

Committee for Socio-economic Analysis (SEAC)

Opinion

on an Annex XV dossier proposing restrictions on

1,4-dichlorobenzene

Draft

8 March 2013

(DRAFT)

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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 EU

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): **1,4-DICHLOROBENZENE**

EC No.: **203-400-5**

CAS No.: **106-46-7**

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

ECHA on a request from the Commission has submitted a proposal for a restriction together with the justification and background information documented in an Annex XV dossier. The Annex XV report conforming to the requirements of Annex XV of the REACH Regulation was made publicly available at <http://echa.europa.eu/web/guest/restrictions-under-consideration> on **19 June 2012**. Interested parties were invited to submit comments and contributions by **19 December 2012**.

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 **8 March 2013**.

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.

The draft opinion was published at <http://echa.europa.eu/web/guest/restrictions-under-consideration> on **19 March 2013**. Interested parties were invited to submit comments on the draft opinion by **17 May 2013**.

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 1,4-dichlorobenzene is the most appropriate EU wide measure to address the identified risks in terms of the proportionality of its socio-economic benefits to its socio-economic costs provided that the conditions are modified.

The conditions of the restriction proposed by SEAC are:

1,4-dichlorobenzene (EC No. 203-400-5, CAS No. 106-46-7)

1. Shall not be placed on the market, or used, as a substance or constituent of mixtures in a concentration equal to or greater than 1 % by weight where the substance or the mixture is intended to be used as an air freshener or to de-odourise toilets, homes, offices and other indoor public areas.
2. Paragraph 1 shall apply from **{date}** corresponding to 12 months after the Commission Regulation amending Annex XVII to REACH Regulation enters into force}.

JUSTIFICATION FOR THE OPINION OF SEAC

JUSTIFICATION THAT ACTION IS REQUIRED ON AN EU WIDE BASIS

SEAC supports the view that action should be taken on a Community-wide basis.

Based on the key principles of ensuring a harmonised level of protection across the Community and of maintaining the free movement of goods within the Community, SEAC supports the view that any action to address risks associated with toilet blocks and air fresheners containing 1,4-dichlorobenzene should be implemented in all Member States (MS).

SEAC has considered if a more local solution may be appropriate and efficient given the small tonnages of 1,4-dichlorobenzene involved and the indications that the market for the products is limited. For example, the RPA (2010) report found that most domestic consumer use of 1,4-dichlorobenzene products appears to be concentrated in Southern and Eastern European MS while professional use occurs throughout Europe. However, on the basis that the products are available in all MS (except Sweden) SEAC agreed that the principles of harmonised protection and free movement of goods must apply in this context.

JUSTIFICATION THAT THE SUGGESTED RESTRICTION IS THE MOST APPROPRIATE EU WIDE MEASURE

Based on the RAC conclusion that exposures to 1,4-dichlorobenzene need to be reduced for domestic and professional users and some evidence that use of toilet blocks and air fresheners containing 1,4-dichlorobenzene will persist in the absence of any intervention, SEAC agreed that a restriction is an appropriate measure.

Data (section E.1.1 of the BD) shows that there has been a steady decline in the use of 1,4-dichlorobenzene in toilet blocks and air fresheners since the early nineties but that this decline has slowed since 2008. SEAC took note of several indications that use of the products will persist in the absence of regulatory intervention. Firstly, a registration dossier received by ECHA of 1,4-dichlorobenzene >100 tonnes/year has been updated to include the use of 1,4-dichlorobenzene as a mixture containing 98-99% of the substance in air fresheners and toilet blocks for consumer and professional use, suggesting that producers foresee a demand for the products and wish to maintain them on the market. Secondly, the analysis of alternatives suggests that there is no direct alternative for 1,4-dichlorobenzene products in circumstances where strong odour masking properties are required i.e. in public toilets that are characterised by high temperatures, high traffic and infrequent cleaning.

