercury is to be reduced. We acknowledge the move into Appendix 1.	RAC issue.

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						observed increase. The influence of these factors is now further investigated." The contribution to the total mercury emissions from the phenylmercury compounds and the different release factor used for release estimates are further discussed in the revised report.		
					Section B.9.3.2.4 Environmental release		/	
					General remarks: The exposure assessment relies on default release estimates based on the TGD, plus (for service life) a read across from reported emissions of mercury from flooring containing phenylmercury acetate. It is therefore likely to represent a worst case, which might not in fact be realistic. We understand that the timing of the production of the dossier has probably not allowed any satisfactory consultation with the relevant industry sectors (also implied by the limited response rate in Section G), but this is an uncertainty that should be reflected in the conclusions.	The choice of the release factors are further discussed and justified in the revised report. Consultations with industry have been performed three times during the production of the dossier (see part G updated).	Overestimations linked to default values or/and consideration of whole mercury amounts can be considered as balanced by the long life of the transformation products that make difficult to predict emissions, as it appears with this surprising increase in mercury in fish caught in Nordic European	RAC issue.

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							countries.	
					Since the polyurethane made using these substances is also used for various coatings, adhesives and sealants, the dossier could have used more specific ESDs that are available for these sectors from the OECD (http://www.oecd.org/officialdocuments/displaydocumentpdf?cote=ENV/JM/MONO(2009)24&doclanguage=en and http://www.oecd.org/officialdocuments/displaydocumentpdf?cote=ENV/JM/MONO(2009)3&doclanguage=en). These documents emphasise the relevance of volatility for estimating releases, but there is little information on this property for these substances.	The only information obtained is that elastomers today take up about 90% of the market of mercury catalysts and about 10% is used for sealants, while for adhesives and coatings the mercury use is small, on the other hand other information indicates that the mercury catalysts are still widely used for coatings. The use of the TGD defaults compared to the OECD ESDs is further discussed in the revised document.	As stated before, the PU system assessment seems sufficient to demonstrate the restriction need. We confirm the improvements by DS about discussions on release factors.	RAC issue.
					Formulation of PU systems		/	
					The dossier compares the EUSES defaults with the plastic additive ESD defaults. The ESD was developed using industry-specific knowledge, and in our view is the more reliable source for estimates from this sector.	This is further discussed in the revised document. Based on the new information obtained it does not seem justified to use the ESD.	Very well.	RAC issue.
					It is assumed that 33 tonnes/year [in our view, 31.5 tonnes] of mercury are used for this life cycle stage as a worst case. The estimated release of 2.4 tonnes to air	Calculations have been corrected. Concerning the mercury catalysts it might be correct that they are decomposed, however the	Assumptions should not be with too much optimism because OC are	RAC issue.

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					represents a 7% loss, which seems high. The releases might well be substantially over-estimated – for example, air emissions drop to 1.65 kg if the plastic additive ESD releases are used (and releases to waste water drop from 100 kg to 1.98 kg). According to this ESD, there are zero releases during polyurethane conversion (processing) not only because the curing agent is destroyed, but also because this stage is generally assumed to take place in an almost completely enclosed system.	decomposition products would be other mercury compounds or elemental mercury, and these might be released into the environment. Furthermore, the assumption that processing of PU typically takes place in totally enclosed systems cannot be concluded based on the information obtained from industry. In small-scale production the application of Hg-containing catalysts either takes place in a well-ventilated area or under a fume hood. Some of the users of the PU systems state that they store and react them in dedicated rooms, fume cupboards and glove-boxes and that containment and removal of the isocyanate vapour would do likewise for any mercury vapour. According to the information obtained exhaust systems are not equipped with specific mercury filters. It must therefore be expected that the major part of mercury released from the process is released to the surroundings by the ventilation air. No information about use of exhaust abatement systems from large-scale processing has been provided by industry.	insufficiently described. In addition some figures could even be lowered. The problem would then be transferred to waste and here the release may be underestimated regarding the diversity which is hidden behind landfilling. So overall, and except for manufacture for which we even propose a slight increase of the release factors to air and water, we are supporting DS approach.	

