Committee for Risk Assessment (RAC)

Opinion

on an Annex XV dossier proposing restrictions on

1,4-dichorobenzene

ECHA/RAC/RES-O-0000003486-69-01/F

Adopted

8 March 2013

Annankatu 18 | P.O. Box 400 | 00121 Helsinki | Finland
www.echa.europa.eu | Tel.: + 358 9 68.61.80

***8 March* 2013**

RES-O-0000003486-69-01/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 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 opinions 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 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 RAC:

Rapporteur, appointed by RAC: ***Yvonne MULLOOLY***

Co-rapporteur, appointed by RAC: ***Lina DUNAUSKIENE***

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 **8 March 2013**.

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 1,4-dichlorobenzene is the most appropriate EU wide measure to address the identified risks in terms of the effectiveness in reducing the risks provided that the conditions are modified.

The conditions of the restriction proposed by RAC 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 RAC

IDENTIFIED HAZARD AND RISK

Description of the health impacts to be addressed by the proposed restriction

RAC agreed that the following health outcome related to consumer and professional exposure by inhalation of 1,4-dichlorobenzene will be addressed by the proposed restriction:

- Possibility of extra cancer cases due to the mitogenic properties of 1,4-dichlorobenzene (a threshold effect).

Description of and justification for targeting of the information on hazard and exposure

The restriction proposal is targeted to health risks related to consumer exposure at home and to professional workers exposed by inhalation in public toilets from 1,4-dichlorobenzene products.

Information on hazard(s)

Key studies – non-human information

The key study is:

- an inhalation study in F344 rats and BDF1 mice (50 mice and rats of both sexes exposed to test substance in inhalation exposure chambers at 0, 20, 75 & 300 ppm 6h per day, 5days/week for 104 weeks) (JBRC, 1995/Aiso et al. 2005).

The findings from this study are outlined in the Background Document.

Dose descriptor selection for DNEL derivation

Inhalation exposure in BDF1 mice and F344 rats in the 2-year study:

Exposure by inhalation induced liver tumours in both sexes of BDF1 mice at the highest dose only. A statistically significant increase in the incidence of hepatocellular carcinomas was noted in both sexes. In addition, a statistically significant increase in hepatoblastomas was observed in male and female animals with hepatocellular carcinomas. Similarly, a statistically significant increase in the incidence of histiocytosarcomas was noted in males with hepatocellular carcinomas. The incidence of hepatic adenomas was statistically significantly increased in females only. Based on these findings, RAC selected a NOAEC of 75 ppm for DNEL derivation based on hepatic carcinogenicity in male and female BDF1 mice following inhalation exposure.

It was noted that liver tumours were also observed in B6C3F1 mice in a 2 yr oral study (NOAEL 300mg/kg/bw/d). However, considering that the route of exposure of relevance for 1,4-dichlorobenzene is inhalation, RAC agreed that the NOAEC of 75ppm was more appropriate for DNEL derivation than the oral NOAEL.

Other effects

Consideration was afforded to all animal studies available and DNELs were derived for all relevant endpoints and may be found in the Background Document. Although a somewhat lower DNEL was calculated for the liver effects observed in the one year oral study in dogs (Naylor et al. 1996), RAC agreed that carcinogenicity is the endpoint of greater relevance for the human health assessment of 1,4-dichlorobenzene. Other DNELs derived were higher than that derived for carcinogenicity.

In conclusion, RAC agreed only to take the DNEL for carcinogenicity forward for risk characterisation.

In addition, epidemiology studies on lung function effects following exposure to volatile organic compounds (VOCs) were evaluated. However, as the data available was not sufficiently robust, it was not possible to establish a causal link between decreased lung function and exposure to 1,4-dichlorobenzene. Hence, the data was found insufficient to support the inclusion of such health impacts in this assessment, as detailed in the Background Document.

DNEL Derivation

DNELs were derived for both consumers and workers based on the carcinogenic effects of 1,4-dichlorobenzene, i.e. the liver tumours observed in mice following long-term inhalation exposure.

