

**Committee for Risk Assessment (RAC)  
Committee for Socio-economic Analysis (SEAC)**

**Response to comments document (RCOM)  
on the Annex XV dossier  
proposing restrictions on  
1,4-dichlorobenzene**

**ECHA/RAC/RES-O-0000003486-69-01/F**  
ECHA/SEAC/[reference code will be issued after the adoption of  
the SEAC opinion]

| <b>SUBSTANCE NAME</b>                          | <b>EC NUMBER</b> | <b>CAS NUMBER</b> |
|------------------------------------------------|------------------|-------------------|
| <b>1,4-Dichlorobenzene (p-dichlorobenzene)</b> | <b>203-400-5</b> | <b>106-46-7</b>   |

**29 April 2013**

Substance: **1,4-Dichlorobenzene (p-dichlorobenzene)**  
 CAS number: **106-46-7**  
 EC number: **203-400-5**

Comments and response to comments on Annex XV restriction report on  
**1,4-Dichlorobenzene (p-dichlorobenzene)**  
 Annex XV report submitted by ECHA 19 April 2012.  
 Public consultation on Annex XV report started on 19 June 2012.

**General comments**

| <b>Ref</b> | <b>Date Country/<br/>Organisation/<br/>MSCA<br/>Comment type</b>                                                                                          | <b>Comment</b>                                                                                                                                                                                                                                                                                                    | <b>DS Response</b>                                                                                                                                                           | <b>RAC Rapporteurs<br/>comments</b>                                                                                                                                                                      | <b>SEAC Rapporteurs<br/>comments</b>                                                                                                                                                                                                                                                                                                                  |
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| <b>222</b> | 2012/12/18 15:08<br><br>Austria / National<br>Authority /<br>Allgemeine<br>Unfallversicherung<br>sanstalt<br><br>Information on<br>hazard and risk<br>(B) | We strongly support 1,4-Dichlorobenzene to be included into Annex XVII. There should not be exemptions for professional use. According to the report (Table C46) the substance can be substituted by cheaper alternatives or slightly more expensive alternatives in the case of urinal blocks (6,1 EURO a year!) | Thank you for this comment.                                                                                                                                                  | Your support for the proposed restriction is noted.                                                                                                                                                      | Note that any restriction must be targeted to an identified risk. The role of SEAC is to ensure that the proposal is proportionate – while in this case the costs of alternatives for professional users are low, the Benefits of the restriction on professional use require consideration in order to establish the proportionality for this group. |
| <b>221</b> | 2012/12/13 16:52<br><br>Sweden / MSCA                                                                                                                     | Swedish CA comments on the 1,4-dichlorobenzene restriction proposal<br><br>The Swedish CA considers that the restriction proposal from ECHA is well documented and we agree with the conclusions drawn i.e. a restriction proposal covering consumer use as well as professional use is                           | Thank you for this comment.<br>We fully agree with your remarks on the mode of action of 1,4-dichlorobenzene for the carcinogenicity end-point. This is further discussed in | The restriction proposal was based on the previously agreed EU risk assessment of 1,4-dichlorobenzene (2004). However, the EU RAR did not consider toilet attendants/cleaners in the assessment. RAC has |                                                                                                                                                                                                                                                                                                                                                       |

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|-----|--------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------|
|     |                                                        | <p>needed. The restriction proposal is based on a previously agreed EU risk assessment of 1,4-dichlorobenzene from year 2004 and the subsequent "Commission Recommendation and Communication" from 2008. By asking ECHA to prepare and submit this restriction proposal COM acknowledges the results from the prior ESR risk assessment and risk reduction activity on 1,4-dichlorobenzene, agreed by 15 MS. The toxic endpoint chosen for the risk assessment, carcinogenicity, has been further studied in recent years and data clearly indicate a non-genotoxic/mitogenic mode of action, indicating a threshold effect.</p> | <p>the report under section B.5.8 on carcinogenicity.</p> | <p>concluded that for both consumers and professionals that while the RCR's were above 1 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 those exposed have developed liver cancers as a result of past exposures. Nevertheless, RCRs of greater than 1 indicate that the exposure needs to be reduced and a restriction will be effective in reducing the exposure to consumers and professionals. The mode of action for carcinogenicity is noted and supported by RAC.</p> |                              |

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|-----|--------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------|
|     |                                                        | <p>Hazard assessment<br/>           MoA for the carcinogenic effect<br/>           We agree with the end-point chosen for the risk assessment, carcinogenicity. We note that beside the hepatocellular carcinomas, there are also findings of more rare tumours, i.e., hepatoblastomas and histiocytosarcomas, showing that DCB not only increases the background incidences of hepatocellular carcinomas. The assumed threshold MoA is also supported. A mitogenic effect appears to underlie the carcinogenicity, but it is not shown how the mitogenic response is triggered. The dose-response both for the mitogenic response and tumor formation is non-linear. The uncertainty in dose-response in different</p> |             | <p>SE support for the carcinogenic endpoint is noted. This endpoint has been selected by RAC as the most relevant health effect to bring forward for risk characterisation. The Background Document outlines how the uncertainties in the dose responses are considered during DNEL derivation. The MoA is not fully known, however, the evidence to date strongly supports a non-genotoxic mitogenic MoA possibly mediated by substituted hydroquinone metabolites. More information on the MoA is provided in the Background Document.</p> |                              |

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|-----|--------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------|
|     |                                                        | species needs to be taken into account in the risk assessment.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |             |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |                              |
|     |                                                        | <p>DNEL for long-term inhalation exposure (the most relevant exposure route)</p> <p>We agree with the DNEL setting based on the mouse inhalation study (in accordance with the EU RAR) resulting in a consumer DNEL of 0.39 mg/m<sup>3</sup> (corresponding to 0.13 mg/kg bw/day) and a worker DNEL of 2.2 mg/m<sup>3</sup>(corresponding to 0.31 mg/kg bw/day). In light of the uncertainties regarding dose-response in different species and the severe effect (carcinogenicity), the additional AF (=5) is supported. The DNELs derived are similar to the estimates for a safe</p> |             | <p>Support of selected DNEL is noted. However, please note that the DNELs for workers and consumers are 0.64 mg/m<sup>3</sup> (0.21 mg/kg bw/day) for consumers and 3.62 mg/m<sup>3</sup> (0.51 mg/kg bw/day) for workers. The changes in the DNELs are as a result of reviewing the AF for severity of effects. An AF of 3, as supported by RAC, was used in DNEL calculations to take account of the fact that this substance is a low potency Cat 2 non-genotoxic carcinogen however there is a steep dose-response observed. Further elaboration is contained in the Background Document.</p> |                              |

