Committee for Risk Assessment (RAC)

Opinion

on an Annex XV dossier proposing restrictions on

Five Phenylmercury compounds

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

Chemicals concerned:

Phenylmercury acetate
Phenylmercury propionate
Phenylmercury 2-ethylhexanoate
Phenylmercury octanoate
Phenylmercury neodecanoate

Adopted

10 June 2011

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10 June 2011
RES-O-0000001362-83-02/F

Opinion of the Committee for Risk Assessment
on an Annex XV dossier proposing restrictions of the manufacture, placing on the market or use of five substances within the Community

Having regard to Regulation (EC) No 1907/2006 of the European Parliament and of the Council 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (the REACH Regulation), and in particular the definition of a restriction in Article 3(31) and Title VIII thereof, the Committee for Risk Assessment (RAC) has adopted an opinion in accordance with Article 70 of the REACH Regulation on the proposal for restriction of

Chemical name(s):	***Phenylmercury acetate***
EC No.:	***200-532-5***
CAS No.:	***62-38-4***
Chemical name(s):	***Phenylmercury propionate***
EC No.:	***203-094-3***
CAS No.:	***103-27-5***
Chemical name(s):	***Phenylmercury 2-ethylhexanoate***
EC No.:	***236-326-7***
CAS No.:	***13302-00-6***
Chemical name(s):	***Phenylmercury octanoate***
EC No.:	**-**
CAS No.:	***13864-38-5***
Chemical name(s):	***Phenylmercury neodecanoate***
EC No.:	***247-783-7***
CAS No.:	***26545-49-3***

This document presents the opinion adopted by RAC. The Background document (BD), as a supportive document to both RAC and SEAC opinions, gives the detailed ground for the opinions.

PROCESS FOR ADOPTION OF THE OPINION

Norway has submitted a proposal for a restriction together with the justification and background information documented in an Annex XV dossier. The dossier conforming to the requirements of Annex XV of the REACH Regulation was made publicly available at ***http://echa.europa.eu/consultations/restrictions/ongoing_consultations_en.asp*** on ***24 September 2010***. Interested parties were invited to submit comments and contributions by ***24 March 2011***.

ADOPTION OF THE OPINION OF RAC

Rapporteur, appointed by RAC: ***Olivier LE CURIEUX-BELFOND***
Co-rapporteur, appointed by RAC: ***Frank JENSEN***

The RAC opinion as to whether the suggested restrictions are appropriate in reducing the risk to human health and/or the environment has been reached in accordance with Article 70 of the REACH Regulation on ***10 June 2011***.

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

The RAC opinion was adopted ***by consensus***.

OPINION

RAC has formulated its opinion on the proposed restriction based on information related to the identified risk and to the identified options to reduce the risk as documented in the Annex XV report and submitted by interested parties as well as other available information as recorded in the Background Document. RAC considers that the proposed restriction on ***five Phenylmercury compounds*** is the most appropriate Community wide measure to address the identified risks in terms of the effectiveness in reducing the risks provided that the scope and/or conditions are modified. The proposed restriction with modifications is as follows:

Phenylmercury acetate
CAS 62-38-4, EC 200-532-5
Phenylmercury propionate
CAS No 103-27-5, EC No 203-094-3
Phenylmercury 2-ethylhexanoate
CAS No 13302-00-6, EC No 236-326-7
Phenylmercury octanoate,
CAS No 13864-38-5, EC Number not available
Phenylmercury neodecanoate
CAS No 26545-49-3, EC No 247-783-7

1. Shall not be manufactured, placed on the market, or used, as a substance or in mixtures after 3 years of the entry into force*.

2. Articles, or parts of articles, containing the substance(s) shall not be placed on the market after 3 years of the entry into force*.

*The provisions referred to in paragraphs 1 and 2 above concerning mixtures and articles are not applicable if the concentration in a mixture or in articles or any parts thereof does not exceed 0.01 % weight by weight (w/w) mercury.

<u>Important consideration</u>

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 other organomercury compounds are not used as alternative to the restricted substances.

**Other organomercury compounds that may be used as catalysts in the polymer production and have the general formula (R-Hg)*n*-X where wherein R is aryl, aralkyl, alkaryl, heterocyclic or straight, branched alkyl, or cyclic lower alkyl; and the halo, amido, carboxy, lower alkoxy or nitro substituted derivatives thereof, X is an saturated or unsaturated, branched, straight or aromatic carboxylate, and *n* is an integer of 1-4.

JUSTIFICATION FOR THE OPINION

Identified hazard and risk

RAC considers the proposed community wide restrictions to be necessary and appropriate. It reduces the risk of exposure to mercury from the manufacture and use of phenylmercury compounds for both man and the environment. Implementation of this restriction will avoid mercury in polyurethane systems and C.A.S.E. (coatings, adhesives, sealants and elastomers) applications present in articles or parts of articles placed on the EU market in addition to any export from Europe. The implementation period should be as short as possible to make this restriction more beneficial from a risk point of view. The available alternatives pose less risk to health and environment and risks seem to be easier controlled than risk posed by mercury. Other organomercury compounds are not suitable alternatives.