SEAC has considered if other approaches might be more suitable to address the requirement to reduce exposures to 1,4-dichlorobenzene. For example, an adjustment to the EU Occupation Exposure Limit (OEL) has the potential to increase the protection of workers in the applications of concern and to promote further reductions in the use of 1,4-dichlorobenzene in toilet blocks and air fresheners. There may also be merit in an approach which combines a revised EU OEL with a restriction on domestic use. In respect of a revised OEL, SEAC took note of RAC's observation that the OEL currently in force of 122 mg/m³ (Directive 2000/39/EC) was developed in 1994 and was not based on carcinogenicity and it is significantly higher (34 times) than the recommended DNEL. RAC further noted that the current OEL needs to be reevaluated to take account of more recent information on carcinogenicity. The EU OEL is scheduled for reassessment by the EU's Scientific Committee on Occupational Exposure Limits (SCOEL) but SEAC understands that the revision referred to by RAC is unlikely to be made within the timeline for this restriction proposal.

The restriction approach would address risks associated with imports of the substance, estimated by RPA (2010) to account for more than 50% of the total amount (approximately 400 tonnes) of 1,4-dichlorobenzene sold to EU manufacturers of air fresheners and toilet blocks.

SEAC noted that the Commission request to prepare the Annex XV dossier indicated that professional workers should be included in the analysis on the basis that 1,4-dichlorobenzene products are primarily used in public toilets where attendants and cleaners may also be exposed. While the opinion of RAC indicates that exposures to 1,4-dichlorobenzene need to be reduced for professional users SEAC observed that this outcome differs from conclusions in previous reports on the risks associated with 1,4-dichlorobenzene. The Risk Assessment Report conducted in 2004 identified a need for specific measures to limit the risks to domestic consumers only. The subsequent Strategy for Limiting Risk published by the Commission in 2008 recommended marketing and use restrictions at Community level for domestic consumers, but stated that existing worker protection legislation provided an adequate framework to limit the risks for workers (it was also recommended that SCOEL would review the EU OEL). The socio-economic evaluation published by RPA in 2010 did some analysis of a restriction on professional use and recommended against a restriction for this group.

Effectiveness in reducing the identified risk, proportionality to the risk

Effectiveness

On the basis of the evidence presented, SEAC supports the view that the proposed restriction would be effective in avoiding any human health risks and related health impacts associated with the use of 1,4-dichlorobenzene by domestic and professional users.

SEAC agrees that on the basis of the evidence presented, the use of 1,4-dichlorobenzene has decreased significantly over the past 20 years and that it has been replaced by alternatives which now dominate the market. It is unclear to what extent the market for air fresheners and toilet blocks containing 1,4-dichlorobenzene could be said to be a minor and niche part of the general market for such products. Furthermore, there is a lack of information on the current volume and historic trend of imports of air fresheners and toilet blocks containing 1,4-dichlorobenzene, which raises further questions as to the use in the future, as well as the overall population at risk, both currently and in the future. However, given that the restriction would apply equally to marketing and use of imported finished products, the uncertainties regarding future usage and imported products, should not influence the effectiveness (and also proportionality) of the restriction.

The restriction entails a ban on the placing on the market and use of toilet blocks and air fresheners containing 1,4-dichlorobenzene within 12 months of its implementation. SEAC agreed that although the time period over which all health impacts would be avoided cannot be predicted, it is expected that any health impacts arising after implementation would be due to any historical legacy.

While SEAC noted the RAC conclusion that the proposed restriction will be effective to the extent that it will eliminate the exposures associated with toilet blocks and air fresheners containing 1,4-dichlorobenzene, evidence of the extent of any health impacts actually associated with their use is limited. In this respect, as highlighted in the RAC opinion, there is insufficient evidence to support robust conclusions on the health impacts of 1,4-dichlorobenzene (carcinogenicity or lung function effects).

The effectiveness of the restriction may also be compromised if professional users were to

switch to camphor-based alternatives in situations where they needed strong odour-masking functionality. The evidence points to a lack of direct alternatives for use by professional users in these circumstances. Camphor is presented as one substance which offers similar functionality but it is not recommended as an alternative due to its human health effects.

Proportionality

Based on the RAC conclusion that exposures to 1,4-dichlorobenzene need to be reduced for domestic users, SEAC is of the opinion that a restriction on air fresheners and toilet blocks containing 1,4-dichlorobenzene is justified and proportionate for this group. While there is insufficient evidence to support the quantification of health impacts, the RAC conclusion that exposures need to be reduced together with the cost savings associated with the alternatives for domestic users, support the SEAC conclusion.