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					The relationship between risk management measures and the default release estimates is unknown, but might a processing site put additional RMM in place if it handles mercury-containing compounds (given their hazard classification)? We note that there is an Existing Substances Regulation Risk Assessment Report (RAR) for methylenediphenyl diisocyanate (CAS no. 26447-40-5), which is also used to make polyurethanes for CASE applications. Based on data provided by the relevant industry groups, the maximum air emission for polymer processing operations was 12 kg per kilotonne processed (i.e. a factor of 1.2 x 10-5); release factors to wastewater were zero. Whilst this substance is a chemical intermediate and reacts during the polymerisation process, might there be a higher level of emission control than the TGD defaults suggest?	See response above. A comparison with the chemical intermediate does not seem justified.	For such low concentrations in process specific RMMs were probably not put in place.	RAC issue.
					In the absence of specific information for CASE applications, we recognise that it is difficult to establish the releases from specific processing operations, but we think it is appropriate to consider that emissions may be lower than presented in the dossier.	We agree that the emissions mainly based on TGD defaults may be considered as conservative.	We are in favour of DS choice to keep the default values if no data are available.	RAC issue.

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					Releases during service life		/	
					We recognise that the basis for the release estimates for this stage in the life cycle is highly uncertain, but we think the document should reflect this uncertainty more.	This is reflected in the revised document.	We confirm that discussions on uncertainties of service-life emissions' estimations were included by DS.	Agree with comment.
					The opening paragraphs refer to the importance of wear and tear as a factor in emissions. However, if the substances are behaving like a typical polymer additive, additional factors that might govern releases from polymer articles include surface area to volume ratio, volatility, solubility in the polymer and migration potential. It is not clear how the emissions of around 8% from flooring for one of the substances compare to other article/substance combinations, but it is presumably one of the worst case scenarios. The subsequent assumption of a 9-10% release to air from all articles might therefore be a significant overestimate. It might have been possible to do some further analysis of this (see for example the EU RARs for tris(chloropropyl)phosphate, medium chain chlorinated paraffins and	The calculations of emissions arriving at the figure 8% are deleted. More information about release rates from old floorings and estimated half-life of phenylmercury compounds in flooring has been found (ATSDR, 2008) and this is included in the revised document. Additional factors governing the release are discussed.	We agree that surface area to volume ratio, volatility, solubility in the polymer and migration potential may influence a lot the emission to air estimations, but it cannot be predicted at this point if it's toward increase or a decrease of the estimation figures.	RAC issue.

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					decabromodiphenyl ether).			
					We note that there is no comparison of the properties of the phenylmercury substances with DEHP. It is therefore unclear how appropriate the comparison is for losses to waste water. The presumption of 'typical' releases of 0.5 - 5% (the top of this range is higher than the loss of 3% assumed for DEHP), averaged to 1% for all article types, appears to be purely speculative. Again, we believe the uncertainty in the reported releases needs to be more clearly expressed in the final summary of emissions.	Some more information about release of Hg from articles is included, however, we agree that there are uncertainties.	Very well. It's to note that we don't have enough information about similarities between DEHP and phenylmercury compounds, notably on how they are bound with the matrix, to use the first as a reference.	RAC issue.
					Editorial: What is the substance mentioned as being released from 3M Tartan Brand flooring under "releases to waste water"?	The measurements concern leachable mercury (ATSDR, 2003), this is clarified in the revised document..	Very well.	This has been clarified.
					Section B.9.4 Waste handling		/	
					Due to the calculation method for losses presented in the preceding sections, it is assumed that 28 tonnes of mercury enters the waste stream in discarded articles. Based on our comments, it could be more than this. If the releases from other parts of the life cycle are reviewed as we suggest, it seems that the releases arising from the	Uncertainties in the releases, in particular from landfills, are further discussed. The effectiveness of the waste legislation in controlling the risks is discussed in part E.	We agree - and told it earlier – the releases from the waste stage seem the important part. However, it shouldn't be considered that the	RAC issue.