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|     |                                                        | <p>inhalation exposure level, 0.6-1.6 mg/m<sup>3</sup>, suggested in the paper by Butterworth et al (2007) using a partly different approach. In that case an assessment factor of 3 was used because of the complex biology and data deficiencies.</p>                                                                                                                                                                                                      |                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                                                                                                                                                                                                                                                                                                                                                                                                                                                   |                              |
|     |                                                        | <p>Exposure assessment<br/>         The modeling approach is supported, although we believe that the measurements in domestic houses (Djohan et al, 2007) and public toilets (Global Werke GmbH, 1986) may be used as supportive data for consumer and worker exposure levels, respectively. The temperature in a bathroom/toilet can often exceed 20 degrees, even in the winter, and clearly so in summer time in southern Europe, indicating that the</p> | <p>The measured data presented in the literature for both private homes and in the public toilets has been used for the comparison with the derived estimations of exposure. The temperature used in the exposure scenario calculation for consumers is based on an average temperature over a 24 hour period in the home. Indeed, the temperature in the toilets may be higher than 20°C, leading to faster sublimation rate and higher exposure. For this reason,</p> | <p>RAC has made comparisons with the monitoring data. The exposure scenarios were also calculated based on daily exposure at 30°C. However, while exposure during the day may reach 30°C RAC considers this to be an unrealistic worst case scenario that exposure over a 24 hour period in a workplace would be at an average 30°C. Therefore RAC calculated exposure at an average working day of 8 hours per day at a temperature of 25°C.</p> |                              |

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|     |                                                        | <p>use of this temperature might lead to an underestimation of the actual air concentrations.</p>                                                                                                                                   | <p>the exposures were also estimated for 30°C (for workers, RAC considered that 25°C is a more appropriate temperature). In the developing of the final conclusions, the exposures at both temperatures have been taken into consideration.</p>                                                                                                           |                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                              |
|     |                                                        | <p>Workers: It would be good to get more clear descriptions of the actual working conditions for toilette attendants, but if not available, we support using a reasonable worst case approach, assuming 8 hours daily exposure.</p> | <p>Workers: In the information available, no detailed description was found of the working conditions of a toilet attendant. The parameters used in the exposure modelling were based on guidance, information available for individual parameters, and personal observations. The duration of 8 hours suggested by you was taken into consideration.</p> | <p>Workers: The observation is noted. While a description of the activities of a toilet attendant was not included in the dossier, it was assumed by RAC that the role of the toilet attendant is to collect money, provide sanitary items (e.g. tissue paper) as well as undertaking a certain amount of cleaning. The dossier calculates exposure based on the toilet attendant spending all their time inside the toilet however RAC also considered that such</p> |                              |

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|     |                                                        |                                                                                                                                                                                                                                                                                                                                                |                                                                                                                                                                                                                                                                                                 | workers could be located for a period of time in the vestibule of the toilet rather than inside the toilet itself.                                                                                                                                                                                                                                                   |                              |
|     |                                                        | Consumers: Unless data indicate otherwise it appears reasonable to use the default ventilation rate for bath rooms/toilets (2 air changes per hour) according to ConsExpo. The time spent in a bathroom (10 m <sup>3</sup> ) may be assumed to be 1 hour, but should probably be shorter (0.5 h) if a toilet (2.5 m <sup>3</sup> ) is assumed. | Consumers: The combination of parameters you suggest was used in the derivation of the exposure of consumers in the original Annex XV proposal. RAC has however retained the bathroom room volume (10 m <sup>3</sup> ) and the corresponding time of 1 hour as the preferred exposure scenario. | Consumer exposure for a 10 m <sup>3</sup> sized bathroom was calculated at a lower air exchange (0.2 air exchanges per hour) to account for internal bathrooms with poor ventilation. However, for the toilet size of 2.5 m <sup>3</sup> using such a low air exchange was not considered appropriate and 2 air exchanges per hour was used in calculating exposure. |                              |
|     |                                                        | Risk characterization<br>Depending on various different assumptions for the exposure assessment, many exposure estimates and therefore also many risk characterization ratios have been calculated. Since                                                                                                                                      | It is correct that in the original Annex XV proposal all except one (scenario of consumer use at home, with the most favourable conditions of exposure) of the calculated risk                                                                                                                  | RAC has considered the DNEL and the exposure scenarios and modified some of the assessment factors and parameters used which have led to some of the RCR's being below one.                                                                                                                                                                                          |                              |



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|     |                                                        | <p>all, except one, ratios exceed one (1), we find that the risk assessment supports the proposed restriction.</p>                                                                                                                                                                      | <p>characterization ratios (RCRs) were above 1. However, RAC has since then revised the exposure conditions and, perhaps most importantly, calculated new DNEL values for the exposure of both consumers and workers. These values have led to different RCR values but which remained of above 1 for many of the assessed scenarios, leading to similar conclusions on risk.</p> |                                                                                                                                                                                                                                                                                                                                     |                              |
|     |                                                        | <p>Alternatives<br/>           We think better cleaning is an obvious alternative to using chemicals, especially in those situations where a toilette attendant is spending a lot of time in, or very close, to the toilette. This alternative needs to be assessed and considered.</p> | <p>We agree with this comment. Better cleaning is discussed in the report under the section on alternative techniques (C.2.4). There, it is highlighted that cleaning can prevent mal-odours related to spillages. These can be significant, especially in public toilets with a high frequency of use. In addition, please note that</p>                                         | <p>We agree that cleaning is an obvious alternative to using chemicals, however where regular and frequent cleaning is not employed in busy public toilets, the only effective chemical alternative (i.e. Camphor) is not considered a suitable safer alternative. This has been further elaborated in the Background Document.</p> |                              |