RAC also indicated that exposures need to be reduced for professional users. However, as with the domestic user group, evidence to support the associated health impacts has not been adequately demonstrated. There is also evidence that professional users will incur some costs as a result of the switch to alternatives. Therefore the proportionality of the restriction on professional users has not been sufficiently demonstrated in terms of a robust comparison of quantified benefits and costs. Nevertheless, given the evidence presented on the scale of costs across all EU member states, SEAC would contend that there are grounds to consider the costs to not be disproportionate. In particular, alongside the evidence that exposures to 1,4-dichlorobenzene need to be reduced for professional users, and hence of possible, albeit unquantified impacts to this group, a discretionary case could be made for supporting the restriction.

The assessment of proportionality in the Background Document is based on a quantitative assessment of the costs and benefits of the proposed restriction. The analysis undertaken aims to provide net benefit estimates on an annualised basis for the proposed restriction as well as for other options that consider separately the sub-category uses (domestic and professional use) of the proposed restriction. This is appropriate as the impacts have a steady state (representative year) nature, and it allows for comparison across options. The analysis of the costs of the restriction follows established procedures for the calculation of financial and economic welfare costs of compliance. The benefits analysis is based on established procedures for the calculation of economic welfare changes as a result of human health risk reductions. A valid and robust general methodological approach thus underpins the proportionality assessment.

Costs

The analysis of the costs of the restriction is based on the data from the assessment of technical and economic feasibility. The available information indicates that a large variety of alternative products are available, though their technical and functional characteristics (deodorising, cleaning and longevity) differ to some extent making 'like for like' comparison difficult. In addition, demand for such consumer products is also based on consumers' preferences for non-technical/functional characteristics, such as "brand loyalty", etc. This has implications for the methodological approach used to assess costs. The assessment of technical and economic feasibility nevertheless clearly indicates that many alternatives are available at a wide range of prices, and that (although no market share data is presented in the evidence available) they dominate the market (as can be substantiated in any retail supermarket). SEAC agrees with the claims that replacement of 1,4-dichlorobenzene is most difficult from a technical feasibility point of view where strong odour-masking properties are requested. Overall, given the reported range of alternatives and the prices they are sold at, the conclusion of technical and economic feasibility is credible. Indeed there is strong evidence that for domestic use, many of the available alternatives are less

expensive and offer cost savings on a comparable use basis. For professional uses in urinals with high flushing frequency, there is some evidence that the alternatives are more expensive on a comparable use basis. Regarding technical feasibility in relation to professional uses, there are good technical reasons why professionals might use 1,4-dichlorobenzene (RPA, 2010). In particular, 1,4-dichlorobenzene is used when there are difficulties with the design of the toilet plumbing, or because they are old and difficult to upgrade, or because of environmental factors such as the climate. Moreover, the odour which 1,4-dichlorobenzene is designed to mask often comes from drains, not from the functioning of toilets, and 1,4-dichlorobenzene is used when it is not possible to clean those drains in such a way that odour can be removed. As such, there are grounds to conclude that there is a lack of perfect substitutes for some professional uses, and that those alternatives which do exist are more expensive.

SEAC has considered the two separate methodological approaches to analysing the costs of the restriction presented in the Background Document. The first is based on the financial costs of switching from 1,4-dichlorobenzene to an alternative (the so called 'substitution cost' approach), whilst the second is based on the consumer surplus change arising from the requirement to cease the use of 1,4-dichlorobenzene and switch to an alternative.

Although the two approaches can be considered as alternative methods for estimating costs, given the uncertainties surrounding the evidence and data necessary for their application they can be considered as complementary approaches in the sense that they provide a check (triangulation) of the magnitude of costs (losses involved). In this respect the two approaches are in general consistent.

For the combined restriction, the analysis produces an overall estimate using the consumer surplus approach of €1.2m cost per year. With regards to the substitution (financial) costs approach, as the alternatives in general are less expensive, the financial impact is estimated to be a saving of €1.4 m per year for the combined restriction (see Table 1).