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					waste disposal stage might make a significant contribution to the overall emissions of mercury from the use of these substances. At the same time there is legislation in place to control mercury emissions from this part of the life cycle. We are unsure whether this aspect has been discussed sufficiently in this document, i.e. why does the current legislation not provide a sufficient framework for controlling the risks from waste?		waste legislation guarantees no emissions as after incineration almost all mercury will be found in solid waste which is not systematically handled as hazardous waste This is all the more the case as concentrations are low and in very various articles.	
					Recycling: it would be helpful to discuss what air pollution abatement techniques are used in metal recycling, and their efficiencies at removing mercury.	Such information has not been considered.	See comment above. Regarding the concentration found in articles, recycling is not considered.	No further comments.
					Municipal solid waste: It would appear that the phenylmercury compounds account for roughly one third of the mercury entering the waste incineration stream, if the Kindbom & Munthe (2007) study is reliable. We think it would be useful to	It should be noted that the use of phenylmercury compounds in PU has not been focused on until recently. Other possible risk management options are considered in Section E.1.1.	Improved abatements techniques for incinerators could be seen as an alternative to	No further comments.

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					make comparisons like this to provide context for the overall emissions from these substances. Since incineration appears to be an important source of mercury release from all consumer product types, and recognising that it might take a long time to remove mercury from such products completely, has it been considered whether the use of improved abatement techniques (i.e. a lower emission limit value) for incinerators would provide a cost effective means of reducing pollution?		restriction, however, the whole emissions wouldn't be covered and all the more the long term issue of PBT transformation products would not be resolved.	
					We recognise that the release from landfills is based on a default factor, of unknown reliability. We are currently consulting other experts on this matter and may be able to provide additional comment in due course.	More information would be welcomed.	See comment above.	RAC issue.
					Section B.9.6.1 Summary of emissions		/	/
					From a total use of 33 [31.5] tonnes of mercury per year, the total environmental emissions are estimated to be 31.6 tonnes (~96%). Is this plausible, or just the consequence of summing several conservative scenarios together? For comparison, a national pollution reduction plan for mercury and its compounds (see	The release estimates in the dossier are based on maximum tonnages for production and consumption (in EU + EFTA) and releases during the life cycles are mainly based on defaults. However, it should be noted that according to the estimations, the majority of the emissions is assumed to	We don't see why the guidance procedure and default values couldn't be considered in this case as plausible. If some	RAC issue.

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					attached) reports release data from the Pollution Inventory for England and Wales and the UK National Air Emissions Inventory (NAEI). We believe that including this sort of data would provide useful additional context for the release estimates.	accumulate in landfills (recalculated to be 25 tonnes), whereas the estimated releases to the environment (to air and waste water) is 6.4 tonnes per year (recalculated). The long-term fate of mercury in the landfill is not known, evidently there is a potential for a release to the environment at a later stage.	overestimations were made by this approach they may compensate the absence of knowledge about the long term fate of waste in which the mercury will never disappear.	
					Table B9.6: The estimated mercury release of 0.3 tonnes to air from landfilling is for a 20-year period. Presumably this should be 0.0135 tonnes/year (using the annual release rate of 0.05%).	You are correct. The release factor for landfills is further discussed and has been amended (release factor 0.01). For further information see revised document.	Very well.	RAC issue.
					As suggested in the earlier comments, the releases to air in particular from some of the life cycle stages appear to be highly conservative. If this figure was lower, the comparison with the total air release of 150 tonnes/year from all sources would then imply a much lower percentage contribution to the emissions.	See response to earlier comments. More data and comparison with reported total air emissions from antropogenic sources in EU-27 for 2008 (and 2005) is now included in the revised report.	We acknowledge.	RAC issue.
					The figures in the dossier are based on maximum tonnages for production and consumption, and although this is an acceptable approach for an initial	As mentioned above, the majority of the emissions are assumed to accumulate in landfills (recalculated to be 25 tonnes), whereas the estimated	We agree that ranges are welcomed to underline the	RAC issue.