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|     |                                                        |         | <p>the odour which 1,4-dichlorobenzene is designed to mask often comes from drains and is due to their design, 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 (this additional clarification on the functioning of 1,4-dichlorobenzene was added in the Background Document).</p> <p>Regarding costs, estimates of the cost of additional cleaning to obtain the same odour effect as with 1,4-dichlorobenzene are reported for urinals, see assumptions in section C.2.5 (RPA, 2010).</p> <p>Finally, the calculations of the consumer surplus</p> |                             |                              |

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|     |                                                        |                                                                                                                                                                                                           | <p>associated with the switch to alternative products, implicitly include costs of eventual additional cleaning. Consequently these are taken into account and do not need to be estimated separately.</p>                                                                                                                                                                                                                                                                                                                    |                                         |                              |
|     |                                                        | <p>Chemical products containing 1,4-diklorbenzen with the intention to mask odor may not be placed on the market or used in Sweden regardless of consumer or professional use since the late 1980 's.</p> | <p>The report makes reference to the Swedish national ban on 1,4-dichlorobenzene. This ban is broader in scope than the proposed restriction. The Annex XV restriction proposal focuses on consumer and professional uses of air fresheners and toilet blocks, specifically addressing uses in toilets or uses as air fresheners in indoor areas. Other uses of 1,4-dichlorobenzene have not been assessed. Some of these other uses (see section B.2.2 of the report for a description of all the known uses and section</p> | <p>Noted, including response of DS.</p> |                              |

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|     |                                                        |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | B.2.4 for a description of the targeting of the restriction) might fall within the scope of the Swedish national ban, but are out of the scope of the proposed restriction.                                                                                                                                                                                                                                                                                                                                                             |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                              |
|     |                                                        | According to information from a Swedish trade organisation the alternatives are mainly different fragrances. Based on information from the Swedish product register, camphor does however not seem to be an alternative in this area of use in Sweden. The content of camphor in products registered in the product register is too low to have the function as an air freshener in professional use. If desirable, information on the use of camphor in products on the Swedish market can be provided from the product register. | <p>We agree that fragrances are the main alternatives and this is the approach taken in the description of the alternatives. However, since most alternatives contain also non-fragrance substances (surfactants, preservatives, colorants, builders etc.), these were also described in the report.</p> <p>We have identified Camphor tablets which are marketed as urinal blocks. Concentrations are similar to those of 1,4-dichlorobenzene, that is 96 % or above. Additional information on the use of Camphor products in the</p> | It is noted by RAC that Camphor is already marketed as an alternative for 1,4-dichlorobenzene. RAC considers that Camphor is unlikely to be used as an alternative product in consumer applications where suitable alternatives already exist. However RAC considers as Camphor is the only equivalent chemical alternative to 1,4-dichlorobenzene which is effective as an air freshener in areas where frequent cleaning is not undertaken and usage is high, coupled with the information that camphor is already marketed as an air |                              |

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|            |                                                                                                                                      |                                                                                                                                                                                                                                                              | Swedish market would have been beneficial. | freshener and insect repellent a restriction on the use of 1,4-dichlorobenzene may result in its increased use in public toilets where constant cleaning is not undertaken and public usage is high. RAC considers that Camphor is not a suitable alternative however consideration needs to be given to the fact that other suitable technical alternatives are more expensive than Camphor when considering the most suitable risk management option. |                              |
| <b>220</b> | 2012/10/22 14:39<br>Individual<br>The proposal (A), Justification for action on a Community-wide basis (D), Why a restriction is the | Dear Sir/ Madam, deodorant blocks are hazardous, using p-dichlorobenzene, a respiratory irritant that can trigger an asthma attack in a person who already has asthma. Exposure to dichlorobenzene occurs primarily indoors, from products such as deodorant | Thank you for these comments.              | Noted                                                                                                                                                                                                                                                                                                                                                                                                                                                   |                              |

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|            | most appropriate<br>Community-wide<br>measure (E)                                                                      | blocks. Dichlorobenzene persists in the environment, and we have reasonable evidence that is a human carcinogen. Other restroom and urinal deodorizing methods are available and should be used, replacing hazardous technologies. |                                                                                                        |                             |                                                                                                               |
|            |                                                                                                                        | In addition, autoflush toilets and urinals may eliminate the need for deodorant blocks in certain situations.                                                                                                                      | We agree with this comment.                                                                            | Noted                       |                                                                                                               |
|            |                                                                                                                        | So, I agree we the proposed restrictions and plea for its enforcement as soon as possible, avoiding further risks to the cleaning workers and population in general.                                                               |                                                                                                        |                             | RAC has concluded that the restriction will be effective in reducing exposure of consumers and professionals. |
| <b>219</b> | 2012/10/08 10:53<br><br>United Kingdom<br><br>The proposal (A),<br>Information on<br>hazard and risk<br>(B), Available | We note that the current restriction proposal is based on the EU RAR for dichlorobenzene. We agree with the general approach, although there seems to have been a selective, and conservative, choice of data,                     | Thank you for these comments. Please find detailed responses on each point that you have raised below. | Noted                       |                                                                                                               |

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|     | <p>information on alternatives (C), Why a restriction is the most appropriate Community-wide measure (E), Socio-economic Assessment of Proposed Restriction (F) MSCA</p> | <p>which is then also interpreted in a precautionary manner. It would be informative to see how the balance of justification for a restriction would appear if median data assumptions were used.</p> <p>It would be helpful to discuss the uncertainties in the available quantitative data in more detail, and the consequences that these uncertainties have for the conclusions on risk and the benefits of the restriction. Please clarify why the health benefits are being assessed on changes in lung function when the DNEL is based on carcinogenicity. We also have a few specific comments on the hazard identification and consumer risk characterisation.</p> | <p>The original Annex XV proposal contains quantified estimates of the expected benefits of the proposed restrictions. As you note, these benefits concern a different end-point than the one addressed in the risk characterisation section of the report. At the request of SEAC rapporteurs' additional sensitivity analysis of costs and benefits were carried out to gauge the magnitude of the uncertainties and their consequences on conclusions reached. However, in the RAC and SEAC discussions it was</p> | <p>RAC has considered these uncertainties which are elaborated in the Background Document accompanying the opinion.</p> | <p>Additional uncertainty analysis has been included in the Background Document in relation to the calculation of the consumer surplus and sensitivity analysis for elasticity and shape of demand curve. During the opinion development phase, the DS also prepared further sensitivity analysis for the calculation of exposed populations and the benefits related to lung function.</p> <p>We agree that a more thorough discussion of uncertainties will improve</p> |