The weight of evidence points to a low potency, non-genotoxic carcinogen which exerts its tumourogenic response via a mitogenic mode of action in mice only. However, a steep dose-response was observed, especially in female mice in the inhalation study, and, in addition, rare tumours (hepatoblastomas, histiocytosarcomas) were induced. Based on this evidence, RAC agreed to the use of an assessment factor (AF) of 3 for the dose-response relationship in the calculation of the DNEL. In choosing this AF, consideration was afforded to uncertainties in the dose descriptor, taking into account the steep-dose response observed, as well as the severity of the carcinogenic effect and the uncertainties associated with quantifying the risk from a low potency Category 2 carcinogen as detailed below:

- 1,4-dichlorobenzene is a category 2 carcinogen, which was classified due to the formation of liver tumours in only one species (mouse). Liver tumours were not observed in F344 rats in either a 2-year oral study or a 2-year inhalation study.
- The hepatoblastomas and histiocytosarcomas, as observed in conjunction with hepatocellular carcinomas, are rare tumours in mice.
- The liver tumours in the two strains of mouse (B6C3F1 mice following oral exposure and BDF1 mice following inhalation exposure) were evident at the highest dose tested only, however, a steep dose-response was observed.
- The EU RAR concluded that the overall weight of evidence from the most reliable genotoxicity studies indicates that 1,4-dichlorobenzene does not have any significant genotoxic potential. Since the publication of that report, further evidence supports a non-genotoxic/mitogenic mode of action. This conclusion is also supported by the lack of apparent liver toxicity in the inhalation study at the dose inducing tumours (increased liver weight and centrilobular hypertrophy was noted at the highest dose).

Assessment factors of 10 and 5 were set for intra-species differences for consumers and workers respectively. For inter-species differences the assessment factor was 2.5.

Table 1: Summary of the dose descriptor selected for DNEL derivation

Study	NOAEC	Endpoint	AF** consumer	DNEL consumer	AF** worker	DNEL worker	Remarks
Carcinogenic effects 2 yr. inhalation study Mice	75 ppm = 451 mg/m^3*	Liver tumors in male and female mice	3*2.5*10	0.21 mg/kg bw/d 0.64 mg/m^3	3*2.5*5	0.51 mg/kg bw/d 3.62 mg/m^3	NOAEC as per EU RAR. AF of 5 for severity of effect was chosen in original Annex XV dossier. AF of 3 now chosen as 1,4-dichlorobenzene is low potency carcinogen.

* 1 ppm = 6.013 mg/m^3

**Where necessary, compensations were made in the calculations for differences in exposure conditions (consumers: 6→24h/d, 5→7d/wk; workers: 6→8h/d, respiratory volume at rest of 6.7 m^3/8 h → 10 m^3/8 h during light work) and for differences in absorption (inhalation: 60% mouse, 100% humans). Consumer: 60 kg bw, 20 m^3/24h; worker: 70 kg bw, 10 m^3/8h.

The DNEL derived for carcinogenic effects for workers is 3.62 mg/m^3 (i.e. 0.6 ppm) and for consumers 0.64 mg/m^3 (i.e. 0.11 ppm).

Information on emissions and exposures

Use

Since the publication of the EU RAR, the use of the substance in air fresheners and toilet blocks has dramatically decreased from 2,285 tonnes/year in 2003 to the current estimated levels of 800 tonnes/year. Data from the EU RAR (2004) and a report from RPA (2010) indicates that the percentage share of the substance formulated into toilet blocks to the total share of air fresheners and toilet blocks has shifted from 40% to 77%. This trend is likely to be maintained, as the product is effective in masking odours in facilities (public toilets) which are frequently used and where regular, frequent cleaning is not undertaken. The RPA report (2010) indicates that approx. 10% of 1,4-dichlorobenzene is currently used to make air fresheners and toilet blocks for the consumer market.

It is estimated that 96 tonnes of 1,4-dichlorobenzene is sold to consumers in the form of air fresheners and toilet blocks. It is estimated that approximately 165,000 consumers are exposed to the substance from its use in the home. The remaining 704 tonnes is used in public toilets.

The substance has been registered under REACH and the registration includes the use of the substance as a mixture containing 98 - 99% of the substance in toilet blocks and air fresheners for consumer and professional uses.

Exposure – general information

The exposure assessed in the Background Document is based on inhalation exposure to 1,4-dichlorobenzene vapours.

The Background Document assesses consumer exposure to 1,4-dichlorobenzene when it is used in the home as an air freshener and in toilet blocks along with consumer exposure when using public toilets. The Background Document also assesses professional exposure of toilet cleaners and toilet attendants to 1,4-dichlorobenzene when it is used as an air freshener and in toilet blocks in public toilets, as this exposure was not considered under the previous EU RAR.

Dermal exposure is considered minimal compared to inhalation exposure from the products subsequent use. It has been noted that there have been cases documented of ingestion of products containing 1,4-dichlorobenzene by children and adults. While exposure via inhalation, ingestion and dermal routes is possible, the most relevant exposure is via inhalation, and it is used for the exposure assessments.