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					conservative assessment, we should recognise that releases might be lower in reality. We think the range of possible emissions should be considered, because they might have implications for the socio-economic assessment, as well as the conclusion about the overall contribution of these substances to the risks arising from mercury emissions.	releases to the environment (to air and waste water) is 6.4 tonnes per year (recalculated). The long-term fate of mercury in the landfill is not known, evidently there is a potential for a release to the environment at a later stage. As mercury as such is persistent (in one form or another) this source cannot be eliminated. Using maximum estimates will affect both costs and benefits. As a result of this the cost effectiveness ratio will not change. It is also important to remember that emissions from imported articles are not included.	possible conservative approach. We support any overestimation that may so include the PBT and LRT concern of transformation products (which is never included in default values).	
					Section B.9.6.2 PECs		/	/
					We question the need for this section, since the overall concern is related to the formation of mercury/methylmercury associated with releases. The uncertainties in the physico-chemical properties and release factors also mean the final estimates have limited reliability (as the dossier recognises).	We recognise that the quantitative risk assessment have limited reliability, this is stated in the document as well. We have included it for the sake of completeness.	We acknowledge.	RAC issue.
					Section B.9.7 Monitoring data		/	/
					The flux of mercury from natural sources is mentioned in this section, but figures are	The section B9.7 monitoring data is moved to a separate appendix since it	We agree that one should consider	

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					not provided to place the emissions of the phenylmercury substances into context. We think this entire section is useful background information, but suggest it is removed to an appendix, since it is linked to all mercury sources. In addition, care must be made about drawing conclusions from monitoring data in the Arctic away from Europe (e.g. Canada), since the emission pattern that leads to the observed concentrations may not be comparable.	presents monitoring data on mercury in general.	only these monitoring data as a global context and this restriction as some contribution that is uneasy to estimate.	
					Section B.10.1.3 (Risk characterisation for) Indirect exposure of humans via the environment		/	/
					We think the paragraphs presented in this section should be deleted because no risk characterisation has been performed for releases related to the specific substances, and the conclusions about increasing mercury levels are a generic concern (which appears to contradict the declining use of these substances).	Risk characterization of man via environment is moved to appendix I, since it is based on intake of methylmercury in general from fish and seafood products.	Similar comment as above: we agree with these rules for placing the data in the report, all in underlining the complexity of a supporting document (the BD) which has several annexes.	RAC issue.
					Section B.10.2 (Risk characterisation for) Environment		/	/

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					We think the estimates in this section need to be reviewed as suggested above, and compared with emissions from other mercury sources to place the conclusions in context. As pointed out above, we do not think it is particularly helpful to present a risk assessment for the individual substances (referred to in Appendix 1).	See responses above.	Same comment.	RAC issue.
					Section C Available information on alternatives		/	
					It seems possible that other organomercury compounds could be used as alternatives for this group of substances – either other carboxylates or other arylmercury compounds. Although this might be unlikely given the current pressures on this type of chemistry, this possibility should be discussed in our view.	This is discussed in the revised report under alternatives (Section C).	Very well. RAC's opinion underlines the inappropriateness of other organomercury compounds as alternatives.	Agree. See section C.
					Silicones are mentioned as an alternative polymer system. It should be recognised that these might contain some impurities with a PBT profile of concern.	Agree.	This information about PBT impurities in silicones should be added.	RAC issue.
					Section C.3 Human health risks related to alternatives		/	/
					(p176) – Several alternative substances have been suggested, but the information on the	To our knowledge only two of the alternative substances were registered	DS can't know which alternative	RAC issue.