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| Ref | Date Country/<br>Organisation/<br>MSCA<br>Comment type | Comment | DS Response                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | RAC Rapporteurs<br>comments | SEAC Rapporteurs<br>comments                                                                                                         |
|-----|--------------------------------------------------------|---------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------|--------------------------------------------------------------------------------------------------------------------------------------|
|     |                                                        |         | <p>recommended not to take into consideration the benefits estimations for concluding on the proportionality of the restrictions.</p> <p>We acknowledge your point regarding a more thorough discussion on uncertainties and have improved this discussion in the final Background Document.</p> <p>As mentioned above the health impact is not used in the final justification of the restriction proposal. However, methodological issues related to choice of endpoint(s) for health impact assessment and whether or not they need to be the same as the endpoint selected as the most critical endpoint in the risk assessment remain to be further discussed in relation to future restriction</p> |                             | <p>the assessment.</p> <p>Regarding the use of different endpoints, the justification for this is discussed in the SEAC opinion.</p> |



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|------------|---------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------|------------------------------|
|            |                                                                           |                                                                                                                                                 | <p>proposals. The reason for using different endpoints in the present case was simply the very limited possibility to quantify the impact due to carcinogenicity (following its threshold mechanism).</p> <p>Regarding the selection of critical endpoint for the risk assessment please see below.</p> |                             |                              |
| <b>210</b> | 2012/09/07 15:47<br>Germany<br>Information on hazard and risk (B)<br>MSCA | The restriction proposal for 1,4-Dichlorobenzene is supported. Some suggestions are made for the section on consumer exposure estimation.       | Thank you for this comment.                                                                                                                                                                                                                                                                             | Noted                       |                              |
| <b>209</b> | 2012/08/29 15:32<br>Norway/<br>MSCA                                       | Norway supports the proposed restrictions on 1,4-dichlorobenzene. However, a more clear definition of the scope of the restriction is welcomed. | Thank you for the comment and support to the proposed restriction. The Background Document has been updated with additional clarifications on the scope of the restriction.                                                                                                                             | Noted                       |                              |

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**Specific comments**

| <b>Ref</b> | <b>Date Country/<br/>Organisation/<br/>MSCA<br/>Comment type</b>                                                                                                                                                                                                 | <b>Comment</b>                                                                                                                                                                                                                                                                                                                                                                                                                         | <b>DS Response</b>                                                                                                                                                                                                                                                                                                                                                                                          | <b>RAC Rapporteurs<br/>comments</b> | <b>SEAC Rapporteurs<br/>comments</b>                                                                                                                    |
|------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>222</b> | 2012/12/18 15:08<br><br>Austria / National<br>Authority /<br>Allgemeine<br>Unfallversicherung<br>sanstalt<br><br>Information on<br>hazard and risk<br>(B)                                                                                                        | Cleaning women and men<br>are very often not that well<br>trained and that makes<br>working processes<br>sometimes more dangerous<br>compared to other<br>branches. Substitution if<br>possible is a must according<br>to 2004/37/EC. The<br>inclusion in Annex XVII will<br>strengthen this aim!                                                                                                                                      | Indeed, the restriction<br>would support the<br>objectives of the Framework<br>Directive (89/391) and<br>Directive 2004/37/EC.                                                                                                                                                                                                                                                                              | Noted                               |                                                                                                                                                         |
| <b>219</b> | 2012/10/08 10:53<br>United Kingdom<br><br>The proposal (A),<br>Information on<br>hazard and risk<br>(B), Available<br>information on<br>alternatives (C),<br>Why a restriction<br>is the most<br>appropriate<br>Community-wide<br>measure (E),<br>Socio-economic | A) Suggested restriction<br>Please can you clarify if<br>embalming agents/coffin<br>hygiene agents will be<br>excluded from the scope of<br>this proposal?<br>We note the suggestion in<br>RPA (2010) that a<br>restriction on the sale of<br>1,4-DCB air fresheners and<br>toilet blocks could affect the<br>economic viability of the<br>flake method of production.<br>This dossier states that the<br>proposal will have no impact | Embalming agents/coffin<br>hygiene agents are out of<br>the scope of this proposal.<br>This has been further<br>clarified in section B.2.4<br>"Description of targeting" in<br>the Background Document.<br><br>We have noted this<br>suggestion from the RPA<br>report (see section F.4<br>Wider economic impacts).<br>This view, coming from a<br>manufacturer of flaked 1,4-<br>dichlorobenzene, suggests | Noted response of DS                | We agree that further<br>consideration and<br>confirmation that the<br>economic viability of the<br>flake method of production<br>should be undertaken. |

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| Ref | Date Country/<br>Organisation/<br>MSCA<br>Comment type | Comment                                                                                                                      | DS Response                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | RAC Rapporteurs<br>comments                                                                                                                        | SEAC Rapporteurs<br>comments |
|-----|--------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------|
|     | Assessment of Proposed Restriction (F) MSCA            | beyond products within scope. Can ECHA confirm that methods of production of 1,4-DCB will not be affected by the proposal?   | that a restriction on air fresheners and toilet blocks will adversely affect the flaking of 1,4-dichlorobenzene and even the production of 1,2-dichlorobenzene, of which 1,4-dichlorobenzene is a by-product. We have not any quantifiable information to corroborate this view. Note that a restriction on air fresheners and toilet blocks will not mean that flaked 1,4-dichlorobenzene will become unavailable. This could be still produced or imported for other applications and even for the production of air fresheners and toilet blocks for export. |                                                                                                                                                    |                              |
|     |                                                        | B) Information on hazard and risk<br>In section B.5.5.3, the conclusion on the human information could be interpreted by non | We would be reluctant to specifically mention occupational asthma as that has not been addressed in any of the reviewed studies. The conclusion in section                                                                                                                                                                                                                                                                                                                                                                                                      | Thank you and the comment has been noted and the conclusion amended as follows: the limited human data available do not allow any firm conclusions |                              |

