



POSITION PAPER

ANEC recommendations on emissions to the indoor air

In view of the Draft Commission decision on the safety requirements to be met by European standards for candles, candle supports, containers and accessories pursuant to Directive 2001/95/EC on general product safety

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ANEC would like to express strong concern regarding the chemical requirements included in the *"Draft Commission Decision on the safety requirements to be met by European standards for candles, candle supports, containers and accessories pursuant to Directive 2001/95/EC of the European Parliament and of the Council on general product safety"* from September 2015.

Too much leeway for industry

We believe the requirements need to be much more detailed and the leeway for CEN's Technical Committee on "Candle fire safety" (CEN TC 369) committee must be restricted ensure that the future normative requirements are adequate. This is all the more important as the mentioned committee consists – apart from some exceptions - almost exclusively of industry representatives. Apart from some NSO officers, one consultant and one test house all representatives attending the March 2015 meeting came from industry.

In view of the composition of the committee it may turn out to be wishful thinking to request that "an appropriate risk assessment shall be made regarding the chemical properties of the materials, substances or mixtures (including fragrances) used in the candles and in candle supports, containers and accessories to ensure that they do not adversely affect human health". Most likely the committee will find that there is no risk whatsoever. To quote the European Candle Association: "No reputable scientific study has ever shown any candle wax, including paraffin, to be harmful to human health"¹.

Hence, ANEC believes that strict and detailed requirements must be set which include at a minimum the following demands concerning chemical requirements:

CMR substances

As a matter of principle substances classified as CMR cat. 1A, 1B and 2 should not be used in consumer products where exposure cannot be excluded. Generally, ANEC considers that current generic bans of CMR substances included in some product regulations (e.g. in the Cosmetics Regulation, Regulation (EC) No 1223/2009) should be extended to cover also other consumer products.

It should be noted that the German RAL Quality Mark ("Gütezeichen") already includes a ban of candle colourants and lacquers which are carcinogenic, mutagenic and toxic for reproduction (all categories)². Furthermore, big retailers such as H&M have also fixed such requirements for candles³.

¹ http://www.eca-candles.com/index.php?newsid=106&sprach_id=en&&SID=6bdb9ocpi7rrgdn9fp4bp4aau7

² <http://guetezeichen-kerzen.de/de/guetezeichen/guete-und-pruefbestimmungen-ral-gz-041>

³ <http://sustainability.hm.com/content/dam/hm/about/documents/masterlanguage/CSR/Policies/HM%20Chemical%20Restrictions%202014.pdf>

ANEC suggests the following provisions for **CMR substances**:

Substances classified as carcinogenic, mutagenic or toxic for reproduction (CMR), category 1A, 1B and 2, pursuant to Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures shall not be used in candles.

Lead

Already in February 2003 the former "Scientific Committee on Toxicity, Ecotoxicity and the Environment" (CSTEE) warned in its opinion on "Potential health risks associated with the use of lead containing candle-wicks"⁴ that such use may result in high indoor air concentrations of lead which presents significant health risks, particularly for children, and pointed out: "Due to the lack of an identifiable threshold for lead induced neurophysiological effects, emission of lead from lead containing candle-wicks results in high lead exposure of sensitive groups of the population and represents a health hazard".

Furthermore, the EFSA Panel on Contaminants in the Food Chain (CONTAM) published a "Scientific Opinion on Lead in Food" in March 2010⁵ which stated that the actual lead exposure of children (the most sensitive population) from food only was in many cases considerably above the BMDL₀₁ of 0,5 µg/kg bw/day which corresponds to a decline of the IQ by 1 point (the IQ is the critical endpoint for neurodevelopmental effects) and " that the possibility of an effect from lead in some consumers, particularly in children from 1-7 years of age, cannot be excluded". Hence, the EFSA CONTAM Panel recommended that "work should continue to reduce exposure to lead, from both dietary and non-dietary sources".