While measured data is preferred to modelling in the evaluation of exposure it still has to fulfil certain quality criteria, i.e. the data needs to be representative and the methodology reliable.

Only one of the monitoring studies available addresses consumer exposure to 1,4-dichlorobenzene in the home from one single source (toilet blocks; Djohan et al. 2007). This study was undertaken in Australia and due to the small sample size along with other uncertainties on concentrations outside of the toilet, ventilation rates, temperature variability, durations of exposure etc. it is not considered as representative of the EU.

The other consumer monitoring studies presented in the Background Document were also not undertaken in the EU and the sources of 1,4-dichlorobenzene were multiple or else not identified. Therefore modelling using ConsExpo version 4.1 was used to determine reasonable worst case and realistic case exposure conditions.

There is only one study available (Globol Werke GmbH, 1986) presenting airborne concentrations of 1,4-dichlorobenzene in public toilets. The data presented in the study was also not considered representative of the EU as it was only from one Member State, the sample size was very small and there are no harmonised standards for ventilation rate, size of public facilities across the EU along with uncertainties related to temperature variability. Therefore modelling data was also used for the exposure assessment of professional use. Some of the information from the study mentioned above, such as the number of air fresheners/toilet blocks used per volume of air, was used as an indication of cleaning industry work practice.

Details of the monitoring data are presented in the Background Document.

Outdoor exposure to 1,4-dichlorobenzene was also included in the original Annex XV dossier. However as the exposure that is of concern relates to indoor concentrations, it has not been included in the opinion as the values are much lower (<0.001 mg/m^3) than indoor monitoring values.

Biomonitoring data: 2,5-dichlorophenol is the main metabolite of 1,4-dichlorobenzene. It is also a metabolite of the insecticide lindane. An exposure to 1 ppm 1,4-dichlorobenzene (equivalent to 6,013 µg / m^3) correlates to an excretion of approx. 450 µg/l 2,5-dichlorophenol in urine (1 µg /l 2,5-dichlorophenol in urine equivalent to 13.5 µg/m^3 1,4-dichlorobenzene). No biomonitoring data on the levels of 2,5-dichlorophenol in toilet attendants and cleaners is available. The only biomonitoring data available is the Hill et al. (1995) study, presented in the EU RAR, which measured the level of 2,5-dichlorophenol, in urine samples and 1,4-dichlorobenzene in blood samples of 1,000 adults in USA. 2,5-dichlorophenol was detected in 98% of urine samples. 1,4-dichlorobenzene was detected in 96% of blood samples, indicating wide-spread exposure to 1,4-dichlorobenzene or lindane at the time of the study. It is not clear whether the presence of the metabolite in blood is attributed to 1,4-dichlorobenzene or lindane. As the volumes of 1,4-dichlorobenzene used in

air fresheners and toilet blocks have been significantly reduced (mothballs and toilet blocks) since 1995 the information is of little relevance in determining whether the current levels of 2,5-dichlorophenol are still at the levels found in 1995. However as the use of 1,4-dichlorobenzene in mothballs and air fresheners and toilet blocks has decreased it is expected that levels will be lower, but no biomonitoring data has been made available to confirm this.

Consumer Exposure

Exposure Modelling

RAC agreed that the ConsExpo version 4.*1* model is the most suitable for the exposure assessments as proposed in the original Annex XV dossier submitted by ECHA.

The modelled exposure level depends on the input variables i.e. use frequency, exposure duration, indoor air temperature, ventilation rate and volume of the area per product used. Reasonable worst case consumer exposure modelling is based on a consumer staying at home for 24 hours and therefore continuously exposed during the whole day. In the realistic case the total exposure time in the home is 16 hours.

The Background Document presents a number of scenarios and a number of variables are used for both reasonable worst case and realistic scenarios. Exposure is calculated for an individual day only, at a temperature of 20 °C and a temperature of 30 °C as data is available on how long the products last at these temperatures. While RAC acknowledged there may be variations within a 24 hours period, 20 °C is considered a reasonable estimation of mean indoor air temperature over a 24 hour period. While 30 °C was considered to represent the variability of conditions between seasons and within Europe it is noted that it is unlikely that 30 °C would be the average temperature over a 24 hour period for an extended period of time. In such high temperature conditions, it is likely that greater ventilation would be employed by the consumer i.e. air conditioning or the opening of windows to allow air to circulate in the home more freely, resulting in lower exposure.

