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SCIENTIFIC COMMITTEE ON HEALTH AND ENVIRONMENTAL RISKS

SCHER

Opinion on the report

"Emission of chemicals by air fresheners Tests on 74 consumer products sold in Europe"

(BEUC report January 2005)

Adopted by the SCHER
during the 9th plenary of 27 January 2006

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1. BACKGROUND

Air quality is one of the major environmental health concerns for Europe. The main goal of the Community policy on air pollution is to achieve levels of air quality that do not result in unacceptable risks to human health.

Most indoor air pollutants consist of chemicals derived from, for example, the use of cleaning products, air fresheners, pesticides and material related to furniture and construction, and heating and cooking appliances but also from outdoor pollution sources. Other aspects of the building such as insulation and ventilation rate also play a role. Many of the pollutants cause symptoms which may not occur for many years, making it difficult to discover the cause. Examples of potentially serious effects due to exposure to indoor air pollutants include asthma, other breathing disorders and cancer.

Pollutants that produce allergies and asthma including microbiological contaminants should also be taken into account.

The European Consumers' Organisation, BEUC (Bureau Européen des Consommateurs), commissioned a study to analyse the chemical substances present in indoor air following the use of air fresheners. Air fresheners included incense, natural products, scented candles, aerosols, liquid and electric diffusers, and gels. BEUC's study report claims that the emissions of certain substances such as volatile organic compounds (VOCs), sensitising substances and benzene give rise to serious concerns, other substances such as formaldehyde, terpenes, di-ethyl-phthalate or toluene are of less, little or no concern.

For this opinion, the BEUC report as well as related information from BEUC on the methodology used for the analyses has been made available to the SCHER.

2. TERMS OF REFERENCE

Taking into account the general approach to risk assessment presented by SCHER in a separate opinion, the committee is asked, in close cooperation with the SCCP, to consider:

A. whether the emissions from air fresheners observed in the study may be a health risk for consumers, including vulnerable groups such as children. Reference should be made to each of the parameters measured;

B. whether, in light of the information and data available to the Committee, the emissions observed in the study could add up to other substances observed in indoor air pollution (such as from construction materials, carpets, furniture) in such a way that the total may be a health risk for consumers, including vulnerable groups;

C. whether further studies are necessary to adequately assess the potential health risks from air fresheners. In the affirmative, please indicate which studies these should be.

3. General Comments

The term “air freshener” can be misleading as these products do not significantly reduce the air pollution, but rather add more substances with a “fresh” odour strong enough to mask a bad odour. The use of these products is widespread and information from manufacturers cited in a Danish report (Pors and Fuhlendorff, 2003) indicates that about 5 % of the Danish population is more or less continuously exposed to emissions from air fresheners, and the use in southern Europe may be higher.

The concentrations of several individual VOCs and also “total VOCs” resulting from the use of several types of air fresheners (incense paper, scented candles, incense[1], gel fresheners, liquid air fresheners, electric diffusers and sprays) are described in the BEUC report. Neither the compositions of the tested products, nor the rationale for the selection of the individual substances studied are given.

The BEUC study is limited to a few VOCs, but also less volatile compounds and particles may be important for the human health impact of the air fresheners, especially those including a combustion or pyrolysis process (incense and candles). The individual compounds included in the reported results are, in most, cases well studied. The highest observed concentrations, for some of them, exceed recommended maximum levels.

In the evaluation of possible health effects due to the emission products, the frequency of the used air freshener, the duration of exposure and the frequency of peak levels need to be considered. In the absence of detailed use pattern information, the SCHER is assuming that the exposure is of chronic nature. The BEUC study presents average VOC concentrations in indoor air during the sampling period.

The indoor air concentrations of VOCs depend on a number of factors, such as ventilation rate, adsorption in/on materials and emissions from other sources, including outdoor air contribution. The emissions from air fresheners add to these from the other sources. It would be necessary to also look at the total exposure, including routes other than inhalation, such as dermal exposure and ingestion for the compounds with low vapour pressure, but such a holistic approach has so far not been applied to indoor air pollutants.

At least three similar studies on air fresheners have been reported (Eggert and Hansen, 2004; Muijser et al, 2005; Spruyt et al, 2005) but altogether the data specifically addressing emissions from air fresheners and the consequent exposure identification is sparse and insufficient for a comprehensive risk assessment. The reported studies show large variations in the measured levels, but the results are in reasonable agreement between the studies taking the huge variability in possible exposure scenarios into account.