In line with a recent opinion published by the German BfR entitled "Blei, Nickel und allergene Duftstoffe in Kerzen sollten begrenzt werden" from November 2013⁶ we call for a complete ban of the use of lead in candles. Given that no threshold can be determined for the neurophysiological effects of lead the limits must be based on the ALARA principle and include all components of the candle (the wick as well as the wax).

The report "Chemical ingredients in candles sold in Danish retail" published by the Danish Environmental Protection Agency in March 2002⁷ includes among other some data concerning the lead content of candle wax and wicks. The lead content of the wax was in the range 0.034 µg/g – 0.11 µg/g, the lead content of the wick in the range <0.2 µg/g - 2.3 µg/g. From this follows that a limit of 0.4 mg/kg as indicated in the latest version of the draft safety requirements may be acceptable for the

⁴ http://ec.europa.eu/health/archive/ph_risk/committees/sct/documents/out176_en.pdf

⁵ <http://www.efsa.europa.eu/de/efsajournal/pub/1570>

⁶ www.bfr.bund.de/cm/343/blei-nickel-und-allergene-duftstoffe-in-kerzen-sollten-begrenzt-werden.pdf

⁷ eng.mst.dk/media/mst/67475/lys_uk.pdf

wick, but for the wax (which will normally be the main contributor to the emissions) the maximum should be 0.1 mg/kg.

According to our calculations this would result in an (acceptable) exposure corresponding to less than 3% of the BMDL₀₁ value indicated above for a child assuming (similar to BfR) that 10 g of a candle are burnt in 1 hour (1 µg lead) in a room of 20 m³ without ventilation (0.05 µg/m³), a respiratory volume of 7,3 m³/day for children aged 2-3 years, an exposure time of 12 hours (0,1825 µg/child), a body mass of the child of 13,5 kg (0,0135 µg/kg child). In ANEC's view the lead exposure from candles must be only a small fraction of the (acceptable) exposure from all sources.

NOTE: Using the emission scenario proposed below (4 candles burning 4 hours 4 times per week, air exchange rate: 0,5 h⁻¹) would result in a time weighted average lead concentration of 0,04 µg/m³ for a room of 20 m³ and, respectively, of 0,03 µg/m³ for a room of 30 m³ (compared to 0.05 µg/m³ in the scenario above).

ANEC suggests the following limits for **lead**:

The limit value of lead shall not exceed 0.1 mg/kg in the wax and 0.5 mg/kg in the wick.

Nickel

Nickel compounds have been classified by IARC as carcinogens (Group 1, Carcinogenic to humans). Also the CLP Regulation has classified many nickel compounds as Carc. 1A. In addition, many nickel compounds are classified as Muta. 2. Hence, no safe threshold can be identified when nickel is inhaled. In view of the possible genotoxic effects the EU Risk Assessment Reports (RARs) conducted by the Danish EPA⁸ concerning nickel carbonate, nickel chloride, nickel nitrate and nickel sulphate used a non-threshold approach for the characterisation of carcinogenicity. Similarly, the WHO Air Quality Guidelines for Europe⁹ published in 2000 assume the absence of a threshold: "Nickel compounds are human carcinogens by inhalation exposure. The present data are derived from studies in occupationally exposed human populations. Assuming a linear dose-response, no safe level for nickel compounds can be recommended".

Again we believe that the ALARA principle should be applied. The above mentioned report "Chemical ingredients in candles sold in Danish retail" gives some values for the nickel content of candle wax and wicks. The nickel content of the wax was in the range 0.16 µg/g – 0.28 µg/g, the nickel content of the wick was always <0.3 µg/g.

This would suggest nickel limits for the wax which are somewhat higher than the limits for lead suggested above (around 0.3 mg/kg). However, such values would

⁸ <http://eng.mst.dk/topics/chemicals/nickel/>

⁹ <http://www.euro.who.int/en/health-topics/environment-and-health/air-quality/publications/pre2009/air-quality-guidelines-for-europe>

be in stark contradiction to the nickel limit proposed by BfR based on an indoor air concentration corresponding to an additional cancer risk of 1×10^{-6} in accordance with the WHO guidance referred to above, i.e. $0.6 \mu\text{g}/\text{kg}$ candle. There is a factor of around 500 missing!