RAC noted the following input parameters as limitations in the consumer exposure modelling results:

- Mode of release is at constant rate. This assumes no "wet" period or that over time - as the product diminishes - the corresponding air concentration will also decrease.
- It is also noted that one hour spent in a bathroom is considered high for a realistic case scenario.

RAC considered the following exposures as relevant model for consumer exposure calculation:

Table 2: Reasonable worst case and realistic case exposure scenarios for consumers

Scenarios	**Exposure Parameters**	**Exposure (mg/m^3)**	
		20°C	30°C
Reasonable worst case scenario (1)	Based on a consumer spending 1 hour in a bathroom size of 10 m^3 with a lower ventilation rate of 0.2 air exchanges per hour, one air freshener of 80 g is used, and a concentration in the rest of the home is 1/3 of the concentration in the toilet for the remaining 23 hours	**2.68**	**5.63**

Reasonable worst case scenario (2) with 2 Air exchanges	Based on a consumer spending 1 hour in a bathroom size of 10 m^3 with a ventilation rate of 2 air exchanges per hour where one air freshener of 80 g is used and the concentration in the rest of the home is 1/3 of the concentration in the toilet for the remaining 23 hours	**1.62**	**3.41**
Realistic case consumer	Based on a consumer spending 1 hour in a bathroom size of 10 m^3 with a ventilation rate of 2 air exchanges per hour where one air freshener of 80 g is used and the concentration in the rest of the home is 1/20 of the concentration in the toilet for the remaining 15 hours	**0.33**	**0.69**

Analysis of exposure scenarios

Reasonable worst case consumer scenarios are calculated based on 24 hours of exposure in the home, whereas the realistic scenario is calculated based on 16 hours of exposure. Exposure of consumers using public toilets was considered in the Background Document but has not been included in the daily exposure data above as it was considered that the dose inhaled at a public facility would be offset against the duration of time spent by the consumer outdoors where there would be no (or very low) exposure. This would result in the consumers' cumulative daily exposure possibly being lower than if only staying at home.

Three exposure scenarios were considered: two reasonable worst case scenarios with differences in ventilation rate and one realistic case. All of the values presented in both reasonable worst case scenarios are above the substance's odour threshold (0.72/1.1 mg/m^3) while the values in the realistic case are below.

By way of comparison Aronson et al. (2007) used the THERdbASE exposure model and calculated concentrations of 1.530 mg/m^3 for the bathroom of 9 m^3 and 0.492 mg/m^3 for the other areas of an apartment, which would result in exposure of 0.535 mg/m^3 averaged for 24 hours exposure (reasonable worst case scenarios) and 0.371 mg/m^3, averaged for 16 hours exposure (realistic case scenario). As the modelling tool used by Aronson is not available, it is difficult to analyse the reason for the differences between the results. However it is noted that the sublimation rates used in the two models differ, as outlined in the Background Document.

Professional Exposure

Exposure of professional workers to 1,4-dichlorobenzene from toilet blocks/air fresheners was also considered by RAC. A toilet attendant is a person who works in a public toilet usually collecting a fee, providing toiletries and undertaking some cleaning.

The concentration of 1,4-dichlorobenzene vapour in a public toilet depends on several variables e.g. the number and size of blocks used, the area/volume of the public toilets facilities, the frequency and duration of the exposure, the rate of ventilation and the temperature.

Exposure Modelling

The use of modelling data for exposure assessment is justified as no representative measurements for the EU are available, and modelled scenarios are certainly conservative assessments due to the chosen parameters. Some of the information from the monitoring studies was used, such as the number of toilet blocks and air freshener used per unit volume of air, as an indication of cleaning industry work practice.

ConsExpo version 4.1 was identified as the most appropriate tool for assessment of

exposure via vapours for cleaning tasks. RAC noted the following input parameters as limitations in the professional exposure modelling results:

- Mode of release is at constant rate. This assumes no "wet" period or that over time - as the product decreases - the air concentration will decrease.
- It is assumed in the original Annex XV dossier that the toilet attendant spends all their time in the toilet area. Toilet attendants are usually located in the vestibule where the concentration would be lower.
- The use of one product per $5m^3$ in the reasonable worst case scenarios in the original Annex XV dossier is considered to overestimate the exposure. The selection of one product per $5m^3$ for modelling was based on a monitoring study where a smaller product size of 41.3g was used rather than the size used in the modelling (80g).