In the next section the results of the BEUC study will be specifically commented upon, evaluated and in section 5 (Answers to questions), the possible health risks of air fresheners isaddressed more generally.

[1] “Incense” has being used as defined in the BEUC report

4. SPECIFIC COMMENTS

4.1. Exposure assessment

4.1.1. The BEUC study

Newly built, empty rooms in a laboratory building were used for the tests. The background concentrations have been checked and subtracted from the reported results, but there are no data on the actual ventilation rate other than that the tests were conducted with the doors closed. The samples were taken two meters from the product being tested.

The two adsorption methods used for the sampling of VOCs and carbonyl compounds are validated methods in common use. US EPA method TO17 with Tenax TA cartridges is best suited for compounds with boiling points between 100 and 400ºC and the use for analyses of e.g. benzene (bp 78ºC) would need a validation. If compounds with low boiling points break through the adsorbent, the results will be lower than the true values. Particles will not be well collected in the used sampling techniques.

The chromatographic conditions used for the analysis should have been given to identify the range of compounds analysed as "total VOCs", but the used sampling technique will not cover the most volatile substances. The quality control of the chemical analyses is not well described. At least some information on the repeatability for repeated analysis of the same product would have been useful for the assessment of the results.

Three other reports (Eggert and Hansen, 2004; Muijser et al, 2005; Spruyt et al, 2005) from investigations of emissions from air fresheners have been identified. Results from those have been used to try to verify the outcome of the BEUC investigation.

4.1.2. VOCs

"Total VOCs" and number of chromatographic peaks are presented for the investigated products. The levels found within the investigated product groups cover wide ranges. The differences between groups are in fact smaller than the within group variation. Of the 76 "total VOCs" results, 11 were below 100 µg/m^3, 27 between 100 and 500 µg/m^3, and 38 above 500 µg/m^3, with maximum levels above 7000 µg/m^3. All results from the BEUC study are presented for the different product groups in Table 1.

TNO (Muijser et al., 2005) has published results from a study parallel to the one performed by BEUC. In the TNO investigation a metal chamber with controlled ventilation was used, but as the product brands used in this study are not identified it is difficult to compare the results between the studies. No VOCs results are given but several identified compounds, especially linalol and benzyl acetate, were found at very high levels (up to 10000 µg/m^3).

In a Danish study (Eggert and Hansen, 2004) of incense, the total emission has been measured and it is therefore difficult to compare to the room and chamber studies. The total VOCs emissions from one stick or cone of incense varied between 6 and 121 mg, and if those amounts were evenly distributed in a 20 m^3 room without ventilation it would result in 300 to 6000 µg/m^3.

4.1.3. *Allergens*

In the BEUC study special interest was paid to the emissions of allergens, and the concentrations of some compounds mentioned in the Scientific Committee on Cosmetic Products and Non-Food Products intended for Consumers opinion “Fragrance allergy in consumers” (SCCNFP, 1999). d-Limonene was found at the highest concentration (2003 µg/m^3) and l-limonene up to 130 µg/m^3.

4.1.4. *Benzene*

The incense sample investigated by BEUC emitted benzene and concentrations of up to 221 µg/m^3 were found in the room air. Liquid air fresheners also emitted this compound and air concentrations up to 8 µg/m^3 were found in those measurements. The other products did not emit any benzene. For most of the samples in the TNO study the chamber air levels were around 1 µg/m^3 or less, but for the candles air levels above 30 µg/m^3 were found. Eggert and Hansen (2004) used a box model to estimate the air concentration of individual chemicals from the results of their study and this resulted in benzene levels between 11 and 281 µg/m^3. A report from an ongoing study (Spruyt et al, 2005) gives results for benzene levels during use of scented candles. Experiments were performed both in “ordinary homes” and in a test chamber and concentrations in the range 0.03 – 3.9 µg/m^3 were found, generally higher in the test chamber than in the homes. A well performed chamber study (Lee S-C and Wang B, 2004) of emissions from ten different brands of incense produced levels of benzene in the range of 18 – 117 µg/m^3 which is in the same region as those reported by BEUC.