1. Mercury threat and future global mercury strategy

Mercury is a very hazardous substance to humans, ecosystems and wildlife, in particular when chemically converted to methylmercury. The nervous system and the developing brain are the most sensitive target organs. Mercury is found both naturally and as an introduced contaminant in the environment. It is considered a global persistent pollutant, as once emitted it enters a complex biogeochemical cycle and can then be found in almost all environmental compartments all over the world. The formation of methylmercury and subsequent biomagnification in food chains are particularly of serious concern. Besides, exposures for workers or for consumers by emissions from articles are also possible. It is thus necessary to reduce any source of exposure to mercury to protect both humans and biodiversity.

The European and future international strategies are also highlighting the global concern with respect to mercury and there is commitment for reducing emissions at local, national, regional and global level. Thus, the EU mercury strategy (EU, 2005) Action 8 specifies that the Commission will further study in the short term the remaining products and applications in the EU that use small amounts of mercury. Among the targets, the use of phenylmercury compounds as catalysts has been identified (COWI for the EC, 2008). In addition, the United Nations Environment Programme agreed to take steps towards a global legally binding instrument to control uses and emissions of mercury (UNEP, 2009) with the goal of completing negotiations by 2013 and implementation as soon as possible; this means that the implementation will probably not be earlier than in 2018. Whether the use of phenylmercury compounds as catalysts will be included in the future Convention is not known at this stage in the negotiations.

2. Grouping

Grouping of these 5 phenylmercury compounds is fully justified due to their common use in polyurethane systems used for C.A.S.E. applications and their common degradation/transformation pathway. RAC believes this grouping should even be extended to other mercury compounds used as catalyst, in order to avoid their use as substitutes for the 5 phenylmercury compounds listed.

These 5 phenylmercury compounds are known (COWI for EC, 2008) to be used as catalysts in polyurethane's systems used for C.A.S.E. (coatings, adhesives, sealants and elastomers) applications (90% of the applications are currently assumed to be used for elastomers). In Europe, the neodecanoate form is almost exclusively used whereas the acetate and 2-ethylhexanoate forms are exported. The octanoate and propionate forms are currently not manufactured in or imported to the European Union. The catalyst function is the only known use identified in Europe. One exception could be the use as preservative in eye products since the acetate and benzoate forms are listed in the Cosmetic Products Regulation (EC) No 1223/2009. However, such use of these two phenylmercury compounds or others has not been mentioned, neither during the survey done by the Dossier Submitter (DS) nor during the public consultation. It should be noted that exported phenylmercury compounds might be used for other purposes, e.g. as active substance in biocides.

In the environment, notably in water, the first degradation stage is a rapid cleavage of the carboxylate bond. The phenylmercury cation or its hydroxide form thus is the common metabolite within the pH ranges usually found in natural waters (pH 5-9) (see chapter B4 and appendix 12 in the Background Document, BD). The pathway will then follow exactly the same fate and behaviour in the environment regardless of what the initial phenylmercury compound was.

The 5 substances included in this restriction proposal are those that are or have been used and manufactured in EU in significant amounts. However, as described in numerous patent applications various mercury compounds are suitable as catalysts, as long as the mercury atom is covalently bound to a carbon atom and the organomercury compound has ionic properties. Thus, instead of the phenyl domain the molecule may contain aryl, aralkyl, alkaryl, heterocyclic or straight, branched alkyl, or cyclic lower alkyl and the halo, amido, carboxy, lower alkoxy or nitro substituted derivatives thereof. The anionic part of the molecule typically comprises a saturated or unsaturated mono- or dicarboxylate with between 2 and 18 atoms. Also halogenated derivates of these carboxylates can be used. When carboxylated and phenylmercury domains are similar to the 5 phenylmercury compounds described in DS' proposal, first degradation steps and half-lives will be very similar; and even if it's not the case, pathway will on a long term end all the same to mercury and methylmercury.

If the phenylmercury compounds currently used as catalysts in European polymer industry are replaced by other organomercury compounds as a result of a restriction, mercury emissions will probably not be reduced efficiently. RAC thus recommends that other organomercury compounds that may be used as catalysts in the polymer production should be clearly identified as not suitable alternatives to these 5 phenylmercury compounds.
The general formula of these not suitable alternatives is (R-Hg)n-X wherein:

- ***"R"* is aryl, aralkyl, alkaryl, heterocyclic or straight, branched alkyl, or cyclic lower alkyl; and the halo, amido, carboxy, lower alkoxy or nitro substituted derivatives thereof;**
- ***"X"* is an saturated or unsaturated, branched, straight or aromatic carboxylate;**
- **and *"n"* is an integer of 1-4.**

3. PBT and LRT properties

(Eco)toxicity data on phenylmercury compounds, mostly based on phenylmercury acetate (PMA), show these compounds are of concern. However, even more concerns arise from their degradation products. The phenylmercury compounds degrade into different mercury compounds which can interconvert. As these reversible conversions may occur according to the environmental conditions, the properties of the different metabolites should be combined to assess the risks which may arise from the phenylmercury compounds. So, by considering the 2 entities, methylmercury (CAS 22967-92-6) and inorganic mercury (CAS 7439-97-6) PBT-like properties can be considered as met and thus requiring risk management measures without threshold:

The "P" criterion is met by mercury. Elemental mercury is by definition persistent. This inorganic form is not covered by Annex XIII; however mercury is not removed from the environment through degradation processes and will always be potentially available for transformation into methylmercury (through complex processes under appropriate conditions, even at equilibrium there is a near constant level of methylmercury in aquatic systems). Any increase in the environmental pool of inorganic mercury will provide an additional source of methylmercury, and this source will persist for many years. It is therefore not relevant to compare half-life data with the Annex XIII "P" criterion. Mercury cycling itself represents an equivalent level of concern for persistence (or even "very persistent"). Furthermore, under anaerobic conditions, the rate of demethylation can be lower than methylation.

The "B" criterion is met by methylmercury as the bioconcentration factor (BCF) in fish can range from 8140 to 85 700 and is thus higher than the threshold value which is 2000 for this criterion (and even than 5000 which is the threshold value for the "very bioaccumulative" criterion). Besides, methylmercury biomagnification is exceptionally high with a typical increase of more than 1 log unit between trophic levels, and may explain an accumulation in living organisms which can reach values 10^7 times higher than the concentration measured in water (Hill et *al.*, 1996; Weiner *et al*., 2003).

The "T" criterion is met by methylmercury which NOEC is 0.26 µg Hg /l which is 2 orders of magnitude below the threshold value of 10 µg/l required by annex XIII. The classifications of methylmercury and mercury for reproductive toxicity category 1A and 1B respectively and mercury for STOT RE category 1 also confirm this "T" criterion (article 58(15) of CLP Regulation (EC) No 1272/ 2008 amending REACH Regulation (EC) No 1907/2006).

If transformation/degradation products with PBT-properties are being generated, the substances themselves must be treated like PBT-substances with regard to emission estimation and exposure control. For this reason, discussions of risks based on PEC/PNEC considerations in the background document are not of particular relevance to the opinion.

4. Long range transport properties

Interconversions of phenylmercury compounds metabolites allow - notably through the elemental and oxidised forms of mercury in the vapour phase or associated with aerosols respectively - long range transport (LRT). These properties make the environmental or

human exposure concentrations unpredictable and thus give an additional reason for reducing any emission as much as possible.

In particular, in the Arctic and circum Polar Regions the atmospheric mercury deposition events result in large seasonal fluxes of mercury to snow and ice surfaces (e.g., Lindberg et *al.*, 2002; Steffen et *al.*, 2008) and contamination of human via food.

5. Health risk

The main toxicological concern is for the neurodevelopment in humans observed after exposure during pregnancy of women consuming notably fish containing methylmercury. This type of effect does not appear to have a threshold and thus calls again for reducing any emission as much as possible.
Although a provisional Tolerable Weekly Intake (PTWI) has been established for methylmercury by JECFA based on the most sensitive toxicological endpoint (developmental neurotoxicity) in the most susceptible species (humans), the non-threshold approach should be considered.
It should also be noted that available data does not allow for quantification of the contribution from these particular compounds to the total intake of methylmercury.

In all species which were examined, phenylmercury-acetate (PMA) was found to be taken up and stored mainly in kidney but also in liver at a maximum level approximately 24 hours after intravenous or oral administration; whereas only minor levels have been found in brain, heart, bone, central nervous system and spleen. PMA enters the kidney and is in part rapidly excreted unchanged in urine and in part metabolised to inorganic mercury compounds which are not as readily available for excretion. The elimination of elemental mercury and Hg^{2+} follow complex kinetics with half-lives in the range of 20 to 90 days (SCHER, 2008). In rats, faecal excretion of PMA increased rapidly with time and two days after intravenous or oral administration 6-8% and 91-93% of the recovered mercury was excreted via urine and faeces, respectively.

The main exposure via environment may be through food in which the phenylmercury compounds' transformation products may be found. Especially methylmercury containing seafood has a marked impact on total mercury concentration in the human brain (Björkman et al., 2007). Estimates for the biological half-life of methylmercury range from 44 to 80 days (UNEP, 2008). However, sufficient information is not available in order to make a quantitative risk assessment of the possible exposure level of man via the environment for methylmercury from the phenylmercury compounds per se, since there are other sources as well.

In adults, the earliest neurological effects of methylmercury poisoning are symptoms such as paraesthesia, discomfort, and blurred vision. At higher exposure the following symptoms may appear: disturbances of the visual field, deafness, dysarthria, ataxia, and ultimately coma and death (UNEP, 2002). The developing nervous system is more sensitive to methylmercury than the adult. Offspring from mothers consuming methylmercury-contaminated food during pregnancy have shown a variety of developmental neurological abnormalities including microcephaly, hyperreflexia, and gross motor and mental impairment (UNEP, 2002; 2008). A provisional classification for methylmercury has been agreed by the TC C&L on acute toxicity, repeated dose toxicity, mutagenicity, carcinogenicity, reproduction toxicity and environmental hazards (T; R48/25; T+; R26/27/28; Muta. Cat. 3; R68; Carc. Cat. 3; R40,

Repr. Cat. 1; R61, Repr. Cat. 3; R62, R64, N; R50/53) (Ex-ECB, 2010). Effects on the central nervous system including ataxia and paresthesia have been observed in subjects with blood mercury levels as low as 200 µg Hg/l, corresponding to 50 µg Hg/g of hair (EPA, 1997).