The following table summarizes reasonable worst case and realistic case scenarios for toilet attendants & cleaners:

Table 3: Reasonable worst case and realistic case exposure scenarios for workers

Scenarios	**Exposure Parameters**	**Exposure (mg/m^3)**	
		20°C	25 °C
Reasonable worst case 1 - toilet attendant and cleaner	Based on spending a full 8 hour day inside the public toilet area with a ventilation rate of 3 air exchanges per hour where one 80g product is used for each $5m^3$ of public toilet room area	10.1	13.7
Reasonable worst case 2 - toilet attendant and cleaner	Based on spending a full 8 hour day inside the public toilet area with a ventilation rate of 3 air exchanges per hour where one 80g product is used for each $15m^3$ of public toilet room area	3.38	4.58
Reasonable worst case 3 - toilet attendant and cleaner	Based on spending 2 hours per day inside the public toilet area and 6 hours in the vestibule area. Ventilation rate of 3 air exchanges per hour where there is high usage of products inside the public toilet (80g of product for every $5m^3$ of public toilet room area) and the concentration in vestibule area is 1/3 the concentration in public toilet.	4.4	5.95
Realistic case - toilet attendant and cleaner	Based on spending 2 hours per day inside the public toilet area with a ventilation rate of 3 air exchanges per hour, where one 80g product is used for every $15m^3$ of public toilet room area and 6 hours per day in the vestibule at a concentration of 1/3 the toilet area.	1.5	1.99

Analysis of exposure scenarios

Three reasonable worst cases exposure scenarios were considered by RAC: the first two were based on a professional worker spending 8 hours inside the toilet area, with differing rate of use of the product, and the third based on the professional spending 2 hours inside the toilet and 6 hours in the vestibule or area where the concentration is 1/3 of the concentration of 1,4-dichlorobenzene in the toilet. RAC considered that it is not plausible that a professional would spend 8 hours inside a toilet area in their working day, especially

with the high rate of use of the product (80g per 5m^3). RAC therefore considered that the third reasonable worst case scenario is more appropriate for professional workers. This latter exposure scenario adequately covers a cleaner; while a cleaner may spend a greater portion of their day cleaning toilets this would be offset by time where there is no exposure to 1,4-dichlorobenzene. In the realistic scenario, the exposure durations are the same as in the third reasonable worst case, but with a use rate of the product of 80g per 15m^3 (reflecting the cleaning industry practice), as assumed from the monitoring study mentioned above.

In addition, RAC noted that conditions where a worker is expected to work for 8 hours in an average temperature of 30 °C may not be consistent with the requirements of EU health and safety working condition requirements. To reduce the level of uncertainty, additional estimations were performed for exposure in 25°C. For this assessment, it was assumed that the changes in longevity of the air freshener/toilet block are linear, as explained in the Background Document.

RAC also considered the additional exposure of workers from 1,4-dichlorobenzene exposure in the workers' home. RAC estimated that the additional exposure would be less than the calculated exposure for the consumer in the realistic case scenario, corresponding to spending 16 hours in the home (0.333mg/m^3 at 20°C), and this exposure would also be reduced by the time spent by the worker outside the home with no exposure to 1,4-dichlorobenzene.

Characterisation of risk(s)

Risks were estimated based on the reasonable worst case and realistic case scenarios from exposure via inhalation. Exposure from handling and accidental ingestion is not included. The following tables are used to demonstrate risk characterization for consumers and professionals.

Risk characterisation - consumers' use

The following table outlines the exposure scenarios and the associated risk characterisation ratios for consumers:

Table 4: RCRs for consumer uses

Scenario	**Conc. mg/m^3**	**DNEL mg/m^3**	**RCR**
Reasonable worst case consumer exposure, 20 °C, 0.2 air exchanges	**2.68**	**0.64**	**4.19**
Reasonable worst case consumer exposure, 30 °C, 0.2 air exchanges	**5.63**	**0.64**	**8.8**
Reasonable worst case consumer exposure, 20 °C, 2 air exchanges	**1.6**	**0.64**	**2.5**
Reasonable worst case consumer exposure, 30 °C, 2 air exchanges	**3.4**	**0.64**	**5.3**
Realistic case consumer exposure, 20 °C, 2 air exchanges	**0.33**	**0.64**	**0.52**
Realistic case consumer exposure, 30 °C, 2 air exchanges	**0.69**	**0.64**	**1.08**

Summary of the risk to consumers

Using a DNEL of 0.64 mg/m^3 the resultant RCR's are significantly greater than 1 under reasonable worst case conditions (range 2.5-8.8) and slightly above 1 in the realistic 30 °C exposure scenario (1.08). This indicates a risk of liver cancer to consumers when they are continually exposed under reasonable worst case conditions to 1,4-dichlorobenzene toilet blocks and air fresheners in poorly ventilated bathrooms and in high temperature environments. Taking account of the hazard profile of the substance (a non genotoxic category 2 carcinogen) whose carcinogenicity to humans is uncertain and that exposure sufficiently high to induce liver cancer would be required, RAC considered that it is questionable whether consumers have developed liver cancers as a result of past exposures.