Table 1: Overview of estimated costs per restriction option

Restriction Option	Change in consumer surplus (€m)	Financial costs (€m)
Domestic use only	2.7	2.0
Professional use only	-4.0	-0.6
Domestic and professional use	-1.2	1.4

Note: positive values indicate savings; negative values indicate costs

The two sets of estimates thus appear broadly consistent in terms of showing limited (or even reductions in) costs. The difference in whether costs or savings are derived can be accounted for by how much professional user demand is a function of DCB's characteristics and how professional users would respond to changes in cost between DCB based products and their alternatives.

Benefits

The quantitative analysis of the benefits of the restriction is based on a health impact assessment using an 'impact pathway' type methodology. This estimates the change in physical health impacts due to changes in exposures as a result of the restriction. The approach is based on linking quantitative relationships between exposure and the health

impact of interest. This general procedure is widely used for the assessment of benefits related to air and other environmental pollutants and is considered to be an appropriate methodological approach. The particular health impacts considered in the quantitative health impact assessment are mortality impacts associated with decreases in lung functioning arising from exposure to 1,4-dichlorobenzene. It should be noted that this is not the same health endpoint (carcinogenicity) which was considered in the risk assessment. The use of the lung function endpoint for the assessment of benefits appears to be based on the greater availability of data for deriving quantitative estimates. However, SEAC noted the RAC conclusion that there is insufficient evidence to support the link between exposure to 1,4-dichlorobenzene and reduced lung function. Therefore, SEAC did not consider it appropriate to use the results of the quantitative health impact assessment to inform the SEAC position.

Cost benefit comparison

Overall, the cost assessment suggests that under the substitution cost approach, any positive (or even zero) value of health benefit would be sufficient to justify the restriction on proportionality grounds, though a higher level of health benefit would be needed in the case of the consumer surplus approach in order to justify the (positive) costs in this case.

For the proposed restriction on domestic use, SEAC concluded that this measure is proportionate, and can do so without the need to consider any quantitative estimate of health benefits in terms of lung function or other health endpoint. This is a consequence of the RAC conclusion that exposures to 1,4-dichlorobenzene need to be reduced for domestic users and that the proposed restriction on domestic use is the most appropriate risk management measure. This infers, qualitatively at least, that there are positive health benefits. The inferred health benefits, combined with the cost savings (consumer surplus gain) found in the cost analysis, allow SEAC to support the view that the proposal to restrict for domestic use is proportionate.

The evidence is less clear for the options to restrict professional use only or to jointly restrict domestic and professional use. While RAC has concluded that there is a need to reduce exposures for professional users, there is limited evidence to support any conclusions on health impacts. In this case, inferred health benefits do not offer sufficient justification for proportionality, since the analysis shows that professional users will incur positive costs as a result of the proposed restriction (in contrast to cost savings for domestic use). Therefore, the cost benefit analysis suggests that costs outweigh quantified benefits for both options involving professional use. This corresponds with the outcome of the cost benefit analysis done by RPA (2010) on a restriction on professional use which found that the costs of such a restriction would outweigh the resulting benefits to health. Based on their analysis RPA recommended against a restriction on professional uses. However, taking account of the scale of costs involved in the combined restriction proposal across all of the EU (-€1.2 million costs according to the consumer surplus approach and €1.4 million savings according to the substitution costs approach), SEAC considered that a discretionary case may be made for considering the proposal to not be disproportionate.

SEAC have considered the assertion that administrative and enforcement costs are low. Whilst this does not appear to be based on any empirical assessment, the rationale given as to their magnitude is plausible.

Table 2: Summary of information informing SEAC opinion

Restriction Option	Exposures to 1,4-dcb need to be reduced?	Costs (€)	Benefits	SEAC conclusion
Domestic use only	Yes	2.7 million* 2.0 million**	Positive but figures not available	Proportionate
Professional use only	Yes	-4.0 million* -0.6 million**	Positive but figures not available	Taking account of the inferred health benefits and the scale of costs involved, SEAC concluded that the proposal may not be considered to be disproportionate.
Domestic and professional use	Yes for domestic Yes for professional	-1.2 million* 1.4 million**	Positive but figures not available	Taking account of the inferred health benefits and the scale of costs involved, SEAC concluded that the proposal may not be considered to be disproportionate.