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| Ref | Date Country/<br>Organisation/<br>MSCA<br>Comment type | Comment                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | DS Response                                                                                                                                                                                         | RAC Rapporteurs<br>comments                                                                                                                                                                                                                                                                                                                                                                                                                      | SEAC Rapporteurs<br>comments |
|-----|--------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------|
|     |                                                        | <p>specialists as indicating that 1,4-dichlorobenzene may induce occupational asthma. It might be preferable, given the limited database to say: The limited human data do not allow any firm conclusions regarding the potential of 1,4-dichlorobenzene to induce occupational asthma.</p>                                                                                                                                                                                                  | <p>B.5.5.3 aims at reflecting the conclusion in the EU RAR.</p>                                                                                                                                     | <p>to be drawn regarding 1,4-dihlorobenzene's sensitising properties.</p>                                                                                                                                                                                                                                                                                                                                                                        |                              |
|     |                                                        | <p>Section B 5.11 – A NOAEC of 75 ppm is used for DNEL derivation. This is based on local and systemic effects observed in rats and mice following lifetime inhalation exposure. However a US evaluation of these studies (ASTDR) identified a NOAEC of 15 ppm based on local site-of-contact effects in the respiratory tract of female rats. It would be helpful if a clearer explanation could be given for the selection of 75 ppm and not 15 ppm as the starting point for the DNEL</p> | <p>The selection of critical endpoint was extensively discussed during the preparation of the proposal. The selection of endpoint is discussed in more detail in the final Background Document.</p> | <p>Carcinogenicity is the leading health effect, and as the route of exposure of concern is inhalation, the NOAEC based on the tumours noted in mouse liver in the inhalation study were taken forward for DNEL derivation. In the Rapporteurs assessment, consideration was afforded to the relevance of all endpoints including the nasal effects. Unfortunately, we have not seen the reference to a NOAEC of 15 ppm so cannot comment on</p> |                              |

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|-----|--------------------------------------------------------|-------------|-------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------|
|     |                                                        | derivation. |             | <p>this (the lowest dose tested in the 2-year inhalation study was 20 ppm).<br/>           As there was no dose response associated with the effects noted, a NOAEC of 75ppm was selected based on slight grade respiratory metaplasia in the nasal gland and eosinophilic changes in respiratory epithelium (of slight grade) in high dose female rats. The lesions were mild, characterised by eosinophilic changes which are typically found in ageing rodents and which were not accompanied by degenerative changes and were concluded as being age-related (not degenerative) and accelerated by treatment.<br/>           Details on the effects and choice of dose descriptor are further elaborated in the Background Document.</p> |                              |

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| Ref | Date Country/<br>Organisation/<br>MSCA<br>Comment type | Comment                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | DS Response                                                                                                                                                                                                                                                                                                                                                                              | RAC Rapporteurs<br>comments                                                                                                                | SEAC Rapporteurs<br>comments |
|-----|--------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------|------------------------------|
|     |                                                        | <p>B.9.1.2 – We note that conservative assumptions have been made to model exposures for professionals and consumers. To help interpret the significance of the high RCRs that have been obtained in section B10, it would be useful to consider for each parameter, the level of conservatism that has been introduced and the proportion of the exposed population that may fall at the most conservative end of the range. For example, although it is possible that some toilet attendants will be exposed for 8 hours, it may be more appropriate to base calculations for the realistic scenario on the 2 hour exposure time estimated for general cleaners.</p> | <p>There is a relatively large uncertainty in relation to exposure due to possible variations in most of the relevant parameters. In the restriction report, the exposures were assessed against reasonable worst case scenarios and realistic scenarios.<br/> A range of parameters was used in developing exposure estimations including as suggested by you 2 hours for cleaners.</p> | <p>RAC has considered and revised the parameters used in the exposure models. These scenarios are outlined in the Background Document.</p> |                              |
|     |                                                        | <p>We consider the ventilation rates that have been</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | <p>We do agree that the parameters chosen for the</p>                                                                                                                                                                                                                                                                                                                                    | <p>RAC has prepared revised exposure scenarios taking</p>                                                                                  |                              |

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| Ref | Date Country/<br>Organisation/<br>MSCA<br>Comment type | Comment                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | DS Response                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | RAC Rapporteurs<br>comments                   | SEAC Rapporteurs<br>comments |
|-----|--------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------|------------------------------|
|     |                                                        | <p>assumed for consumers and professionals are likely to be at the most conservative end of the range. For consumers, it is likely that householders will tend to keep doors and windows open on hotter days for comfort. According to Ch 15 of the CSR guidance, a ventilation rate of 2 ACH applies to "normal" conditions. Ventilation rates of 4.2 and 6.2 have been reported for situations where doors and windows are open therefore, particularly for the 30°C scenario, the use of 0.2 or 2 ACH seems highly conservative. For professionals, the number of air changes per hour is likely to be higher in busy toilets due to frequent entry and exit of users. This could justify the use of a higher ventilation rate in the</p> | <p>derivation of exposure estimations are conservative. However, for the regulatory purposes, the parameters used must be well justifiable, based on the guidance available, and represent the 'reasonable worst case' conditions. It may not be appropriate to use ventilation conditions that may be relevant for a fragment of the year only. Therefore, for consumer use the ventilation rates proposed by the ECHA guidance and ConsExpo were used. For the professional use, following the recommendation of RAC, higher than proposed by the ConsExpo guidance ventilation rate has been used (based on CIB SE guidance) for the derivation of the exposure estimations.</p> | <p>account of comments and uncertainties.</p> |                              |

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| Ref | Date Country/<br>Organisation/<br>MSCA<br>Comment type | Comment                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | DS Response                                                                                                                                                                                                                                                                                                                                                 | RAC Rapporteurs<br>comments | SEAC Rapporteurs<br>comments |
|-----|--------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------|------------------------------|
|     |                                                        | <p>calculations for professionals.</p> <p>Another source of conservatism for consumers is the worst case assumption that the concentration of 1,4-DCB will be only 1/3 lower in the rest of the house compared to the concentration in the toilet/bathroom. The data from Djohan do not support such a conservative estimate. We think that the 1/20 ratio is the most appropriate basis to calculate realistic exposures. The use of a low ventilation rate combined with a minimal difference between air concentrations in the toilet and the rest of the house is likely to produce unrealistically high exposure estimates for consumers.</p> | <p>The parameters used in developing exposure estimations include possible 'reasonable worst case' conditions. However, the examination of the conditions of exposure and possible resulting exposure levels is not limited to them. The suggested by you concentration of the substance in other areas of the house was also taken into consideration.</p> |                             |                              |