4.1.5. *Formaldehyde*

BEUC found the highest levels of formaldehyde emitted from incense, and the air concentrations ranged from 51 to 69 µg/m^3. The scented candles and electric diffusers gave levels up to 13 µg/m^3, while the other air fresheners gave lower or no formaldehyde emissions. The chamber studies performed at TNO gave air concentrations of more than 300 µg/m^3 for scented candles (no incense studied) while the Danish investigators estimated 49 - 210 µg/m^3 in their study of incense samples. The report from Spruyt et al. (2005) also gives results for formaldehyde concentrations, and the contribution to rather high background levels were in the range 4 – 28 µg/m^3 in homes. The formaldehyde concentrations found in the chamber experiment varied from 0.76 to 18 µg/m^3.

4.1.6. *Terpenes*

One of the subjects of interest the BEUC report focuses on is called terpenes, but seems to be focused on limonene, which exist in two forms, d-limonene (in oranges) and l-limonene (in lemons). As these substances smell “fresh” they are often added to air fresheners and the variation between the investigated samples probably reflect the level in the product. Air concentrations of d-limonene varied from ND to 2000 µg/m^3 in the BEUC study, the highest values obtained from sprays, gel air fresheners and electric diffusers. TNO did not report any limonene data, but one of the products in the Danish investigation gave levels close to the highest found by BEUC.

4.1.7. *Styrene*

Some samples from all the product groups investigated by BEUC gave rise to styrene in the air, and sprays gave variable concentrations up to 185 µg/m^3. TNO found very low levels of this compound in their chambers, except for the candles where concentrations up to 70 µg/m^3 were found, and in the Danish study the concentration of styrene was estimated to be in the range 3 – 21 µg/m^3.

4.1.8. *Diethyl phthalate*

BEUC found comparably high air levels of diethyl phthalate in some of the incense and aerosol experiments, and levels around 1000 µg/m^3 could be detected from incense. This compound was not reported in the parallel studies.

4.1.9. *Toluene*

Most samples investigated in the above mentioned studies gave limited air concentrations of toluene, with the highest value being 67 µg/m^3.

4.1.10. *Conclusion*

For most of the parameters analysed by BEUC maximum values of the same magnitude have also been reported by other investigators. The results in the BEUC study may therefore in a first approximation be regarded as realistic worst case values.

4.2. Effect assessment

The BEUC report has looked briefly at the toxicology of the compounds investigated. In general the measured concentrations have been compared to Guidance values from national and international organisations (OSH, ACGIH, ATSDR, WHO and US-EPA). If available, preference was given to values referring to consumer exposure. In principle this approach is reasonable.

SCHER has not given detailed comments compound by compound on the effect part of the BEUC report, but has elaborated an own text. Since many of the chemicals identified in the BEUC study have been the object of international projects (see e.g. INDEX, 2005) and have been evaluated by international bodies (EU, USEPA, WHO), only the most relevant information for the specific topic will be reported here.

In the BEUC report attention is given to secondary pollutants, i.e. the reaction products of emitted VOCs (known as primary pollutants) with photochemical oxidizing agents, such as ozone. Although this type of reaction has been demonstrated, there is little information available yet on the actual toxicity of such products (Nöjgaard et al., 2005). The reactions also produce fine and ultra fine particles (Wainman et al., 2000; Liu et al., 2004) but their concentrations were not measured in the BEUC study.

In addition, the report dedicates a chapter to allergens. Many of the VOCs detected in air fresheners have irritating properties, but among the key compounds considered here, only d-limonene and formaldehyde are classified as skin sensitizer. Although this toxicological effect should not be disregarded, some consideration in the report might be misleading, particularly when mentioning that skin allergens are likely to provoke respiratory allergies, without any experimental indication about their possible respiratory sensitizing properties.

The pattern of exposure may greatly vary depending on the nature of the product (i.e. sprays *vs.* slow release gels): indeed in many cases subchronic/chronic effects can be considered the relevant endpoints due to repeated use of the products. On the contrary, when sprays are used or diffusers are located in small spaces (i.e. cars) effects can be more appropriately related to acute/short term effects. For this reason, both kinds of effects are reported in the following.

4.2.1. Benzene

Following inhalation exposure, about 50% of the benzene is absorbed in rats. Once thoroughly distributed benzene is bioactivated to a number of metabolites, which are very likely responsible for its adverse effects.