The monitoring data in the Faroe Islands have been used to epidemiologically link the exposures through seafood – notably the traditional consumption of pilot whale meat - and the IQ effects in infants (Grandjean et *al.* 1997). The Joint FAO/ WHO Joint Expert Committee on Food Additives (JECFA) established a provisional Tolerable Weekly Intake (PTWI) for methylmercury to 1.6 µg/kg body weight / week (WHO, 2003). This Committee determined that a steady-state daily ingestion of methylmercury of 1.5 µg/kg bw/day would result in concentrations in maternal blood estimated to be without appreciable adverse effects in the offspring in the Faroe and Seychelles Island studies. From this figure, a general-population DNEL long-term for the oral route can be calculated by using the assessment factors 10 for the intraspecies differences (general public) and 1 for the quality of the whole database: DNEL = LOAEL/AF = 1.5/10 = 0.15 µg/kg bw/day.

According to EFSA the estimated intake of mercury from food (in the form of methylmercury) in Europe varies between countries and is in most cases below the PTWI, but may exceed it in some high intake cases or/and in children. Empirical probability of exceeding the JECFA's PTWI (number of subjects with an intake greater than PTWI divided by the total number of subjects in the survey) was estimated 11.3% for children (in France) 3-6 years old (EFSA, 2004).

In Nordic European countries a significant increase of the mercury levels has been observed in 2008 compared to levels in fish caught in the period 1990 – 2001 (Ranneklev et *al.*, 2009). The concentrations (Norway, Sweden and Finland) increase with fish size, and the EU maximum level for placing fish products on the market - 0.5 mg Hg/kg (EC, 2006) – in average has been often exceeded (about 50-80% of the more than 1500 monitored lakes) and even regularly has exceeded 1.0 mg/kg which is an accepted limit for some fish in 5-20% of the lakes (Munthe et *al*., 2009).

6. Emissions estimations in 2008

Regarding the PBT-like properties of the transformation products, the combination of all emissions during the life-cycle should be considered.

Phenylmercury compounds, in fact essentially phenylmercury-neodecanoate, are used as catalyst in PU systems used for C.A.S.E. products in concentrations within the 0.1-0.8% range. Estimated quantity of phenylmercury-neodecanoate used in Europe in 2008 is 36-70 t/y; with 44.7% mercury content, it corresponds to 16.1-31.3 t mercury. The life cycle includes less than 4 manufactures, more than 100 formulators and more than 1000 users. Because of the high number of industrial users (sites) and the numerous different articles for both professional and consumer use emissions can be considered as wide dispersive. The combination of all these sources provides the realistic worst case of environmental exposures. It should be noted that manufactured quantities for exports are - as mercury - 2.6-2.9 times higher than what is manufactured for use in Europe.

Emission factors for air and wastewater proposed by DS, based on site specific data from manufacturing, are 0.0016% and 0.00015%. These are much lower than default values (ECHA's guidance R16 recommends in a first approach with the environmental release

category 1 - ERC1 - the default release factors to air, wastewater and soil of 5%, 6% and 0.1% respectively).
However, data are not numerous and were associated with uncertainties. It could be notably noticed a conflict between the operational hours per year put forward by manufacturers and the continuous process mentioned in monitoring documents, and the absence of information about solid waste (e.g. filters). Moreover, the monitoring values were not checked against mass balance calculations. RAC thus conclude that default values cannot be used in this case and that release factors are higher than the ones calculated from manufacture data.

Emission factors for air, wastewater and landfills can be estimated to be 7.5%, 0.06% and 0.001% for formulation and processing. Default values proposed in TGD (2003) were chosen instead of values proposed for example by the Emission Scenario Document (ESD) for Plastic Additives which applies for liquid curing agents (OECD, 2004) to take account of the transformation during the process into more hazardous products for the case of phenyl mercury catalysts. Mercury emissions from the formulation and processing stages can then be estimated 2.35, 0.02 and 0.003 t/y to air, water and landfills, respectively.

Emission factor to air during service-life was estimated by using gym flooring for which a mercury half-life of 16 years was calculated (ATSDR, 2008). If transposed to a service life of 5 or 10 years, 19.5% or 35.2% of the mercury is likely to be released from articles to air during their service life. As many factors may affect the releases from articles, like the surface to volume ratio, the degree of transformation of the initial phenylmercury compound (etc...), it was chosen to use an average of about 9-10 % (0.095) of the mercury content emitted to air during service life of articles. Releases of mercury to wastewater may take place for example when washing the articles. In the absence of actual emission factors, an average factor of 1% (0.010) for all applications was thus applied. For sub-sea and maritime applications, the total quantity emitted is probably low. Mercury emissions for the service life stage can then be estimated to 2.75, 0.26 and 18.4 t/y to air, water and landfills, respectively.