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					specific hazards for these alternatives is limited. We note on p 176 that four potential alternatives were due to be registered by 30 Nov 2010. Will it be possible to consult these registration dossiers for more information?	in 2010, relevant information in the registration dossiers could be included when obtained.	will be chosen for each application. The assessment of the alternatives can thus only be preliminary screening.	
					2-ethylhexanoic acid is classified as DSD Repr. Cat 3. The information for developmental toxicity presented in table C.3 (p 179) for this substance does not highlight this concern (although it is mentioned in the summary section). This potential hazard needs to be clearly presented in the table.	The source for the information in the table C.3 is US EPA. A footnote is inserted in the table with information on the classification in the CLP regulation. The text is amended accordingly in the summary that follows the table.	Very well	RAC issue.
					Section C.4 Environment risks related to alternatives		/	/
					Some of the organotin compounds have been considered by the former TC NES PBT Working Group. Their conclusions should be reflected here.	Catalysts based on organotin compounds are no longer specifically marketed as alternatives for the current uses of phenylmercury catalysts. However, the risks of organotin compounds in general are high and the use of several organotin compounds are regulated in the EU. Reference to REACH Annex XVII entry 20 (organostannic compounds) are	Reference to the annex XVII organostannic entry was made + it was clearly highlighted that the organotins are not appropriate alternatives.	RAC issue.

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						included in the background document and more detailed consideration of the risks of the use of organotins are included in section C.1.2.4, C.3.2 and C.4.		
					Although in principle the environmental hazards of the other metal substances appears to be lower than for mercury, is there any indication that any of them might form methylated substances? This could be discussed from a chemical viewpoint, and would provide reassurance that there are no unintended consequences of their use. The hazard classifications could also be reviewed (e.g. once the CLP Inventory has been established). For example, zinc ions are known to be toxic to aquatic organisms and certain zinc compounds are classified as Aquatic Acute 1/Aquatic Chronic 1.	A table with available classifications has been compiled. No information about the potential to form methylated substances has been obtained.	Very well.	RAC issue.
					Table C.4: A log Kow has been presented for zirconium 2-ethylhexanoate. It is unclear what chemical species it refers to, and whether it is reliable.	The data was obtained from the US EPA HPV chemical challenge program and has not been further scrutinised.	We acknowledge.	RAC issue.
					C.5 (p184) – The dossier states that 70% of the use of phenyl mercury catalysts may be replaced relatively easily while 30% will require additional time. Some information is	We have contacted all identified manufacturers and formulators of these compounds. They state that they expect that it will be possible to	We agree with this comment of the UK MSCA. We also found that no	RAC issue.

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					provided about the 30% of uses where substitution is difficult. We are not convinced that the dossier has demonstrated that substitution will be possible for these uses within 5 years. The dossier should discuss whether there is any need for derogations in the event that suitable alternatives cannot be found for essential uses In order to assess the feasibility of this restriction more information is required on the spheres of use for TDI systems and aliphatic amine systems and the reasons why suitable alternatives are not currently available for these uses. .	substitute the use of phenylmercury within 5 years. Our findings have later been supported by the lack of comments from industry on this point so far.	real demonstration was made that substitution will be possible within 5 years. This is a key point weighting in our proposal to shorten the implementation period to 3 years ("option-3).	
					On p185 the document talks about tin catalysts as an alternative but it is not clear that these will be safer than mercury based catalysts even though they may cost less.	See response regarding organotin compounds above.	See also corresponding comment above (C4).	RAC issue.
					E.1.1		/	
					P189 – Given our concerns about the exposure assessment for consumers we disagree that a risk has been demonstrated for the majority of cases as claimed in the	No further information regarding consumer exposure has been obtained, see responses above.	We acknowledge the weaknesses of the consumer risk assessment.	Agree. See DS responses above on the same issue.