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|-----|--------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------|------------------------------|
|     |                                                        | <p>B.9.3.2 - Please can clarification be provided for the way ConsExpo has been used to generate exposure estimates? As it has been used, the air concentration is assumed to be zero at t = 0. Hence, for short exposure durations, the exposure estimate is generated for time periods before steady state has been reached. In reality, emissions will be continuous and in most cases, the worker or consumer will be entering a room that has already reached steady state. We suggest that ConsExpo should be used to calculate the steady state concentration by setting the exposure duration to 24 hours per day and the equation on page 64 should then be used to calculate TWA exposures based on the length of time spent in</p> | <p>Indeed, it was assumed that prior to use of the air freshener the concentration of the substance in the toilet / bathroom air was 0. This is one of the possible options of an exposure situation. It could also be ventured that after reaching steady state the concentration of the substance in the indoor air declines as the surface of the products becomes smaller, as they are used up. Towards the end of their useful life the concentration might be significantly lower. Then, the products are replaced and the cycle starts again. It is also possible, that the block would not be replaced immediately - there may be some hours or even days when there is no air freshener in the facility. We have however not taken into</p> |                             |                              |

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|-----|--------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------|------------------------------|
|     |                                                        | and away from areas where 1,4-DCB may be present.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | account such effects in our calculations.<br>In principle, the methodology proposed by you would lead to higher exposure values.                                                                                                                                                   |                             |                              |
|     |                                                        | Page 69 and 74 – Comparisons have been made between exposure values and lifetime cancer risks. In order to interpret these comparisons in a meaningful way, it is necessary to have information on the basis on which these cancer risk estimates have been derived (e.g. starting point, choice of extrapolation model, suitability of the model for the likely mechanism of action of the substance, consideration of uncertainties in the approach, etc). In the absence of this information, we question whether these comparisons add anything | In page 69 and 74 (see original Annex XV proposal) we discuss some studies in relation to exposure. The cancer risk estimates used in these studies are under revision and will be better described in the final version of the Background Document, to be published in June 2013. |                             |                              |

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|-----|--------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------|
|     |                                                        | useful to the restriction dossier.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |                                                                                                                                                                                                                                                                                                                                                        |                              |
|     |                                                        | Section B.10 – We have identified several sources of uncertainty in the hazard and exposure assessment. In some cases, if alternative values are used for the risk assessment (e.g. the use of a lower NOAEC as a starting point or basing exposure calculations on steady state concentrations) higher risk characterisation ratios will be calculated. For other cases(e.g. the use of higher ventilation rates and less precautionary assumptions about the differences between concentrations in the toilet and in the rest of a house) lower risk characterisation ratios will be calculated. We recognise that there will always be | Generation of exposures for ranges of parameters was considered in the development of the exposure estimations. It was advised against, however, by the tool developer, as explained in the ConsExpo manual and quoted in section B.9.3.2.2. It was considered that the next best option is to present possible exposures for possible ends of the spectrum. It is likely that the real exposures would be between the high and low values presented. Choice of a different assessment factor used for derivation of DNEL would also affect the RCR, as would the choice of a | Your comment is noted and justification for use of the NOAEC brought forward for risk characterisation is explained in the Background Document. Carcinogenicity (liver tumours observed in mice) is the leading health effect and the relevant route of exposure for 1,4-dichlorobenzene is inhalation and therefore the NOAEC of 75 ppm was selected. |                              |

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|-----|--------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------|------------------------------|
|     |                                                        | <p>uncertainty in risk assessments but think that it is important to provide some assessment in the dossier of the level of uncertainty that surrounds each risk characterisation ratio. One way to achieve this could be to generate exposure ranges rather than point estimates to explore the effect that certain assumptions have on the level of risk that is estimated. We think that this will improve the transparency of the dossier and will help with the socio-economic assessment of costs vs benefits.</p> | <p>different endpoint and set of toxicological data. This is always an issue of expert judgement which in a regulatory setting should be done following the relevant guidance.<br/>         The socioeconomic analysis, following the conclusions of the exposue assessment, was in its original form not totally dependent on the exposure estimates as the impacts on lung function occur at relatively low exposure levels. We agree however with your statement that uncertainties should be carefully described and tried to reflect them in the proposal.</p> |                                                                                    |                              |
|     |                                                        | <p>Table B34 – We note that this table focuses on worst case estimates. Since these will only be relevant for a small section of the population it would be useful to present the</p>                                                                                                                                                                                                                                                                                                                                    | <p>In the Background Document, developed following consultation process, table B34 has been replaced by one presenting both reasonable worst case and realistic exposure</p>                                                                                                                                                                                                                                                                                                                                                                                        | <p>The Background Document has been updated with new exposure scenario tables.</p> |                              |

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|-----|--------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------|
|     |                                                        | realistic exposures and RCRs for comparison.                                                                                                                                                                                                                                                                                                                                                                 | levels.                                                                                                                                                                                                                                                                                                                                                                                                                         |                                                                                                                                                                                 |                              |
|     |                                                        | <p>C) Information on alternatives<br/>           Page 85 – Please justify why the DNEL for 1,4-DCB was used as a benchmark to assess exposures to d-limonene and beta-pinene.<br/>           Page 85 – We do not think that it is appropriate to use oral data to conclude on the likelihood of adverse effects from inhalation where there is the potential for local effects in the respiratory tract.</p> | <p>The reference to the DNEL for 1,4-dichlorobenzene was inserted for comparison with the modeled level of 1,4-dichlorobenzene, not to assess the exposure to fragrances. After reading your comment we consider the reference misleading and have deleted the sentence.<br/>           We acknowledge the comment regarding oral data but please note that these were used due to the absence of relevant inhalation data.</p> | <p>As per the DS comment, the reference to the DNEL has been deleted.<br/><br/>           Regarding the comment on the use of oral data, this is being addressed by the DS.</p> |                              |
|     |                                                        | Page 86 – The conclusion that alternative fragrances pose a lower level of hazard seems to be based mostly on the expected lower exposure levels rather than                                                                                                                                                                                                                                                 | This is correct and has been reflected in the Background Document.                                                                                                                                                                                                                                                                                                                                                              | Noted                                                                                                                                                                           |                              |

