

Committee for Socio-economic Analysis (SEAC)

Opinion

on an Annex XV dossier proposing restrictions on five phenylmercury compounds

Draft 16 June 2011



(DRAFT) 16 June 2011

Opinion of the Committee for Socio-economic Analysis on an Annex XV dossier proposing restrictions of the manufacture, placing on the market or use of a substance 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 and the Committee for Socio-economic Analysis (SEAC) has adopted an opinion in accordance with Article 71 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 draft opinion as agreed by SEAC. 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 OPINIONS

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 SEAC

The draft opinion of SEAC

The draft opinion of SEAC on the suggested restriction has been agreed in accordance with Article 71(1) of the REACH Regulation on 16 June 2011.

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

Thedraftopinionwaspublishedathttp://echa.europa.eu/reach/restriction/restrictions_under_consideration_en.aspon 17 June2011. Interested parties were invited to submit comments on the draft opinion by 16 August2011.

OPINION

SEAC has formulated its opinion on the proposed restriction based on information related to socio-economic benefits and costs documented in the Annex XV report and submitted by interested parties as well as other available information as recorded in the Background Document.

SEAC 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 proportionality of its socio-economic benefits to its socio-economic costs.

The proposed restriction 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 Phenylmercuric octanoate, CAS No 13864-38-5, EC No Na* 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 5 years of the entry into force.
- 2. Articles, or parts of articles, containing the substance(s) shall not be placed on the market after 5 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.

*Na: not available

JUSTIFICATION FOR THE OPINIONS OF SEAC

Justification that action is required on a Community-wide basis

SEAC considers that action is required on a community-wide basis. This opinion is based on the fact that the five phenylmercury substances are manufactured and used in extensive amounts in the EU as well as considerations related to the impacts to human health and the environment, economic impacts and the availability of alternatives. The uses of certain phenylmercury compounds as catalysts in polyurethane systems were identified as significant applications of mercury. In 2008 the total reported production volumes were around 75 - 150tonnes for phenylmercury neodecanoate, 50 - 100 tonnes for phenylmercury 2-ethylhexanoate and 5 - 10 tonnes for phenylmercury acetate. Many professional and consumer products containing phenylmercury compounds are both manufactured in and imported into the European Union. As the goods need to circulate freely within the EU, a community wide action ensures an appropriate reduction of the identified risks for human health and environment and an equal treatment for the producers and distributors of the substances and articles in different member states. Furthermore, a community-wide action is consistent with and adds to the efforts already made at EU/UN level to reduce global mercury emissions¹.

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

The use of the phenylmercury compounds as well as of articles containing phenylmercury is wide dispersive. Existing community-wide risk management measures such as Directive 2008/1/EC on Integrated Pollution Prevention and Control, the Water framework Directive 2000/60/EC, the Waste Framework Directive 2008/98/EC, the Waste incineration Directive 2000/76/EC or the End of life vehicles Directive (2000/53/EC) are not sufficient to regulate wide dispersive emissions as they focus on specific sectors or uses or on point sources emissions, i.e. that these risk management measures might not completely reduce the risk. According to the dossier submitter, no information for phenylmercury emissions from imported articles could be obtained from consultation or other sources. Moreover, no quantitative data is available on the import of articles likely to contain phenylmercury compounds. It is however expected that these articles are the same category as those produced in the EU (see section F.2.1 of the Background Document). The use of mercury as a catalyst in polyurethane is widespread around the world. Articles containing phenylmercury compounds (e.g. certain plastics) are widely used in the EU so emissions from such articles might be important contributors. However, this statement is based on very uncertain assumptions and could not be verified by SEAC. In addition SEAC regards that a restriction is the most appropriate Community-wide measure as some pieces of legislation are not regarded appropriate from the perspective of timing and scope, e.g. the REACH Authorisation process does not regulate imported articles containing the substances. Therefore, a restriction concerning imported articles would anyhow be necessary in addition to the Authorisation process. Therefore, no other EU legislation with the same potential to reduce the risks was identified by the dossier submitter and SEAC agrees on this conclusion. Voluntary action by industry has not been considered to be an appropriate risk management option by the dossier submitter. Although proportional in terms of cost it will be very difficult to implement and enforce a voluntary agreement for imported articles as, according to the dossier submitters'

¹ There might also be indirect and wide negative effects of the restriction, especially if manufacture was transferred outside EU. But the situation could be worse if no action was implemented in the EU. A EU restriction has primarily to be seen as a further step in the global effort to reduce Hg emissions.

conclusions, these products are not imported and used by a specific industry (section E.1.2. of the Background Document). Therefore SEAC agrees with the conclusion of the dossier submitter that the proposed restriction is the most appropriate Community-wide measure. An overview of all considered risk management options is given in Table E.1 "Assessment matrix for risk management options against three criteria" of the Background Document.