Risk characterisation - professional use toilet attendants and cleaners

The following table outlines the exposure scenarios and the associated risk characterisation ratios for professionals:

Table 5: RCRs for professional uses

Scenario	Conc. mg/m^3	DNEL mg/m^3	RCR
Reasonable worst case 2 : 8 hours per day in the public toilet area, ventilation rate of 3 air exchanges per hour. 80g of product is used for each 15m3, at 20 °C	**3.38**	**3.62**	**0.94**
Reasonable worst case 2: 8 hours per day in the public toilet area, with a ventilation rate of 3 air exchanges per hour. 80g of product is used for each 15m3 of public toilet area, at 25 °C	**4.58**	**3.62**	**1.26**
Reasonable worst case 3: 2 hours per day inside the public toilet area and 6 hours in the vestibule area, ventilation rate of 3 air exchanges per hour 80g of product for every 5m3 of public toilet area and the concentration in vestibule area is 1/3 the concentration in public toilet, at 20 °C	**4.4**	**3.62**	**1.21**
Reasonable worst case 3: 2 hours per day inside the public toilet area and 6 hours in the vestibule area, ventilation rate of 3 air exchanges per hour 80g of product for every 5m3 of public toilet area and the concentration in vestibule area is 1/3 the concentration in public toilet, at 25 °C	**5.95**	**3.62**	**1.64**
Realistic case 2 hours per day in the public toilet with a ventilation rate of 3 air exchanges per hour one 80g product is used for each 15m3 of public toilet room area 6 hours vestibule 1/3 conc in bathroom at 20 °C	**1.5**	**3.62**	**0.41**
Realistic case 2 hours per day in the public toilet with a ventilation rate of 3 air exchanges per hour one 80g product is used for each 15m3 of public toilet room area 6 hours vestibule 1/3 conc in bathroom at 25 °C	**1.99**	**3.62**	**0.55**

Summary of the risk to workers

Using a DNEL of 3.62 mg/m^3 (i.e. <1 ppm) developed for professional exposure, the resultant RCR's are above 1 (range 1.21-1.64) for reasonable worst case exposure scenarios and below 1 for realistic case scenarios. RAC also considered the uncertainties of including typical breaks for the workers in the modelling calculations but concluded that RCR's for reasonable worst case scenarios would still be above 1 (1.1-1.5). Taking account

of the hazard profile of the substance (a non genotoxic category 2 carcinogen) whose carcinogenicity to humans is uncertain and that exposures sufficiently high to induce liver cancer would be required, RAC considered that it is questionable whether professional toilet attendants and cleaners have developed liver cancers as a result of past exposures. Nevertheless, RCRs of greater than 1 indicate that the exposure needs to be reduced for workers working in high temperature, poorly ventilated environments (<3 air exchanges per hour).

JUSTIFICATION THAT ACTION IS REQUIRED ON AN EU WIDE BASIS

The main reason to act on an EU-wide basis is the protection of human health from the adverse effects of 1,4-dichlorobenzene. Based on available information 1,4-dichlorobenzene is potentially used in all Member States while the use is higher in some Eastern and Southern Member States. Consumers are at risk when they use air fresheners and toilet blocks containing 1,4-dichlorobenzene continuously at home under reasonable worst case conditions. In addition RAC agrees that the exposure of professional toilet attendants' and cleaners' needs to be reduced where poorly ventilated toilets are involved. The human health risk is thus an EU-wide problem. Currently one Member State (Sweden) has a national restriction on 1,4-dichlorobenzene. Thus, to ensure a similar level of protection of human health across the EU, action should be taken on an EU-wide basis.

While no information is available on imported products containing 1,4-dichlorobenzene, if a restriction is agreed at EU level then any risks from imported products will also be controlled.

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

Recent data indicate a shift in use pattern, within the decreasing total tonnage, towards toilet blocks. This suggests a continued desire for the product especially in toilets where usage is high and cleaning is infrequent. 1,4-dichlorobenzene does not have an alternative product (with the exception of camphor which is also marketed as urinal blocks however camphor is not considered a safer alternative) effective in masking odours for facilities (public toilets) which are frequently used and regular continuous cleaning is not undertaken. However, technically cleaning is considered as an effective alternative.