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| Ref | Date Country/<br>Organisation/<br>MSCA<br>Comment type | Comment                                                                                                                                                                                                                                                                                     | DS Response                                                                                                                                                                                      | RAC Rapporteurs<br>comments | SEAC Rapporteurs<br>comments                           |
|-----|--------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------|--------------------------------------------------------|
|     |                                                        | comparative toxicity data. It would be useful to recognise this uncertainty in the dossier.                                                                                                                                                                                                 |                                                                                                                                                                                                  |                             |                                                        |
|     |                                                        | E) Why a restriction is the most appropriate EU-wide measure<br>Table E47 – It is not clear how the realistic value for consumers using the substance at home has been calculated. Also there is an inconsistency in the way other exposure values have been taken forward into this table. | All values were calculated as the average of the values provided by all the scenarios considered in each case. The inconsistencies present in the table have now been corrected.                 | Noted                       | The figures in this table (now E49) have been amended. |
|     |                                                        | Professionals:<br>Worst case for cleaners = exposure value calculated at 20°C.<br>Worst case for toilet attendants = exposure value at 30°C.<br>Realistic values for professionals = the average of the exposure values calculated at 20 and 30°C.                                          | Worst case for cleaners:<br>This figure has been corrected.<br>Worst case for toilet attendants: this figure has been corrected.<br>Realistic values for professionals: This figure was correct. |                             |                                                        |

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|-----|--------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|     |                                                        | <p>It would be helpful to provide additional justification for the selection of these exposure values, particularly since these are used to estimate the fraction of the population that are potentially exposed to concentrations above the DNEL.</p> | <p>The exposure values correspond to the exposure scenarios considered. As for each group of users there were several exposure scenarios, average values were used. These averages were calculated separately for each set of realistic scenarios and for each set of worst case scenarios. Note that this calculation was carried out to obtain only the approximate order of magnitude of the populations exposed above DNEL.</p> | <p>Noted the Exposure scenarios have been updated.</p> |                                                                                                                                                                                                                                                       |
|     |                                                        | <p>Page 106 – It would help to put the estimate of 200 premature deaths per year into context if the uncertainties surrounding the calculations were described in more detail.</p>                                                                     | <p>Additional sensitivity calculations of the benefits were carried out. Notwithstanding, the research studies on which these benefits were based on, were judged as too uncertain for our purposes by RAC. Consequently, the results of the benefit calculation were not</p>                                                                                                                                                       |                                                        | <p>SEAC rapporteurs have considered the results of the HIA, including the estimate of 200 deaths, and will assess whether the uncertainties are considered sufficiently robust for the HIA to be taken account of during the opinion development.</p> |

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| Ref | Date Country/<br>Organisation/<br>MSCA<br>Comment type | Comment                                                                                                                                                                                                                                                                                                                                                                                                | DS Response                                                                                                                          | RAC Rapporteurs<br>comments | SEAC Rapporteurs<br>comments                                                                                                                                                                                                                                                                                                                                               |
|-----|--------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------|-----------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|     |                                                        |                                                                                                                                                                                                                                                                                                                                                                                                        | considered in the justifications of the final restriction proposal by RAC and SEAC and were not included in the Background Document. |                             |                                                                                                                                                                                                                                                                                                                                                                            |
|     |                                                        | Page 111 – We note that the estimates for consumer savings in E.2.1.1.2.2 do not match the figures in table C46. There also seems to be a mismatch in section E.2.2.1.2.2.                                                                                                                                                                                                                             | The figures have been corrected in the Background Document.                                                                          |                             | The figures have been corrected in the Background Document.                                                                                                                                                                                                                                                                                                                |
|     |                                                        | Section E2 – It would be helpful to put the numerical estimates for persons at risk and mortality burdens into context if the uncertainties surrounding these values were described in more detail. One way to do this would be to calculate estimates based on the least and most conservative assumptions to give a range of possible values. This would provide some quantification of the level of | Please see response by SEAC Rapporteurs.                                                                                             |                             | The DS prepared a sensitivity analysis of the benefits related to lung function. Ranges were proposed for the key parameters. This additional analysis has been considered by the SEAC rapporteurs alongside their consideration of the evidence used to support the basis of the HIA (i.e. the link between exposure to 1,4-dichlorobenzene and lung function) – see next |



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| Ref | Date Country/<br>Organisation/<br>MSCA<br>Comment type | Comment                                                                                                                                                                                                                                                                 | DS Response                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | RAC Rapporteurs<br>comments | SEAC Rapporteurs<br>comments                                                                                                                                                                                                                                                                                                                                                                           |
|-----|--------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|     |                                                        | uncertainty.                                                                                                                                                                                                                                                            |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                             | comment. The Opinion and Background Document has been updated to take into account the SEAC rapporteurs conclusions.                                                                                                                                                                                                                                                                                   |
|     |                                                        | F) Socio-economic Assessment of proposed restriction Section F.1 - We note that several assumptions have been made in order to quantify the health benefits associated with the proposed restriction but the consequences of these assumptions have not been discussed. | You are correct that a number of assumptions were used, and it was highlighted in the report that these assumptions convey uncertainty to the calculations. Note that in each of the assumptions a "cautious" approach was taken. For example, we have noticed that the level of exposures which led to decrements in lung function in the Elliott study were, depending on the scenario, ~10-100 times higher than the exposure encountered in our exposed populations. This seemed as sufficient evidence to assume that similar lung function decrements would similarly occur. Given though that |                             | The rapporteurs have considered these assumptions in their evaluation of the dossier and, based on initial conclusions from RAC, have found that there is insufficient evidence to support the basis of the HIA (i.e. the link between exposure to 1,4-dichlorobenzene and lung function). The Opinion and Background Document has been updated to take into account the SEAC rapporteurs conclusions. |