The consultation undertaken by the dossier submitter indicates that there are significant efforts to further replace mercury-based catalysts in polyurethane products but no comprehensive data are available on the likely pace of future decline in use of the substances (sections B.2.3. and C.5. of the Background Document). As stated in the Background Document, whilst there is uncertainty in the rate of decline, it seems clear that there will continue to be a decline in use. However, it also seems clear that there are some uses of these compounds that will require additional time and effort to make substitution possible. Therefore, SEAC supports the argument that "it is unlikely that these substances will be fully replaced by alternatives in the short to medium term without any additional regulatory pressure" as stated by the dossier submitter. Industry clearly stated during stakeholder consultation that a 5-years-phase out period allows for substitution of all applications. A shorter time frame would increase the risk reduction capacity but would be less proportionate and simple to implement because necessary alternatives are not expected to be available earlier for about 30 % of the applications. This may lead to higher costs and potentially unforeseen consequences associated with the end uses in which the polyurethane systems are applied. With a shorter phase-out period than five years it is more likely that the five restricted phenylmercury compounds will be replaced by the "easiest" available alternatives, which might be other phenylmercury compounds. The main cost to industry will arise through the replacement of mercury containing polyurethane systems by mercury free systems (replacement costs mainly include R&D costs for those systems that are more difficult to be replaced. More information on these costs is provided in the Background Document section F.2.1.). Although the statement on the time frame (5 years needed to substitute all the applications) made by industry during the first stakeholder consultation has been doublechecked by the dossier submitter in a second step and has not been disproved by comments from industry during the public consultation of the original proposal, there is uncertainty on the actual period needed for substitution. Verification is very complicated from a technical point of view. More information on enforcement and monitoring is given in the relevant sections of this document as well as in the Background Document in sections E.2. and F.2.

Effectiveness in reducing the identified risks, proportionality to the risks

The proposed restriction covers the manufacture, placing on the market and use of five phenylmercury compounds as substances or in mixtures and placing on the market of articles containing more than 0.01 % w/w Hg. This will progressively lead to a consequent reduction in releases and exposure from all life cycle stages. However, exposure and releases to the environment continue until implementation of the restriction and removal of articles from circulation.

RAC considers that if the five phenylmercury substances which are subject to restriction were to be replaced by other organomercury compounds² this restriction could become ineffective.

 $^{^{2}}$ 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

However, direct or indirect inclusion of other substances goes beyond the remit of the Committees, which should provide their opinion only on the proposed restriction. Such a widening should be part of a separate Annex XV dossier, including an elaboration of economic impacts and availability of alternatives. SEAC supports the recommendation of RAC stating that necessary measures for verifying and controlling that other organomercury compounds are not used as alternatives to the restricted substances should be considered.

Proportionality of restricting the placing on the market and us:

Based on the information available and despite uncertainties on calculations made by the dossier submitter SEAC considers a restriction of the placing on the market and use of the five phenylmercury substances proportionate compared to the risks identified. The dossier submitter concluded that the potential benefits of reduced mercury emissions are significant and expected to outweigh the costs (the assessment of costs and benefits is provided in sections F.7 and F.2.9.3 of the Background Document). It is moreover indicated that 70 % of the mercury containing polyurethane systems can easily be replaced within 2 - 3 years; the remaining 30 % would be more difficult but after some R&D activities substitution is regarded to be possible after 3 - 5 years. Entering into force after five years of the adoption of the restriction would allow industry to adequately prepare for substitution. Information on the phenylmercury substances and their use as catalysts in polyurethane systems as well as the availability and feasibility of alternatives has been obtained through consultation with EUbased manufactures of the phenylmercury compounds, EU-based formulators of phenylmercury catalysts, EU-based suppliers of the substances and phenylmercury catalysts, EU-based suppliers of alternative catalysts, EU-based producers of polyurethane based articles containing phenylmercury compounds as well as trade associations. More information can be found in section G. of the Background Document.