Emission factors during waste stage can be split in incineration and landfilling. For incineration, when taking into account that installations are equipped with specific abatement systems, emission factors are 10% and 0.02% to air and water, respectively; leading to the assumption that 0.25 t mercury may have been emitted to air in 2008. Mercury is ultimately land-filled; either as municipal solid waste or as residue from incineration. Only an emission factor to air was considered: 1%. As the total quantity of mercury which ends in landfilling was 25.16 t/y, emissions from landfilling to air are estimated to be 0.25 t/y. It can be noted here that landfilling conditions can be very varied and that in some cases – like use as under road layer – emissions to soil and water may not be negligible. It seems not necessary here to refine but this point may counterbalance any conservative approach used in other parts of these emission estimations.

All together, from the around 31.3 t mercury (in phenylmercury compounds) used in Europe in 2008, 6.1 tonnes are estimated to be released to air, 0.28 t to wastewater, and 25.16 t to landfills (rounded values make the total equal to 31.54). The estimated 6.1 t mercury emitted to air can be compared to the total volume emitted to air from all applications in EU27 in 2008 (European Union emission inventory report 1990-2008 under the UNECE Convention on Long-range Transboundary Air Pollution, LRTAP). Phenylmercury compounds may represent around 7% of the total mercury air emissions in Europe in 2008. This percentage was estimated based on UNEP data to be around 4% in 2005. The comparison of these 2005 UNEP data to the EU data reported under LRTAP can be

considered as acceptable. On one side, these 4% could be overestimated because referring mostly to default emission factors, but on the other side several gaps may counterbalance any conservative approach. Such gaps include an estimation of average emissions based only on emission data from old gym flooring or no refinement of the long-term emissions that may occur from solid waste. Moreover the emission factors were derived from the TGD (2003, A&B tables) which may include risk management measures. Overall, these estimations may still be realistic.

7. Exports

Exported quantities are 2.4-2.7 times higher (93-194 t/y phenylmercury-acetate, –2-ethylhexanoate and -neodecanoate) than the 36-70 t/y (38-71 t/y when considering more accurately the uncertainties, see table in BD) phenylmercury-neodecanoate used in Europe. This corresponds to 44-91 t/y mercury, meaning that the mercury quantity exported is 2.6-2.9 times of what is used in Europe.

The mercury emission factors outside Europe can be considered the same as in Europe if considering only the applications in elastomers (other uses, like biocide, may result in higher emissions). If Restriction “option-1”, “option-3” or “option-2” (5-, 3- or 2-year delay for implementation respectively) is applied, emissions that could be avoided from exports between 2015 and 2030 (see paragraph 1c in section “Justification that the suggested restriction is the most appropriate Community-wide measure” of this opinion document) can be estimated to 58.3, 75.1, and 85.0 t mercury.

The mercury emitted to the atmospheric compartment due to use of exported volumes may partially “come back” to Europe through air, but also via food and articles. The known atmospheric global mercury fluxes cannot be linked specifically to the use of phenylmercury compounds. In addition, no data were available for food and articles.

The risk reduction benefit may be much greater if the restriction includes manufacture –as proposed by the dossier submitter - because beside the avoided emissions from manufacture itself, the contribution to global emissions from the uses outside Europe will also be avoided.

8. Conclusion about risks:

Regarding the chemical breakdown similarities, it is fully justified to group the 5 phenylmercury compounds. The cycling of mercury in the biosphere entails that the source of this transformation product is always present once released. Furthermore, as other phenylmercury compounds are expected to follow the same degradation pathway as the 5 phenylmercury compounds in nature and thereby represent an equivalent risk; RAC recommends that it is made clear that any other mercury compound is not suitable as alternative.

Regarding the reversible transformations between the different degradation products, it can be concluded that there is an equivalent level of concern to PBT substances and therefore non-threshold effect. This is a strong argument to restrict these 5 phenylmercury compounds and even other mercury compounds that may be used as alternatives. The long-range transport (LRT) properties of the elemental mercury form and the high biomagnification potential of methylmercury are also underlining the non-threshold approach. Last but not least, even if a decrease of IQ may be quantified, the neurodevelopment effects are initially rather considered without threshold. So, these phenylmercury compounds – and any other mercury-containing catalyst - should be totally avoided as soon as possible.

Keeping manufacture in the proposed restriction is highly recommended by RAC as emissions outside Europe from the exported quantities can be estimated as high as 2.9 times the mercury emissions from uses in Europe.

Justification that action is required on a Community-wide basis

1. Wide dispersive

The use of these phenylmercury compounds should be considered as wide dispersive. Indeed, hundreds of formulators and thousands of industrial users emit these phenylmercury compounds to air and wastewater and there are numerous different articles that are used both by professionals and by consumers. Solid waste ends up in landfills either directly or after incineration without destruction of the mercury contents. Moreover, the mercury is not collected for proper waste handling from the great variety of articles which can be found on the market because there is no requirement to collect most of the articles separately due to the low concentration in the articles.