RAC considers a restriction on 1,4-dichlorobenzene will be effective in reducing the exposure of professionals working in poorly ventilated toilets.

Effectiveness in reducing the identified risk, proportionality to the risk

The substance is registered in the EU and includes the consumer and professional use of 1,4-dichlorobenzene in air fresheners and toilet blocks. This indicates the desire by those manufacturing or importing 1,4-dichlorobenzene products to maintain the product on the EU market. Therefore, it is expected that the current tonnages used in air fresheners and toilet blocks (even though they have been significantly reduced since the publication of the EU RAR) will be maintained. While no information is available on imported products containing 1,4-dichlorobenzene, when a restriction is agreed at EU level, then any risks from imported products will also be controlled.

RAC considered that a restriction would be appropriate to control the exposure of 1,4-dichlorobenzene in consumers and professional workers.
After the implementation of the proposed restriction, 1,4-dichlorobenzene in air fresheners and toilet blocks would not be available on the European market. The products containing 1,4-dichlorobenzene will be removed from the market in all Member States within 12 months from the implementation of the restriction. The exposure from 1,4-dichlorobenzene in the above products will cease when all air fresheners and toilet blocks currently on the market are used up, i.e. very soon after the implementation of the restriction. It is noted that alternative consumer products are already commonly used and are considered safer in relation to human health.

Assessment of risk management measures

Consumer risk management measures

The regulatory provisions applicable to consumer risk management measures are presented in detail in the Background Document.

Since the 1990's, a reduction in the use of the substance as an air freshener and toilet block has been recorded. Following the reclassification of the substance as a Carcinogen Category 2, there has been a further significant reduction in the amount of the substance used in consumer air fresheners and toilet blocks. Nevertheless, the use continues.

RAC agreed that consumer exposure levels are very dependent on ventilation rates. 'Sufficient ventilation' is also the only risk management measure proposed by the registrant for this use. However, it is very difficult for a consumer to conform to any requirements related to this parameter. In addition a greater risk has been identified when the products are used where the ambient temperature is higher, for example in southern Europe.

Therefore, ventilation is not considered as an appropriate risk management measure to ensure that consumer exposure does not cause a risk.

Professional (worker) risk management measures

The regulatory provisions applicable to professional risk management measures are presented in detail in the Background Document

While reduction in the use of the substance as an air freshener and toilet block observed since the 1990's has continued following the reclassification of the substance as a Carcinogen Category 2, the use still exists. As stated in the Background Document, the volume of the substance used in public toilets is significantly higher than that used by the consumer market.

According to currently available information, no other risk management measures than 'sufficient ventilation' have been proposed by the registrant to control the exposure of toilet attendants and cleaners. However, there is no recommendation from the manufacturer of the product what is a sufficient ventilation rate. Therefore, RAC considers that appropriate risk management measures to ensure that worker exposure does not result in RCRs above 1 are not adequately detailed in the registration dossier.

RAC considered a number of risk management methods to reduce exposure as outlined in the background document:

- Voluntary agreement by the cleaning industry to phase out the use of 1,4-dichlorobenzene

- Increased ventilation
- Artificial temperature control
- Change in exposure duration – shorter shifts/job rotation
- Use of personal protection equipment
- Worker legislation, in particular application of occupational exposure limits
- Restriction

RAC considered that the specific category of professional workers (i.e. toilet attendants and toilet cleaners) could be more vulnerable than other sectors where chemical substances are used (for example laboratories, industrial sites etc.) due to a low awareness of the risks from chemical substances and the difficulty in applying efficient risk management measures. Taking into account the above, RAC considered that the suggested restriction of 1,4-dichlorobenzene in toilet blocks and air fresheners to professionals would result in reduced exposure of 1,4-dichlorobenzene to toilet attendants and cleaners.

RAC noted that the OEL currently in force of 122 mg/m^3 (Directive 2000/39/EC) was developed in 1994, was not based on carcinogenicity and that 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.

Conclusion

RAC considers that the risk management measures implemented as the result of the existing legal requirements at the EU level have not been effective in reducing the exposure to EU consumers and professionals. There is evidence to suggest that the exposure continues and the current measures are therefore not sufficient to protect them.

RAC noted that the RCRs values for consumers and workers are >1. However taking account of the hazard profile of the substance RAC considers it is questionable whether consumers or workers have developed liver cancers as a result of past exposures.