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| Ref | Date Country/<br>Organisation/<br>MSCA<br>Comment type | Comment                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | DS Response                                                                                                                                                                                                                                                                                                 | RAC Rapporteurs<br>comments | SEAC Rapporteurs<br>comments |
|-----|--------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------|------------------------------|
|     |                                                        |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | <p>RAC discussions suggested that there is not enough weight of evidence to link 1,4-dichlorobenzene exposure to decreasing lung function these assumptions were not used in the final justifications for the opinions of the Committees.</p>                                                               |                             |                              |
|     |                                                        | <p>For example, there are several uncertainties in the data of Elliott et al. We note that the error bars surrounding the FEV1 coefficients calculated for each exposure decile are large. Also, it is not clear if the lung function that would be expected for each individual within the study was taken into account when the decrements for each exposure decile were calculated. If this was not taken into account, and there was a greater proportion of subjects who had lower FEV1 due to their</p> | <p>Elliott et al. used age- and height-adjusted FEV<sub>1</sub> in their study, meaning that the changes observed were controlled for such factors. They also corrected for a number of possible confounders. The description of the Elliott et al. study has been improved in the Background Document.</p> |                             |                              |

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|-----|--------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------|------------------------------|
|     |                                                        | <p>age and height in the higher exposure deciles, this could mean that physiological differences rather than 1,4-DCB exposure contributed to the apparent decrements in lung function. If this is the case, then the mortality "over-risk" that has been calculated will be smaller and the value of the health benefits will also be lower.</p> |                                                                                                                                                                                                                                                                                                |                             |                              |
|     |                                                        | <p>We question whether it is appropriate to use relative hazard ratios to calculate mortality "over-risk" and would like additional justification for this approach.</p>                                                                                                                                                                         | <p>To compare hazard ratios between studies they would have to be relative. How else would you do it? We could try to better justify our approach but given the very limited importance of the health impact assessment on the final restriction proposal it might not be very meaningful.</p> |                             |                              |
|     |                                                        | <p>We also note that the relative hazard ratios that were established by Hole et al were based on comparisons between</p>                                                                                                                                                                                                                        | <p>The Hole study states that "The subjects are representative of the general population in this industrial conurbation"</p>                                                                                                                                                                   |                             |                              |

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|------------|-----------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------|------------------------------|
|            |                                                                                   | individuals with lung function measurements suggestive of clinical impairment at the start of the study and individuals with exceptionally good lung function. This seems to be a worst case approach and it would be useful if further justification could be provided for the use of this data. | (west Scotland). Note that we have not assessed how the levels of FEV <sub>1</sub> of the Hole study would compare with the levels of FEV <sub>1</sub> of other populations or the level of FEV <sub>1</sub> of an "average" individual. |                                                  |                              |
| <b>210</b> | 2012/09/07 15:47<br><br>Germany<br><br>Information on hazard and risk (B)<br>MSCA | B 9.3.2.2 Consumer exposure estimation<br>-The decision to use ConsExpo for modelling consumer exposure from use of toilet blocks is supported.                                                                                                                                                   |                                                                                                                                                                                                                                          |                                                  |                              |
|            |                                                                                   | - Model parameters are well documented in general. In table B19 the concentration of the substance in other areas of the home is missing, and no equation is given for the calculation of the combined                                                                                            | Indeed, the concentration of the substance in other areas of the house is not included in this table. The formula used for calculation of the 24 hour exposure is provided in section B.9.3.2.1.                                         | Noted, the Background Document has been updated. |                              |

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|-----|--------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------|
|     |                                                        | uptake from exposure in the toilet and in the other areas of the house.                                                                                                               |                                                                                                                                                                                                  |                                                                                                                                                                             |                              |
|     |                                                        | Therefore, these calculations can hardly be reproduced at present.<br>- We would also suggest to review the cited concentrations from Logue et al (2011), (see supplement, table S2). | The article by Logue (2011) is included in the section presenting the review of literature discussing exposure to 1,4-dichlorobenzene.                                                           | Noted                                                                                                                                                                       |                              |
|     |                                                        | - For a better readability, the calculations could be streamlined to the ones which are relevant for the risk characterisation.                                                       | In the Background Document the presentation of results of exposure modelling and their comparison to DNELs (derivation of RCRs) is different than in the original Annex XV restriction proposal. | Noted                                                                                                                                                                       |                              |
|     |                                                        | - An uncertainty discussion could be helpful. It could also refer to other calculations like children exposure.                                                                       | The scale of uncertainties related to the parameters of exposure and their effect on the possible exposure level were presented through derived exposure estimations for a range of              | RAC has considered the uncertainties in the opinion development and these are reflected within the opinion and supporting Background Document. Exposure assessment and Risk |                              |

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| <b>Ref</b> | <b>Date Country/<br/>Organisation/<br/>MSCA<br/>Comment type</b> | <b>Comment</b> | <b>DS Response</b>                                                                                             | <b>RAC Rapporteurs<br/>comments</b>                                                | <b>SEAC Rapporteurs<br/>comments</b> |
|------------|------------------------------------------------------------------|----------------|----------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------|--------------------------------------|
|            |                                                                  |                | combinations of parameters.<br>The exposure of children<br>was not used in the final<br>version of the report. | characterisation has been<br>based on inhalation as the<br>main route of exposure. |                                      |

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**Specific question: Alternatives**

Please provide any information on alternative substances used in air fresheners or toilet blocks that have the same odour masking function as 1,4-dichlorobenzene (in addition to what has been provided in the Annex XV report or other report referred therein).

| Ref | Date Country/<br>Organisation/<br>MSCA<br>Comment type                                                                                                                                                      | Comment                                                                                                                                     | DS Response                                                                                                                                                                                                                                                                                                                                                           | RAC Rapporteurs<br>comments | SEAC Rapporteurs<br>comments |
|-----|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------|------------------------------|
| 220 | 2012/10/22 14:39<br><br>Individual<br><br>The proposal (A),<br>Justification for action<br>on a Community-wide<br>basis (D), Why a<br>restriction is the most<br>appropriate Community-<br>wide measure (E) | Essential oils also have excellent properties and can be used in good combinations for natural air fresheners to fit specific environments. | Thank you for this comment. It is quite certain that a variety of alternative products exist in the market. However, it is challenging to compare and quantify the performance of these products in odour masking. In the discussion on technical feasibility (section C.2.4) some elements of qualitative and quantitative (based on costs) comparison are provided. | Response of DS noted.       |                              |