2. Long range transport

Mercury is volatile even at low temperatures and can easily be transported over long distances through both air and biota; this justifies an action at Community level to address the adverse impacts of mercury and its transformation products not only at the whole European but also at the worldwide level.

3. European and global policy contexts

As recalled in the introduction of the risk section of this document, this restriction is also in coherence with both the European global strategy (2005) and the UN global instrument (UNEP, 2009), which has to be finalised by 2013. At the European level, the Water Framework Directive requires establishment of environmental quality standards (EQS) applicable to aquatic ecosystems. For mercury, the EQS values set at 0.02 mg/kg wet weight in freshwater fish and 0.05 μg/l in water are sometimes exceeded (see last paragraph in subsection 5 about health risks of this opinion document).

4. Conclusion about the need of a wide-community action

RAC considers that a Community-wide action is required, because of the widespread use across the EU countries, the long-range transport properties and the European and global policy contexts.

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

1. Comparison of the different options with the baseline "business as usual".

The 2008 data and information from industry indicated that volumes used 10 years ago were 2.5 times higher (industry stated between 2 and 3 times higher). DS concluded that the trend in use could be considered as an exponential decay. DS compared option-1 (5 years from adoption in 2012) and option-2 (2 years implementation from adoption in 2012) with a baseline corresponding to the possible mercury emissions that could be avoided during the first 10 years after implementation. Estimations showed that option-1 (5 years delay, period 2018-2027) would result in a reduction of 15 t mercury released to the environment and option-2 (2 years delay, period 2015-2024) would result in a reduction in mercury of 17 t.

According to RAC, several assumptions in these estimations could be seen slightly different:

a) Industry stated that 2-3 years might be needed for substitution of 70% of the applications where mercury-containing catalysts are used, and that this may be too ambitious; however, no delay was put forward for total substitution (COWI and Concorde East/West, 2008). Therefore, it seems appropriate to introduce a third option, a 3 years delay. A shorter delay than 5 years is also considered relevant because as decay is considered exponential, the earlier the restriction is applied the more efficient it will be (quantities are much higher in the beginning of an exponential decay). The 2 years phase out might be too rapid tempting suppliers to just make a simple switch to other mercury-containing substances unless this is also covered by the restriction.

b) Considering the substitution difficulties, instead of a simple exponential decay one could consider the hypothesis of the addition of two exponential decays, a first one exactly as calculated previously but only for 70% of the uses, and a second one with a lower decay rate constant to reflect the difficulties that may arise for 30% of the applications. This calculation alternative would increase the predicted emissions and delay the "natural decay" end. RAC doesn't think that this refinement is needed, but wants to note that DS emissions predictions may be underestimated.

c) To compare the restriction options with the baseline, end-of-emissions if no risk management option is applied has to be fixed and calculations for all options adjusted to the same starting and end-of-emissions years. By end of 2012 the restriction may be adopted but as the shorter option may only be implemented 2 years later, 2015 should be the starting-year to assess what may be the benefit of the different options. On the other end, considering on one side a "natural decay" that may end within 10 years (this means around 2021) and on the other side a global ban (possibly implemented in 2018), a possible end-of-emissions year for calculation of the baseline could be 2020. However, two uncertainties need to be considered here: the natural decay could slow down at a lower rate if no external signal is given by authorities to industry, or/and some derogations or delays could be introduced in UN's global ban. One should thus consider as reasonable end-of-emissions in year 2030.

By applying all these modifications, predicted emissions and avoided emissions in EU can be estimated as summarised in the following table (these figures are calculated with the same rules as used by DS but changing the starting and the end-of-emissions years) (for details, see section E.2.3 in BD):

Tonnes mercury	**from 2015** (implementation of the shorter delay restriction option) **until 2030** (global mercury ban)	
	Emitted	**Avoided emissions**
Baseline "**business as usual**"	**29.3**	**0.0**
"Option-1" **5-year delay**; proposed by DS	**9.2**	**20.1**
"Option-3" **3-year delay**; proposed by RAC	**3.3**	**25.9**
"Option-2" **2-year delay**; used by DS for comparison with option-1	**0.0**	**29.3**

When comparing the different delay options of this restriction with the emissions baseline ("Business as usual") it has to be underlined that implementation should take place as soon as possible to provide a real benefice in term of avoided risks: if the 2-year-delay is not chosen, one additional year (option-3) will lead to 11% more mercury emissions, and 3 additional years (option-1) will lead to as much as 31% more mercury emissions.

2. Assessment of other pieces of legislation as alternative options to restriction

Several existing pieces of legislation (IPPC, WFD, end of life vehicles directive, waste directive) may potentially reduce the risks arising from mercury in different stages of the life-cycle of phenylmercury compounds used in polyurethane systems.

However no clear information is available on how efficient they may be and how they cover all potential emissions, especially as the sources may be very numerous. In addition, IPPC and WFD do not specifically cover articles and waste which are the main sources of concern. The low concentrations in articles do not require recovering or classification as hazardous waste according to current legislation. Furthermore, as mercury and mercury compounds, when considered together, may be regarded as PBT and long-range transport substances, none of the measures currently in place can be considered as sufficient to remove the concern. The proposed restriction is much more appropriate to deal with all the sources and the specific properties of mercury compounds.