Following short term exposure by inhalation, the critical end-point is bone marrow damage both in animals and in humans. In animal studies, 32 mg/m^3 has been indicated in male mice (the most sensitive species) as the NOAEC for 1 week exposure (Farris et al, 1997), while the lowest subchronic NOAEC (3.5 mg/m^3) has been detected by Green et al (1981). In humans, a similar NOAEC (3.2 mg/m^3) has been predicted by WHO for hematological effects related to 10 years exposure to benzene (WHO, 1993). Recently ECB indicated the same NOAEC value in a risk assessment report (EC, 2003a).

Some reproductive and developmental effects such as bone marrow haematopoietic changes in the offspring have also been reported after benzene inhalation, although at doses higher than the above mentioned NOAEC.

The weight of evidence coming from experimental data show that benzene is a genotoxic chemical, both in vitro and in vivo, causing chromosomal damage and mutations also in occupationally exposed humans. Benzene has been shown to be carcinogenic in several studies in experimental animals causing lymphomas and leukemia of various types. Similarly, epidemiological studies show evidence that chronic exposure to benzene induces leukemia. Benzene can be considered a genotoxic carcinogen and has been classified by IARC and USEPA as a Group 1 and A carcinogen (i.e. known human carcinogen), respectively (IARC, 1987; USEPA, 2003).

The EU limits value in ambient air according to the Directive 2000/69/EEC, set on ALARA (as low as reasonably achievable) principle, is 5 μg/m^3. For chronic benzene exposure in the range 13 - 45 μg/m^3 different regulatory bodies have calculated risk values of 2 - 8 $\times 10^{-6}$ for tumor induction on the basis of the available data (WHO, 1993, 2000; USEPA 1998, 2003).

4.2.2. Formaldehyde

Formaldehyde is readily and completely (> 90%) absorbed by the upper respiratory tract in rat and monkey (IARC, 1995). The main effects evidenced after acute and short-term formaldehyde inhalation are on the respiratory tract: altered breathing frequency and dyspnoea are paralleled by eye irritation, vomiting, spasm and death at very high concentration (120 mg/m^3). Damage and irritation to nasal epithelium are the most sensitive end-points after long-term exposure. The overall NOEC in animals can be considered around 1 mg/m^3. Humans exposed to formaldehyde levels ≥ 0.1 mg/m^3 have experienced sensory irritation (WHO, 2002). Upper and lower airways irritation is associated with cytotoxicity, hyperplasia and metaplasia of the respiratory epithelium.

Formaldehyde is mutagenic in vitro, but in vivo appears to induce genotoxic damages only at cytotoxic doses. Several experimental studies on rodents evidenced induction of squamous cell carcinomas of the nasal epithelium at doses >18 mg/m^3. Epidemiological studies on occupationally exposed individuals have pointed out a possible association between formaldehyde and nasal cavity cancer and leukemia. On this basis, IARC has recently classified formaldehyde as Class 1 carcinogen (known human carcinogen) (IARC, 2004). Considering its mode of action, it has been postulated that the carcinogenicity of formaldehyde is due to a combination of its cytotoxicity and genotoxicity indicating that formaldehyde poses a carcinogenic hazard to humans at doses able to cause a sustained regenerative cell proliferation, subsequent to overt cytotoxicity (WHO, 2002).

On the basis of these data, WHO recommended in the air quality guideline a 30 min average limit value of 100 μg/m^3 formaldehyde to prevent significant sensory irritation in the general population (WHO, 2000).

4.2.3. Terpenes

About 65% of the inhaled d-limonene is absorbed and readily metabolized. Its major health effects are associated with irritative (skin and eye) and sensitizing properties, the latter being strongly dependent on the oxidation status of the molecule. In this respect, it has been proposed that the reaction products between d-limonene and ozone or other free radicals present in the atmosphere are actually responsible for irritation. A NOAEC = 225 mg/m^3 and a LOAEC = 450 mg/m^3 for short term d-limonene inhalation have been identified on the basis of decreased lung function (vital capacity) (Falk Filipsson et al, 1993)

Neither limonene nor the corresponding epoxide are genotoxic.

No information is available on long term effects of chronic inhalation of d-limonene either in animals or in humans. Oral administration of d-limonene causes renal tumours in male rats but the mechanism is not considered relevant to humans (involvement of α_2-u-globulin in male rats). The IARC has concluded that there is not adequate evidence for limonene carcinogenicity in human (IARC, 1999).