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					final paragraph on this page.			
					p191 – Please provide evidence to support the statement that use of phenyl mercury compounds was 2-3 times greater in 1997 compared to 2007. Please justify the assumption that there will be an exponential decrease up to 2030.	We have contacted all identified manufacturers and formulators of these compounds. From these consultations it is clear that the use of these compounds have been decreasing the last 10 years. All the information we have received also indicates that the use will continue to drop. On the basis of this we have made the assumption about the exponential decrease. It is important to note that in the absence of such a decrease both the benefits and costs of the restriction would be different.	We accept to work with this uncertainty although it's a big one, notably as the heart of the dossier is the properties equivalent to PBT substances.	The trends described in the dossier are supported indeed by industry statements. DS double checked information obtained from industry and no contrary information was obtained during public consultation.
					E.1.2 (p194) – The inclusion of manufacture and placing on the market in the restriction will limit the availability of these phenyl mercury compounds for uses where it may be present in a preparation at less than 0.01% (e.g. eye medication and cosmetics). This has not been considered so it is not possible to fully assess the consequences of this proposal. Also no consideration has been given to methods for determining the mercury content in articles to assess compliance with the 0.01% limit.	Regulation 1223/2009 sets a condition of maximum 0.007 % (of Hg) in eye cosmetic products. It is recognised that the prohibition of manufacture and placing on the market will limit the availability of these phenyl mercury compounds for such products. Use in eye cosmetics has not been indicated by industry during the consultations and the actual need for use in eye cosmetics today, and consequently the implications in this area has not been investigated further.	See also earlier comment about the use as cosmetic product.	Agree that the restriction proposal might have some indirect impacts on outside-REACH areas such as this specific use. However, given that this use is outside the scope of REACH and of this proposal, a possible impact can be recognised but

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						Information about analytical methods for determining mercury content in articles has been included (new Appendix 10).		SEAC rapporteurs have doubts about the proportionality of further investigation. Moreover, no objection from industry or other stakeholders against the inclusion of manufacture has been obtained during consultation by DS as well as during public consultation.
					E.1.3 Other Community-wide risk management options than restriction		/	
					We agree that non-REACH options are not appropriate.		We acknowledge.	
					Clearly, restriction is an appropriate tool to consider in the case of imported articles, but the dismissal of the case for authorisation is not strong enough in our view. For example, could inclusion of all mercury compounds on Annex XIV be a way to encourage suppliers to make their own case for continued use, with an associated substitution plan? In that way, substitution	Authorisation has been discussed further in the dossier.	Authorisation option could have been further discussed, however due to the numerous applications and the need to apply a measure as soon as	See the revised BD.

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					of one mercury compound by another would be prevented, and an overall emissions cap could be part of the authorisation requirements.		possible, the restriction seems really the best way to handle these mercury compounds.	
					Also, in the light of the footnote on page 198, it is not clear that all remaining uses for phenyl mercury catalysts can be substituted within the 5 year time frame and it is not possible to identify whether any of these difficult to substitute uses are in safety critical applications. The authorisation process will send the same regulatory message to industry about the need to find alternatives but will also enable Member States to consider any uses where substitution cannot be accomplished on a case-by-case basis. We note the concern that criteria for identifying a substance as an SVHC on the basis of equivalent concern have not been developed where the key concern is degradation products but consider that a lack of clear criteria should not be seen as a barrier to the further exploration of this option.	We have contacted all identified manufacturers and formulators of these compounds. They state that they expect that it will be possible to substitute use of phenylmercury within 5 years. Our findings have later been supported by the lack of comments from industry on this point so far.	The SVHC was already commented above. The substitution difficulties also.	Agree with DS response. The timeframe is indeed supported (and not disputed during consultation so far) by industry.
					E.2.1.2 Practicality		/	