3. Conclusion about the appropriateness of restriction

Regarding the emissions which cannot be avoided with the existing legal rules and the high concern represented by these compounds, RAC considers restriction as the most appropriate community-wide measure.

The highest release will take place in the next few years because these uses are decreasing exponentially. Therefore, to ensure the efficiency of this restriction, implementation from a risk point of view should be as soon as possible, this means no later than 3 years after adoption.

Effectiveness in reducing the identified risks, proportionality to the risks

1. Identified alternatives are numerous

Three groups of alternatives were described: Same PU systems with non-mercury catalyst (using the same polyol and isocyanate components), other PU systems with non-mercury catalyst (reformulating the system using other polyol or isocyanate components), and non-mercury systems based on other polymers (e.g. silicones). Among these numerous alternatives described, DS has compared phenylmercury acetate, other phenylmercury compounds and methylmercury with the following possible alternatives to phenylmercury compounds: bismuth carboxylates, zinc carboxylates, zirconium carboxylates, titanium chelates and tertiary amines. **When checking classification and potential PBT properties all these alternatives appear as less hazardous.**

Some organotins compounds were also mentioned as alternatives; for example for silicone and polyurethane systems, catalysts based on dibutyltin diacetate (CAS No 1067-33-0), dibutyltin dilaurate (CAS No 77-58-7), dimetylbis[(1-oxoneodecyl)oxy]stannate (CAS No 68928-76-7), dibutyltin oxide (CAS No 818-08-6) and dioctyltin dilaurate (CAS No 3648-18-8) can be used. However, entry 20 of Annex XVII of REACH already contains restrictions on organostannic compounds used as biocide in free association paint or to prevent the fouling, or used in the treatment of industrial waters. In addition, Commission Regulation (EU) No 276/2010 completes this annex XVII with a ban on tri-substituted organostannic compounds, and restrictions on dibutyltin compounds and dioctyltin compounds. **These restrictions should be considered as a clear signal that organostannic compounds are not suitable alternatives** (see also section C of BD containing information about PBT and CMR assessments of four groups of organostannic compounds).

Nevertheless, it should be underlined that this preliminary screening of CMR classification and PBT properties does not take into consideration the fate and behaviour of these potential alternatives in the environment and in living organisms during processing or use of articles, and thus does not replace a full risk assessment.

2. Purpose is to avoid any mercury emissions

The purpose of this restriction is to avoid any mercury emissions from the use of phenylmercury compounds in polyurethane systems and C.AS.E applications. Besides the benefice of total reduction of emissions to air, this restriction will also fully resolve the solid waste issue which is of concern on a long-term scale as inorganic mercury forms are totally stable and can enter the geochemical and biological cycle at any time.

According to RAC the effectiveness of this restriction will be guaranteed only if extended to other mercury compounds that may be used as catalysts in PU systems and C.A.S.E. applications. RAC thus recommends considering necessary measures for verifying and controlling that other organomercury compounds are not used as alternative to the restricted substances, but without delaying implementation of this restriction. In addition, RAC underlines that – as proposed by DS - manufacture should be kept in this restriction (see justifications in the risk section / grouping subsection of this opinion document).

3. Objective is to contribute to global mercury reduction

This restriction would contribute to the reduction of the global mercury pool. Considering that the European strategy adopted in 2005 identified the mercury emissions as a main concern and decided that use and emissions should be reduced, this restriction can be considered as proportionate to the risks. Even though mercury compounds in polyurethane systems contribute only partially to the global mercury emissions, it should be recalled that the long-range transport drives accumulation in some specific areas of the earth. Once released mercury does not disappear, and may be transformed back into organic forms like methylmercury and can then biomagnify in the food web resulting in toxicological effects notably in organisms in development.

4. Conclusion about effectiveness and proportionality

Regarding the numerous identified alternatives which may exhibit less risk, the efficiency of a restriction of all emission sources and in the context of the European strategy, RAC supports this restriction proposal (which includes manufacturing, use and placing on the market), its earlier implementation and even strongly recommends to consider measures for other organomercury compounds.

RAC considers that there are uncertainties regarding the delay needed to put in place all alternatives (the only indication is 70% substitution within 2-3 years and no data states the improvement in term of substitutions if delay is extended from 3 to 5 years), the option-3, a total ban within a 3-year delay, appears to be the most appropriate risk management measure from a risk assessment point of view.

Practicality, incl. enforceability

1. Manufacture

As the number of current manufacturers is small, control at this stage should not represent a significant additional burden for the authorities involved. As imports are included in the EDEXIM database (assuming that imports are being notified in accordance with the Rotterdam Convention), it should be also relatively straightforward to monitor any import of these substances into the EU.

2. Implementation period

On the industry side, in the majority of cases alternatives may be applied rapidly in less than two years, maximum three years. Many alternatives are available within three very different substitution strategies, this gives to industry a lot of possibilities which most have already been applied. No details are available on how much additional delay would be needed to guarantee substitution of all phenylmercury compounds used as catalyst in PUs or C.A.S.E. systems. As the mercury issue is known since decades and global strategy moves towards a convention covering all aspects of mercury, industry has already anticipated substitution and a 3-year-delay is thus reasonable.