The main (net) cost impact on industry arises through the replacement of mercury containing polyurethane systems by mercury free systems and some further R&D costs for those systems that are more difficult to be replaced. This has been indicated by industry during stakeholder consultation and information has been double-checked by the dossier submitter. No converse information has been obtained through the public consultation. According to the information obtained by the dossier submitter, there is no evidence that social or any wider economic impacts will occur due to the restriction. Calculations of costs of restricting placing on the market and use as well as the respective sources are provided in section F.2.7 of the Background Document. A number of studies that try to estimate the benefits of reducing emissions of mercury have been published. In the restriction dossier on mercury in measuring devices (ECHA 2010, appendix 2) a survey of different valuation studies is presented. None of these studies on health benefits of reducing mercury emissions are fully transferable to emission reductions from the five phenylmercury compounds in this document. Nevertheless, in the restriction dossier on mercury in measuring devices the dossier submitter concludes that the majority of the studies reviewed have a benefit estimate between € 5 000 – 20 000 per kg Hg reduced. SEAC concludes that - despite many uncertainties and caution related to the assumptions made for the costs and benefits calculation - there is an indication that the health benefits outweigh the estimated costs of restricting the placing on the market and use of the five phenylmercury compounds.

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.

No differentiation was made between impacts for SMEs and other firms.

Proportionality of restricting manufacture

<u>The</u> dossier submitter_proposes a restriction of manufacture in addition to the restriction on use and placing on the market of the five phenylmercury compounds in order to reduce the overall input of mercury to the environment and to therefore reduce the impact of mercury on health and the environment in Europe and globally.

This approach is supported by the RAC:

Including manufacture in the restriction scope is <u>highly recommended by the Risk</u> <u>Assessment Committee</u>. The dossier submitter initially concluded that manufacture seems to have only a minor contribution to the total emissions (close to 0, detailed information on calculations can be found in section B.9.5 of the Background Document). However, there are emissions from manufacture, even though they might be small and RAC concluded that all emissions, i.e. emissions from manufacture, placing on the market and use, should be avoided as soon as possible. Emissions from substances such as the five phenylmercury compounds (due to the long range transport- and PBT-properties) are not desirable from a risk point of view and no other suitable risk management option was identified to address those risks. The risk reduction capacity is expected to be higher if the restriction also covers manufacture (more information can be found in the RAC adopted opinion.).

Restricting manufacture is supported by the Forum for exchange of information on enforcement:

Restricting manufacture is recommended by the Forum as far as enforceability is concerned. According to the Forum, the monitorability, practicality and enforceability of the restriction proposal decrease if manufacture is excluded from the restriction. It could be difficult to make the difference between phenylmercury compounds produced for export only and for placing on the EU-market, respectively. Including a ban on manufacture could also eliminate sources for illegal delivering and placing on the market of restricted phenylmercury substances.

Restricting manufacture from a cost-benefit point of view:

In order to evaluate whether restricting manufacture is proportionate from a cost-benefit point of view a break-even analysis was carried out, based on input data provided by the dossier submitter and RAC (including emissions values, benefit values of mercury emissions avoided, cost estimations, exponential decline rate of the use of phenylmercury substances, volumes for use and exports). The details on input factors and an explanation of the calculations can be extracted from the Background Document as well as the adopted RAC opinion. The analysis considered what percentage of non-EU users would have to substitute to Hg-free alternatives in order for the restriction on manufacturing to be cost neutral (i.e., costs equal benefits) assuming that a given amount of emissions will come back to the EU. The analysis showed that the outcome strongly depends on the substitution rate, unit benefit values for mercury emissions avoided, and the amount of emissions coming back to the EU. The substitution rate and the amount of emissions likely to come back to the EU are highly uncertain factors and SEAC cannot conclude on their "actual" value. Nevertheless, based on the calculations undertaken, SEAC concludes that the costs are not disproportionate to the benefits. Furthermore, the benefits could potentially be underestimated, especially if global impacts, occupational health and environmental benefits³ were taken into account.

³ Occupational health and environmental benefits were not taken into account in the analysis due to lack of data.