A guidance value for inhalation of d-limonene has not yet been established, since only oral uptake is considered as a relevant exposure route by WHO. An exposure limit value 450 μg/m^3 has been proposed in the INDEX report for long-term exposure, calculated by applying 1000 as the safety factor to the above mentioned LOAEC (INDEX 2005). The application of 100 on the NOAEC would have resulted in an exposure limit of 2250 μg/m^3, and as the values are based on effects in humans, even lower uncertainty factors may be discussed.

4.2.4 Styrene

Following inhalation both animals and humans absorb styrene rapidly and extensively (60 – 70%). Styrene is metabolized to the corresponding 7,8-oxide, which has been detected in the blood of workers exposed to 43 – 311 mg/m^3 at levels linearly proportional to the external dose.

The acute toxicity of styrene is moderate both in animals (LC_{50} in rats about 12000 mg/m^3) and humans. After short term exposure (25 min) to about 1600 mg/m^3 humans have experienced nausea, very likely secondary to CNS depression and at lower doses (about 400 mg/m^3) eye and throat irritation. Sensory irritation, impaired balance, muscle weakness and loss of coordination indicative of neurotoxicity (cerebellar damage and CNS depression) are the most common styrene-induced non cancer effects. In addition, the reactive styrene 7,8-oxide can bind covalently to cellular proteins and DNA to trigger adverse effects and to act as a hapten responsible for contact allergies in some susceptible individuals. For short term exposure a NOAEC = 217 mg/m^3 has been established in humans.

Several occupational studies have indicated that long-term exposure to styrene affects mainly the CNS. For example, subtle cognitive effects in workers exposed for an average 8 years have been observed with an average LOAEC = 64 – 107 mg/m^3. From these data a reference dose 25 mg/m^3 has been adjusted by uncertainty factors.

At present no clear association has been demonstrated between occupational exposure to styrene and reproductive or developmental toxicity.

Genotoxicity in vitro (after metabolic activation) and in vivo has been equivocal but, in humans, genotoxic effects (DNA breaks and sister chromatid exchange) have been shown in blood cells of workers exposed to styrene concentrations of 43 – 128 mg/m^3 and above. Styrene is classified as a 2B carcinogen (IARC, 1994, 2002) based on a weak in vivo genotoxicity and some evidence of carcinogenicity in man. However, the genotoxic effects were not considered critical endpoints for the recent reference value extrapolation of WHO (WHO, 2000).

On the basis of the above mentioned LOAEC of 107 mg/m^3, after conversion of the occupational exposure to continuous exposure concentration and the application of a safety factor of 100, WHO recommended in the air quality guideline a limit value of 260 $\mu g/m^3$ styrene (WHO, 2000).

4.2.5 Diethyl phthalate

Diethyl phthalate toxicity has been recently reviewed by SCCPNFP (2002, 2003), since the compound is present in cosmetic products. Most available toxicity data are related to exposure via dermal and oral route. The general toxicity is low; the critical effect is irritation. No reproductive effects are shown in mice or rats nor any genotoxic potential. The only limit value related to inhalation exposure is the permissible limit of 5 mg/m^3 for occupational exposure proposed by ACGIH to protect workers.

4.2.6 Toluene

About 50% of inhaled toluene is absorbed in the respiratory tract. Toluene is sequentially oxidized to hippuric acid, the main urinary metabolite, frequently used as a biomarker of exposure to toluene.

The main effects due to toluene exposure are lacrimation and water discharge from eye and nose, mild nose irritation, and narcotic effects on CNS (headache, sleepiness, dizziness). The NOAEC 150 mg/m^3 (6h inhalation) and a LOAEC 280 - 380 mg/m^3 have been established for these effects (Andersen et al, 1983). It has been classified harmful through inhalation and irritating to skin.

Accidental or intentional (sniffing) exposure to very high concentrations has caused kidney damage and renal failure in humans. However, CNS is the main target of toxicity. Workers exposed to toluene for an average period of 5 - 7 years, have experienced subtle neurobehavioral deficits (manual dexterity, visual and verbal memory) at 332 mg/m^3 (LOAEC) to yield the LOAEC value 118 mg/m^3 when adjusted for continuous exposure (Foo et al, 1990). These values are only indicative, since the period of exposure of the available studies was not adequately documented and the neuropsychological effects are believed to be acute effects (EC, 2003b). However, on the basis of the available data, the EU classified toluene as able to cause damage to health by prolonged exposure through inhalation, such as impairment of auditory function and other CNS effects (EC, 2003b).