3. Authorisation versus restriction

It should also be noted that the authorisation process could have been chosen as a risk management measure regarding the SVHC properties of the phenylmercury compounds. However, the restriction process was considered as more practical, since there are numerous applications. In addition, there is a general lack of data regarding import and it is known that the use of mercury as a catalyst in PU is widespread around the world.

4. Conclusion about practicality

As the market is already turning to alternatives, a 5-year period for implementation of this restriction is too long. RAC is thus in favour of a 3-year implementation delay (see "option 3" proposal in the "Justification that the suggested restriction is the most appropriate Community-wide measure" section of this opinion document).

Monitorability

1. Measure of mercury versus phenylmercury compounds

There is no standardised quantitative method available for measuring phenylmercury compounds in polyurethanes. Nevertheless, a semi-quantitative method could be foreseen if an appropriate extraction method is further developed. **However, the form in which the phenylmercury compounds are during processing and in articles during service-life is unknown.** Indeed a part of the phenylmercury compounds may be transformed. In support of this hypothesis, data from gym floorings may indicate that mercury air content is higher than expected and this may mean that volatile mercury compounds are formed within the gym flooring by degradation of the phenylmercury compounds. To add complexity these transformations may be different from one process to another, from one article to another and from one phenylmercury compound to another.

Other restrictions (e.g. lead and its compounds in jewellery; it should however be underlined that it includes an "escape" with a second step measuring migration rate) and the Cosmetic Products Regulation (EC) No 1223/2009 (entry-17 covers phenylmercuric salts, -acetate and -benzoate, which should not be found higher than 0.007% Hg) monitor the total metallic amount rather than each form separately.

This approach appears all the more usable as no other sources of mercury were mentioned by any stakeholder. If necessary, enforcement of the restriction could also include the request for documentary evidence (e.g. safety data sheets/supply chain lists/certificates of compliance from suppliers etc.) of absence of use of these compounds or/and the use of allowed mercury compounds in order to prove the absence of correlation between total mercury measured and the restricted phenylmercury substances.

2. Limit value of mercury

The limit value of 0.01% Hg w/w is consistent with the amounts needed to obtain an efficient catalytic activity, i.e. around 0.1 to 0.8% Hg/total weight. For total mercury analysis several well standardised methods are available. For example, within the context of the Hazardous Substances (RoHS) Directive (2002/95/EC) an application note can be found which describes the quantification of mercury in plastic materials by external calibration using an Inductively Coupled Plasma Mass Spectrometry (ICP-MS) system; limit of quantification for the whole method is then 17.2 µg/g, corresponding to 0.00172% Hg (rounded: 0.002%). It should be noted that there is no major difficulty for sampling, as no complex preparation is required for measuring methods which are based on a measure made online during burning of the raw sample. It can also be noted that a ban currently in place in Norway uses a 0.001 % limit w/w as mercury and that the proposing limit of 0.01% Hg w/w was chosen to take into account the possible difficulties to measure the substance in matrixes such as polyurethanes.

If necessary, a two-step approach could be put in place: firstly measuring total mercury; and only if concentration is above 0.01% Hg w/w, to ask for confirming that some phenylmercury compounds are present by a semi-quantitative measure of phenylmercury compounds, or by documentary evidence that other sources of mercury are not present in the process. However, according to RAC, the mercury content measure could be appropriate especially as no other

mercury is known to be used and as the scope of this restriction after a review may be extended to other organomercury compounds.

3. Conclusion about monitorability

The measurement of mercury seems most appropriate, as methods exist and are already used in EU legislation. Limit of quantification is at least equal to the concentration limit proposed in this restriction. In addition monitoring mercury content rather than phenylmercury compounds would allow covering all five phenylmercury compounds even if some degradation of the compounds occurs during the process or during service-life.

BASIS FOR THE OPINION

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

RAC.

Based on a thorough evaluation of the available information, RAC proposes to restrict the use of five phenylmercury compounds in polyurethane systems and applications like coatings, adhesives, sealants and elastomers by banning the manufacturing, placing on the market or use as a substance or in mixtures as well as banning the placing on the market of articles. The content limit is 0.01 % w/w of mercury.

The two main new issues introduced in the opinion of RAC compared to the restrictions proposed in the Annex XV restriction dossier submitted by *Norway* are as follows:

1) From the risk point of view, reduction of the implementation period to 3 years is recommended because the uses are still essentially high in the coming years, and will decrease exponentially to much lower quantities later on. This reasoning is all the more appropriate as metabolites/transformation products have PBT and LRT properties, and as the European and international activities are in favour of a reduction of all mercury emissions sources.

2) From the risk point of view, a recommendation not to use other organomercury compounds as alternatives should be added to this restriction, because the degradation/ transformation pathway will raise the same metabolites of concern, notably mercury and methylmercury. However, as other organomercury compounds were not covered by the original proposal, RAC recommends that steps are taken to ensure that no other organomercury compounds are used as alternatives.