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					P199 No mention is made of whether or not analytical methods with suitable limits of detection are available to enable industry to demonstrate that articles comply with the restriction.	See new Appendix 10.	Improvements have been brought about by exchanges with forum and further investigations by DS.	Agree. See new Appendix 10.
					E.2.1.3 (p200) – It is not clear how effectively a restriction on the import of articles containing > 0.01% mercury can be monitored/enforced if such articles can only be distinguished from articles made with other catalysts by chemical analysis. Monitoring/enforcement will require regular inspections including sampling and analysis of articles and it is not clear that MS have the resources to take on this additional task. The costs for monitoring/enforcement should be considered in the socio-economic analysis.	See new Appendix 10	/	Agree. See new Appendix 10.
					Section F		/	
					The dossier lacks substantive evidence on the costs of mercury free PU systems versus mercury containing PU systems. Further information on the price of alternatives according to application, and whether those apps for which substitution is particularly difficult might face significantly higher	In order to understand exactly which uses and products would be most difficult to replace it would be necessary to consult with the actual users of the polyurethane systems. Unfortunately, this has not been possible as the producers of these	No comment / SEA issue.	Agree with the comment about the lack of data on the differential price between mercury free PU systems and mercury containing

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					substitution costs should be included.	systems were not willing to give information about their customers due to commercial confidentiality. According to COWI and Concorde East/West (2008) Hg-free PU systems are not in general more costly than mercury-containing PU elastomer systems. In some cases they are even less costly. Therefore, the mere fact of being obliged to use a mercury-free system instead of a mercury-catalyzed system does in general not imply any change in cost. It is understood from one producer of polyurethane systems that changes to end products from the use of systems without mercury catalysts would not, in their opinion, result in compromises to the safety of the use of the end products. However, this cannot be ruled out for other companies and uses. We have extended this discussion in chapter C and F of the report.		PU systems. This information would have been useful to have incorporated in the SEA in section F. However, apparently this information couldn't be obtained directly from the users (for understandable reasons). Other sources have thus been used to get an idea of this differential. It is not fully satisfactory but it seems to be the only available information source.
					The conclusion on economic feasibility is unclear, as are the criteria or benchmarks by which something is deemed to be economically feasible. For example, the cost of replacing systems using mercury catalysts is not expected to impose significant costs to industry according to the dossier, though it is unclear how and why this conclusion is reached.		No comment / SEA issue.	
					There is insufficient analysis of any change in product characteristics and any implications for use in applications		No comment / SEA issue.	
					This is a distinct lack of information on the historical and future manufacture and use of the phenylmercury substances. Such basic data ought to be a key component of the evidence presented in the dossier.		We agree that emissions from exported articles could be discussed as it is a way to underline the impact that may be bigger than "only" air emissions. We thus added a discussion and a rough estimation of what could "come back" from air	

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							LRT, food and articles.	
					The data on imports and emissions from imported articles is lacking, even though the restriction is partly based on the need to restrict imported articles. Further information in this respect would be desirable.	There is a general lack of data related to imports of articles in the EU. We agree that this is a problem. It has not been possible for us to solve this problem during this work.	See previous comment.	Agree with the fact that this information would be desirable. But SEAC rapporteurs also rely on DS in all the efforts they had made to find the information and DS has highlighted the fact that no data on imported articles could have been obtained.
					The dossier needs to provide further details on the conclusion that authorities have appropriate control systems in place with respect to enforceability.	There is a small number of manufacturers of phenylmercury compounds and formulators of phenylmercury catalysts (less than 8). This restriction should not be more difficult to enforce than a great number of other EU regulations.	/	Agree with DS response.
					More detail is needed on what elements are included in the cost information regarding the annual cost of restriction option 2.	This is included in the revised report.	No comment / SEA issue.	Agree with DS.
					More discussion and justification is needed	This is based on the information given	We agree also on	Agree with response