Toluene causes reduced sperm counts in rats and developmental neurotoxicity (impairment of learning ability in prenatal exposed offspring) at about ten-fold higher doses. An association with increased spontaneous abortion has been suggested at dose levels around 330 mg/m^3 (EC, 2003b). This concentration is considered the LOAEC for this effect.

There is no evidence that toluene was genotoxic. Carcinogenicity in man is not known.

On the basis of these data, WHO recommended in the air quality guideline a limit value for toluene of 260 μg/m^3 to prevent significant effects in the general population (WHO, 2000).

4.3. Evaluation of potential health risks for consumers

In the BEUC study the concentrations of some individual and "total" VOCs in indoor air were compared to international and national exposure guide values for the general public. The main conclusions of the report were that for most products tested the emitted total VOC values exceeded 200 μg/m^3, the proposed maximum limit value in indoor air in several countries and the emissions contained substances classified carcinogenic, such as benzene and formaldehyde, at rather high concentrations. The opinions on health implications, as stated in the BEUC report, of the observed VOC concentrations are strongly conclusive. The general message is that the reference values were exceeded to cause concern and further activity should be launched by the authorities. Recommendations were given on wider testing of the products, better definition of the exposure and evaluation of the interactions between the compounds.

SCHER was asked to evaluate whether the emissions from air fresheners observed in the BEUC study may be a health risk for consumers. SCHER notes that currently the data on exposure to emissions from air fresheners are yet too limited for an overall risk assessment on air fresheners. More data, on e.g. the use pattern of these products, are required to allow assessment of the actual exposure of the residents. However, since the BEUC report indicated the health risks associated to the exposure to emission products, SCHER evaluates the results of the study on the basis of current knowledge to indicate potential points for which further information may be required for a future evaluation on air fresheners.

The air concentrations reported by BEUC are compared with guidance values for ambient air which have been developed for such an exposure situation, assuming that if the air fresheners are regularly used, repeated exposure to emissions occur and the exposure may last even the whole day.. The only exception is formaldehyde, for which the value refers to an exposure of 30 minutes. The WHO values contain a safety margin for most of the general population, but very sensitive persons may perceive symptoms at these concentrations. Table 1 presents a summary on the concentrations of the substances measured in the BEUC study and the guidance values considered by SCHER. In the next paragraphs the health effects of the observed concentrations in the BEUC study are assessed.

The concentrations of "total VOCs" are highly variable (Table 1), in addition the health effects cannot be assessed specifically on the basis of these values as the effects depend on the concentrations of individual compounds. Therefore increased concentration of "total VOCs" may only be taken as an indication of increased emissions.

The health risks of limonene from air fresheners are difficult to assess. Altogether, there are only short term exposure data of inhaled limonene and the health consequences of the reaction products with oxidants (especially ozone) are not yet known. Limonene is a commonly used flavouring agent in food, this route of exposure accounting for >90% of limonene intake in humans. Acutely 4500 µg limonene/m^3 (i.e.10-fold higher than the limit value suggested for repeated exposure) may cause irritation (INDEX, 2005). The highest concentrations caused by the emissions from the air fresheners were 2000 µg/m^3, i.e. below acutely irritating concentrations.

No safe level may be established for benzene in indoor air. The highest concentration measured from incense burning (221 µg/m^3) would correspond to an excess lifetime risk of leukaemia of 1/1000 of the risk estimate of WHO (unit risk per 1 µg/m^3 6×10^{-6}, WHO 2000) providing such exposure was chronic. The emissions from other products remained within typical indoor air concentrations (Table 1). It has been recommended that no products emitting benzene should be used indoors to avoid unnecessary exposure (INDEX 2005).

The concentration of formaldehyde mainly remained below the odour threshold (30 µg/m^3) and was always lower than the concentration considered a limit value for irritative effects (100 µg/m^3, WHO 2000). The most sensitive persons may react to formaldehyde already around the indicated limit value (no safety margin). On the top of typical indoor air concentrations of formaldehyde (Table 1), the emissions from burning of incense (51 to 69 µg/m^3) may reach or even exceed the guidance value. The cancer risk of formaldehyde at non-cytotoxic concentrations is likely to be low.

The observed emissions of styrene and toluene remain below the limit values for adverse health effects, even when added on the top of the typical residential background. The maximum levels of styrene emitted exceed the odour threshold 70 µg/m^3 (WHO 2000).