Restricting manufacture; views expressed in consultations with industry:

<u>Industry</u> did not express concern with the proposed ban on manufacturing neither during consultation by the dossier submitter when preparing the restriction proposal nor during the public consultation. It was indicated by industry during consultation that a restriction excluding manufacture would have the same effect as a restriction including manufacture because in both scenarios the export market would not continue. As explained in the Background Document, the EU market for phenylmercury compounds is dependent on the export market and vice versa. This is because the price paid for raw material (i.e. mercury) is dependent on the volume bought. Also there are fixed costs for processing the products including costs for environmental controls that are not volume dependent. Industry clearly stated that "it would therefore not be viable to have an export market alone" (Table G.2 of the Background Document). Restricting placing on the market, uses and articles would affect the production of phenylmercury compounds by increasing the production costs and negatively impacting the profitability of the production and sale of these substances⁴.

In conclusion, based on the original proposal of the dossier submitter, on the clear recommendation of RAC, the Forum advice, the results of the cost-benefit analysis and the fact that industry has not expressed concern, SEAC also supports keeping the manufacture of the five phenylmercury compounds in the scope of the restriction.

Practicality, including enforceability

Authorities need to check compliance with the proposed restriction. Appropriate control systems with respect to enforcement of restrictions should already be in place in the Member States so SEAC expects that enforcement activities are to be managed within the remit of systems already in place. SEAC concludes that the five years phase-out period which was suggested by the dossier submitter provides involved authorities sufficient time to prepare for monitoring of phenylmercury compounds. The choice of the restriction process for this case is considered practical since there are numerous applications of the five phenylmercury compounds. Moreover, as the proposed restriction applies to all current uses of the phenylmercury compounds, no problems in determining use patterns (in case only certain uses would be restricted) are expected. In addition there is a general lack of data regarding the import of articles but it is known that mercury as a catalyst in polyurethane is widely used around the world and imported products may account for a significant part of the end-uses of the substances. These products are also covered by the proposed restriction. The number of manufactures and importers of the five phenylmercury substances is far smaller than the number of formulators and users of polyurethane systems so effective enforcement at the level of manufactures and importers should be sufficient to check compliance with the restriction. The monitoring of the import of phenylmercury substances, phenylmercury containing mixtures and articles is covered by an already existing system (EDEXIM database, Regulation EC 689/2008 on export and import of dangerous chemicals) so no additional burden/costs are expected.

⁴ Therefore, one can note that, in that case, if export losses should occur, these may not be necessarily connected to manufacture restriction but could also be related to the restriction on placing on the market and use. The costs of restricting manufacture or not would thus be the same.

The proposed approach of restricting phenylmercury compounds but testing for the Hgcontent is already applied in EU legislation (see Annex V of the REGULATION (EC) No 1223/2009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 30 November 2009 on cosmetic products, entry n° 17 on phenylmercuric compounds). According to the dossier submitter and confirmed by RAC this approach seems most appropriate as there are currently no standardised quantitative methods available for measuring phenylmercury compounds in polyurethane articles. Moreover the characteristics of phenylmercury compounds during processing and in articles during service-life are unknown. A part of the phenylmercury compounds may be transformed in the article during its service life. Transformation may be different from one process to another as well as from one article to another and from one phenylmercury compound to another. Industry has not mentioned any other sources of mercury within polyurethane products. Therefore the dossier submitter as well as RAC conclude and SEAC agrees that the measurement of the Hg content in articles seems most appropriate. The relevant methods exist and are already applied in EU legislation. Moreover, measuring the Hg content rather than the phenylmercury compounds allows covering all five phenylmercury compounds even if some degradation occurs during the process or during service-life. Nevertheless, SEAC notes that there might be a problem for enforcement as long as it is infeasible to distinguish effectively between restricted and not restricted organomercury compounds.

Monitorability

_For information on *Monitorability*, see section *Practicality*, *including enforceability* above.

BASIS FOR THE OPINIONS OF SEAC

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

The changes introduced in the restriction as suggested in this opinion compared to the restrictions proposed in the Annex XV restriction dossier submitted by Norway are basically editorial. They were made to make the text clearer and to take into account the advice from the Forum for exchange of information on enforcement.

The opinion supports the restriction as proposed in the Annex XV restriction dossier submitted by Norway.²