Note: positive values indicate savings; negative values indicate costs

* consumer surplus approach

** substitution cost approach

SEAC also noted the view that the proposed restriction would impact different actors in the supply chain, including manufacturers of 1,4-dichlorobenzene, producers of air fresheners and toilet blocks as well as actors in the supply chain of alternative products. SEAC agrees that the distributional impacts of the restriction are not societal costs as such, since the negative impacts on 1,4-dichlorobenzene actors will be counterbalanced by positive impacts on the alternative products actors. However, there are costs to the individual companies concerned, such as the losses, estimated in the region of €55,000 per company, on the market value of capital equipment following the restriction. There is also a concern that the competitiveness of EU manufacturers of 1,2-dichlorobenzene could be affected if alternative markets for the by-product 1,4-dichlorobenzene are not found. This depends on the belief that non-EU markets would still be available and toilet blocks and air fresheners containing 1,4-dichlorobenzene may be produced for export. Separately, the RPA (2010) report concludes that a restriction on professional use could have considerable competitiveness impacts, possibly on a global scale, for manufacturers of the products and producers of the substance. SEAC considered that there is insufficient data to support any conclusion of the potential for these wider economic impacts.

SEAC observed that while there are some uncertainties with respect to the total volume of 1,4-dichlorobenzene on the market (for example, lack of information on imports of finished

1,4-dichlorobenzene air freshener and toilet block products) this would not affect the outcome of the proportionality assessment, since any additional volumes would not affect the relative benefits and costs of the restriction and hence its overall proportionality.

SEAC is of the opinion that, subject to the various caveats already made, the conclusions on the proportionality of the restriction are robust given the conclusions of the RAC and the range of cost estimates indicated.

Practicality, including enforceability

Based on the evidence provided, SEAC supports the view that the proposed restriction is implementable and enforceable.

Figures showing the significant decline in the use of 1,4-dichlorobenzene in toilet blocks and air fresheners and the extensive availability and use of alternatives clearly indicate that the restriction is unlikely to present any practical problems for users.

However, SEAC notes the evidence that some professional users may encounter implementation difficulties. There is information from a manufacturer of products containing 1,4-dichlorobenzene and an industry expert that there are no direct alternatives for situations where the strong odour-masking properties of 1,4-dichlorobenzene are particularly required, e.g., urinal blocks in public toilets with high traffic levels. SEAC recognizes that camphor-based products are not recommended as an alternative in this scenario due to the human health risks associated with the substance but also noted the concerns of RAC that use of camphor products may increase as a result of the proposed restriction.

The costs which will be incurred by the small number of producers who need to change equipment or processes should not present a significant barrier to implementation at EU level.

The proposed transition period of 12 months would seem to be practical for all parties given the relatively short supply chain for the products (i.e. the time to manufacture and distribute). The data in the Background Document confirms that most producers are already producing alternatives or have the capacity to do so. Distributors should not incur losses due to large unsold stocks of the products because most products have an expiry of one year.

Following advice from FORUM a concentration limit of 1% by weight was introduced to the restriction proposal. FORUM advised that a concentration limit will facilitate enforcement by ensuring that any products containing 1,4-dichlorobenzene as a technical impurity will not be unduly affected. SEAC agreed with the introduction of the concentration limit but noted that the necessity for enforcement authorities to undertake potentially expensive testing for specific concentrations of the substance will be limited.

Monitorability

SEAC agreed that monitoring the proposed restriction should not present difficulties.

SEAC notes that the most direct measure of the effectiveness of the restriction would be to measure negative health impacts avoided. In the absence of such data, SEAC agreed that monitoring by enforcement authorities of contraventions of the restriction offers an indirect indicator. Any results from testing of air or blood level concentrations of 1,4-dichlorobenzene may also be used to monitor the impact of the restriction.

BASIS FOR THE OPINION

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

The main change introduced in the restriction as suggested in this opinion compared to the restrictions proposed in the Annex XV restriction dossier submitted by ECHA on a request from the Commission is that a concentration limit of 1% w/w has been added to the restriction text.