The possible irritation effects on the respiratory system related to observed emissions of diethyl phthalate and "allergens" cannot be assessed due to lack of information for this endpoint.

Emissions from air fresheners contain many more compounds than those assessed by BEUC, and several of these may also give health effects. Furthermore, several of the primary emitted compounds may undergo reactions (e.g. with ozone, hydroxyl or nitrate radicals) to form new compounds with other effects. The real situation may be even more complicated as there may be combined effects between some of these substances, but the knowledge in this field is so far very limited.

Table 1. Comparison between air concentrations of "substances of interest" in the BEUC study and the guidance values used by SCHER

Compound	"Normal" indoor air concentration (µg/m³) from Index, 2005	Indoor air concentrations above background levels found in the BEUC study (µg/m³) from							Critical effect	Guidance value** (µg/m³)	Reference
		natural products (n = 3)	scented candles (n = 16)	incense (n = 4)	gel fresheners (n = 9)	liquid air fresheners (n = 10)	electric diffusers (n = 16)	sprays (n = 21)			
Benzene	2 - 13	nd(2)* – 3	3	19 – 221	nd(9)	4 – 8	nd(16)	nd(21)	Cancer	Safe level not established	WHO 2000
Form-aldehyde	8 - 41	nd(1) – 42	1 – 13	51 – 69	nd(9)	nd(9) - 6	2 - 13	nd(20) - 1	Sensory irritation	100 (30 min average)	WHO 2000
d-Limonene	14 - 30	nd(2) - 911	nd(1) – 31	nd(1) – 19	nd(3) - 735	nd(1) - 107	1 – 499	nd(4)-2003	Irritation	450	INDEX 2005
Styrene	1 - 6	nd(1) – 61	nd(4)– 112	1 – 78	nd(3) – 18	nd(2) – 98	nd(6) – 39	nd(9) - 185	CNS effects	260 (weekly average)	WHO 2000
Diethyl phthalate		nd(3)	nd(14) – 15	2 – 1251	nd(6) - 19	nd(7) - 67	nd(13) - 7	nd(8) - 571		Not established	
Toluene	20 - 87	nd(2) – 3	nd(8) – 15	nd(1) – 35	nd(2) – 18	nd(4) – 15	nd(7) – 14	nd(10) - 21	CNS effects and irritation	260 (weekly average)	WHO 2000
"Total VOCs"		78 – 1668	12 – 670	415 – 1725	76 – 1203	78 – 1956	55 – 3163	63 - 7228	Depends on the composition		

* nd(n) not detected in n samples

** A health based guidance value or recommendation for the concentration which should not be exceeded

5. ANSWERS TO QUESTIONS

5.1. Question A

Are the emissions from air fresheners observed in the study a health risk for consumers, including vulnerable groups such as children? Reference should be made to each of the parameters measured.

Current scientific knowledge on the use of air fresheners, emissions and resulting concentrations in indoor air is limited. In particular, the actual exposure of the residents in the long term (in quantitative terms) is as yet unknown. It depends on a number of factors (e.g. the product used, the frequency of use, residential characteristics, ventilation rate, time spent in the environment, etc.) and the exposure to emissions is highly variable and poorly predictable. Altogether, the data on air fresheners available to the SCHER are insufficient for an overall risk evaluation for consumers.

The BEUC study is the first one to measure emissions directly in indoor air from air fresheners but it is not yet known how representative the measured concentrations are for general use of the products. The study report also lacks some essential information (e.g. the ventilation rate in rooms) which limits the evaluation of the results. The air levels of the investigated compounds varied over wide ranges in the BEUC study, also for different products in the same category. The uncertainty in those results is unknown, as the quality of them is not well described, and the variability between different experiments with the same product is unknown. Overall, the BEUC study may be taken as an indication that under certain conditions notable concentrations of VOCs may result in indoor air from air fresheners.

Despite the limitations of the BEUC study, some observations may be made from the emissions in this specific case. Burning of incense produced abnormally high benzene concentrations in the indoor air. Because benzene is a human carcinogen, such benzene emissions need attention to diminish the exposure. For formaldehyde, styrene and toluene the highest values found in the BEUC study are below the WHO guidance values. d-Limonene concentrations obtained from natural products, gel fresheners and sprays exceed the upper value suggested for repeated exposure but not a limit based on the NOAEC found in the critical effect study (reflecting acute irritation). The concentrations of “total VOCs” caused by samples from all categories exceed the limit values adopted in several countries. However, this parameter is a poor predictor of health effects because “total VOCs” composition varies from case to case and individual compounds have to be considered. Limonene dominated “total VOCs” for several of the highest concentrations in the BEUC study.