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					regarding the conclusion that the introduction of Restriction option 2 over a period of 2 years could be disproportionate in technical and financial terms.	to us from the industry. We have consulted all identified manufacturers of Phenylmercury compounds and formulators of Phenylmercury catalysts.	the need for some information on the technical terms to be convinced that a shorter delay is not appropriate as a shorter delay would be more appropriate from a risk point of view.	by DS.
					The description of impacts is very general and could benefit from a more qualitative or quantitative analysis being undertaken.	Agree. But it has not been possible to assess damage to health and environment that can be directly contributed to emissions of Hg from these products.	We acknowledge.	Agree with the comment and with DS response.
					The main cost of finding suitable alternative systems would according to the dossier be one-off R&D costs. What about any ongoing costs and consequent increase in price associated with cost increases arising from a potential need to change the materials and/or quantities used in mercury free products.	We have not received any information about such costs from the consultations.	No comment / SEA issue.	Please see comment by DS.
					Mercury products are considered to be premium products (presumably commanding a premium price), but it is unclear if and how this has been taken into	We have calculated replacement costs. We have not added any "premium product" costs.	No comment / SEA issue.	Including premium product costs would have allowed a little more refined and

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					account in the compliance costs assessment of replacing them?			precise calculation but it should not be really necessary for the purposes of the dossier.
					The dossier often relies heavily on unsubstantiated assumptions and assertions in terms of the SEA analysis. More emphasis should be given to developing the evidence base and collection of information to further substantiate the claims made. Furthermore, the information given is often partial and provides only an incomplete picture of the situation, such that robust conclusions are difficult to make on the justification for the restriction in terms of impacts and its proportionality.	Assumptions are based on consultation with industry. See chapter G. There is however a limit due to availability of this information and the costs of obtaining it. It has not been possible to collect any more information within the limits of this work.	No comment / SEA issue.	Agree with the comment that more substantial information on costs would have been desirable. However, SEAC rapporteurs also agree with DS that the information and the robustness of the SEA are dependent on the availability of the information and especially on the industry's willingness to provide it.
								General comment: Rapporteurs agree with the DS responses. One general remark

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								to MS' comments referring to the need for more information: rapporteurs find it important to keep in mind being proportional when preparing / evaluating a restriction proposal; more information would always be desirable but it is important to keep in mind what is "nice-to-know" and what is a "need-to-know". Regarding certain parts of the restriction proposal (e.g. information on costs of substitution, information about availability and feasibility of alternatives, phase-out periods, etc.) authorities are generally dependent

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								on information provided by industry. In this specific case, the DS double checked information with industry and no converse information has been received during public consultation so far. The information collected and the assumptions made by the DS are thus considered to be correct, coherent and plausible and the calculations have been carried out in a sound and systematic way.

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Specific question 1

Ref	Att	Date	Country/ Organisation/ MSCA	Type	Comment	DS Response	RAC Rapporteurs comments	SEAC Rapporteurs comments
84	N	2010/12/21 12:14	/ / Ireland MSCA	(A) (B), (C), (D) (E), (F)	The Health and Safety Authority has no relevant information.		/	

Specific question 2

Ref	Att	Date	Country/ Organisation/ MSCA	Type	Comment	DS Response	RAC Rapporteurs comments	SEAC Rapporteurs comments
84	N	2010/12/21 12:14	/ / Ireland MSCA	(A) (B), (C), (D) (E), (F)	The Health and Safety Authority has no relevant information.		/	

Specific question 3

* (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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84	N	2010/12/21 12:14	/ / Ireland MSCA	(A) (B), (C), (D) (E), (F)	The Health and Safety Authority has no relevant information.		/	

Specific question 4

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84	N	2010/12/21 12:14	/ / Ireland MSCA	(A) (B), (C), (D) (E), (F)	The Health and Safety Authority has no relevant information.		/	

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