Assessment of alternatives

A number of products are identified in the Background Document as suggested chemical alternatives to 1,4-dichlorobenzene. However, camphor is the only chemical alternative in terms of its odour masking capacity in frequently used toilets. Camphor (CAS no. 76-22-2) is currently marketed as urinal blocks typically in a concentration of ≥96%. It also has a similar vapour pressure to 1,4-dichlorobenzene so its main route of exposure is also by inhalation. RAC agreed with the Dossier Submitter that because of its hazard profile, as outlined in the Background Document, camphor is not a suitable alternative. RAC however noted that it is the only alternative product currently marketed which has similar odour masking properties to 1,4-dichlorobenzene.

With the exception of camphor, the other alternatives listed in the Background Document contain, for the most part, a number of different substances e.g. fragrances, stabilisers, dyes etc. The health concerns associated with these substances are skin irritation, respiratory irritation, eye irritation and skin sensitisation. As the nature of consumer use does not involve direct handling of the substance skin irritation and sensitisation would not be of major concern. One of the alternative products refered to in the background document are aerosol air fresheners containing between 0.5- 5% fragrances. If fragrances where used as aerosol air freshener sprays there may be some concern for respiratory irritation however this was not examined in the original Annex XV dossier.

Carcinogenicity is the endpoint of concern. Although there are health concerns for ethanol

(present as a solvent in alternative products), these are primarily for the oral route of exposure and not by inhalation of the substance in cleaning/air freshener products.
The environmental hazards associated with the selected alternatives for the fragrances show no greater hazard than 1,4-dichlorobenzene.

In conclusion, camphor is the only comparable chemical alternative to 1,4-dichlorobenzene in terms of odour masking capacity in frequently used toilets. However, while it may not be classified for carcinogenicity it is not considered as a suitable alternative due to its hazard profile. Nevertheless, it is not possible to predict how the market will react to withdrawal of 1,4-dichlorobenzene air fresheners and toilet blocks.

For all products not involving camphor, based on the limited data available, there appears to be no major concern regarding both the health and environmental effects from substances used in alternative products. They primarily focus on preventing the build-up of soiling which would result in odours or they prevent the development of microorganisms causing the odours. These alternatives masking capacity would not be comparable to 1,4-dichlorobenzene however they are considered suitable products in the consumer setting and in professional settings where use traffic is not high or where frequent cleaning is employed.

There are also a number of technical alternatives to using 1,4-dichlorobenzene i.e. more frequent cleaning, automatic flush toilets, greater ventilation etc. These can be employed and are effective in both the consumer and professional setting. However, while frequent cleaning of public toilet is a suitable alternative this may not be practically feasible or possible. In addition, while there are alternative that could be used by professionals RAC did not consider that these are suitable for use in public toilets where the use frequency is high and the cleaning is infrenquent.

RAC agreed that there are enough suitable alternative products that can be used by consumers and suitable techniques that can be used for public facilities. Therefore a restriction on import and sale of 1,4-dichlorobenzene air fresheners and toilet blocks would be effective in removing potential human health risks for consumers and reducing the exposure of professionals working in toilets.

Practicality, including enforceability

The enforcement of the proposed restriction can be undertaken under existing market surveillance activities by verifying if producers, importers and distributors still supply 1,4-dichlorobenzene based air fresheners and toilet blocks to the market., e.g. by checking retailers under market surveillance and checking the product information in their catalogues or packages.

In addition RAC recommended that the restriction specifies a concentration of 1% to assist Member States in enforcing the restriction on 1,4-dichlorobenzene in air fresheners and toilet blocks. This corresponds to the limit of concentration which triggers classification of a mixture as a category 2 carcinogen (Regulation EC No 1272/2008 on classification , labelling and packaging of substances and mixtures). No risk assessment has been carried out on mixtures having such low concentrations of 1,4-dichlorobenzene.

Monitorability

The effect of the restriction on the uses of 1,4-dichlorobenzene can be monitored through standard enforcement and no additional monitoring is envisioned. The monitoring can be mainly done by verifying if the products containing 1,4-dichlorobenzene are still supplied to the market. RAC does however recommend based on the comments from the Forum that in

order to assist demonstrating compliance with enforcement a concentration limit of 1% is included within the legal text of the restriction. It is noted that if there is any need for additional monitoring, there are readily available methods that can be used to quantitatively analyse 1,4-dichlorobenzene products or monitor blood and air concentrations of 1,4-dichlorobenzene.

RAC agreed that compliance checks can be undertaken as part of Member State existing monitoring programmes under Market Surveillance.

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.