The guidance values used in the SCHER evaluation cover to some extent the vulnerable groups but the most sensitive persons (e.g. people having asthma, children) may already react at these concentrations. Persons reacting exceptionally sensitively to chemicals have also reported symptoms from air fresheners (Caress and Steinemann 2004, 2005) among other chemical products (Caress and Steinemann, 2003). Persons with asthma have reported breathing difficulties from air fresheners and irritation from scented products (Caress and Steinemann, 2005). A report from the US EPA (2001) gives reference to several studies on links or associations between the use of incense and illnesses, including cancer (Preston-Martin et al, 1982), asthma (Dawod and Hussain,

1995) and contact dermatitis (Hayakawa et al., 1987, Roveri et al, 1998). However, the causality and the responsible possibly compounds so far remain uncertain. The evidence together suggests that some types of air fresheners may cause or aggravate symptoms in highly sensitive persons.

SCHER recalls that even higher concentrations than measured may be formed from air fresheners under different conditions (e.g. concomitant use of several air fresheners, smaller room volumes, less ventilation, addition to high background values from other sources). The substances studied by BEUC all have higher vapour densities than air, and concentrations close to the floor may therefore be higher than in the point of measurement. Also droplets from spray products may reach the floor before total evaporation, which may increase the concentrations there. These circumstances can give an elevated exposure to children playing on the floor, due also to a breathing rate which, calculated per unit bodyweight, is twice that of an adult over the first 12 years of life (Gerdes et al, 2004).

The emissions from the air fresheners contain many more compounds than those assessed by BEUC, and several of these may also give rise to health effects. Furthermore, several of the primary emitted compounds may undergo reactions (e.g. with ozone, hydroxyl or nitrate radicals) to form new compounds with other effects. The real situation may be even more complicated as there may be combined effects between some of those substances, but the knowledge in this field is so far very limited.

5.2 Question B

Can, in light of the information and data available to the Committee, the emissions observed in the study add up to other substances observed in indoor air pollution (such as from construction materials, carpets, furniture) in such a way that the total may be a health risk for consumers, including vulnerable groups?

In general, all indoor air contains some background pollution, the composition of which depends on the materials and activities (e.g. smoking) in the building. Because outdoor air also contributes significantly to the quality of indoor air, the “base line” from other sources is highly variable and strictly local. As shown in Table 1, the emissions of formaldehyde from incense could add to these from other sources to cause irritation in the most sensitive persons. The emission of benzene from incense can constitute the major source of benzene that will add to emissions from other sources, such as smoking. Some of the mentioned pollutants (e.g. limonene) cannot yet be similarly assessed.

5.3 Question C

Are further studies necessary to adequately assess the potential health risks from air fresheners? In the affirmative, please indicate which studies these should be.

Further quantification of emissions from and consumers use pattern of air fresheners is needed. Data on used volumes of air fresheners in different Member States would also be useful. New studies would need to identify compounds in the emissions, especially from the combustion/pyrolysis processes (candles and incense), including dioxins as the temperature seems to be in the optimal range for formation of these types of compounds. In addition fine and ultra fine particles should also be measured.

6. ABBREVIATIONS

ACGIH	American Conference of Governmental Industrial Hygienists
ALARA	As Low as Reasonable Achievable
BEUC	Bureau Européen des Unions de Consommateurs
CNS	Central Nervous System
IARC	International Agency for Research on Cancer
LC_{50}	Concentration that kill 50 % of the experiment animals
LOAEC	Lowest Observed Adverse Effect Concentration
ND	Not Detected
NOAEC	No Observed Adverse Effect Concentration
NOEC	No Observed Effect Concentration
SCCP	Scientific Committee on Consumer Products
SCCPNFP	Scientific Committee on Cosmetic Products and Non-Food Products intended for Consumer
SCHER	Scientific Committee on Health and Environmental Risks
TNO	Netherlands Organisation for Applied Scientific Research
US EPA	United States Environmental Protection Agency
VOCs	Volatile Organic Compounds

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