ANEC believes that some more research must be carried out to identify best practices in candle manufacturing. A limit of $0.5 \text{ mg}/\text{kg}$ as indicated in the latest version of the draft safety requirements is clearly too high and therefore not acceptable.

ANEC suggests the following limits for **nickel**:

The limit value of nickel shall correspond to the lowest achievable limits in line with best manufacturing practices and shall be as close as possible to $0.6 \mu\text{g}/\text{kg}$ candle. However, any limit which may result in an additional cancer risk of more than 1×10^{-6} in line with the calculation above should only be accepted for an interim period of time.

Sulphur

Paraffin may be contaminated with sulphur as a result of inadequate cleaning processes. This results in the release of SO_2 during burning. For example, the German Test Magazine "Ökotest" found elevated sulphur levels in candles from various manufacturers¹⁰. A limit for the sulphur content of paraffin should be included. The RAL Quality mark mentioned above includes a limit of $20 \text{ mg}/\text{kg}$. However, ANEC believes this limit is too high. Assuming that 10 g of a candle is burnt this may release $200 \mu\text{g}$ of SO_2 . Assuming an unventilated room of a size of 20 m^2 this results in a concentration of $10 \mu\text{g}/\text{m}^3$. The relevant WHO $20 \mu\text{g}/\text{m}^3$ 24-hour mean. As pointed out below only a tenth of the value should be allocated to candles, i.e. $2 \mu\text{g}/\text{m}^3$. From this follows that a Sulphur content of $4 \text{ mg}/\text{kg}$ may be more appropriate.

ANEC suggests the following limits for **sulphur**:

The content of sulphur in paraffin wax shall not exceed $4 \text{ mg}/\text{kg}$

Fragrances

The use of fragrances becomes more and more widespread which raises considerable concern among health institutions. As the German Environmental Protection Agency (UBA) puts it: "This omnipresence of fragrances can be problematic, especially in sensitised individuals"¹¹. Hence, the Agency recommends

¹⁰ <http://www.oekotest.de/cgi/index.cgi?artnr=101083&bernr=01&seite=01&suche=Kerzen>

¹¹ <http://www.umweltbundesamt.de/en/topics/health/environmental-impact-on-people/chemical-substances/fragrances>

"exercising caution with scented oil lamps, incense sticks, and the like. The same goes for so-called wellness and aromatherapy products meant to be inhaled".

Although there is some evidence that fragrances do not normally trigger allergic symptoms following inhalation (though there are exceptions and data are rather limited), other health effects may occur. In its opinion on "Fragrance allergens in cosmetic products" the "Scientific Committee on Consumer Safety" (SCCS) stated: "The Fragrances are volatile and therefore, in addition to skin exposure, a perfume also exposes the eyes and naso-respiratory tract. It is estimated that 2–4 % of the adult population is affected by respiratory or eye symptoms by such an exposure". This includes exacerbation of pre-existing asthma or provocation of asthma-like symptoms.

It is acknowledged that the (avoidance of) symptoms described above are difficult to handle in legislative or normative provisions. The more so as in some cases not the fragrances themselves but their reaction products (e.g. oxidation products) may act as irritants.

However, consumers must at least be able to identify fragrances which may adversely affect their health in order to be able to avoid such products. In fact, we are talking about millions of people affected in the EU. The Cosmetics Regulation as well as the Toy Safety Directive (2009/48/EC) include labelling requirements for allergenic fragrances (in addition to substance bans) which may trigger contact allergy. In case of cosmetics the thresholds are 0.001% (=10 ppm) for leave-on products and 0.01% (=100 ppm) for rinse-off products. The latter limit is used also in the Toy Safety Directive.

Bearing in mind on the one hand that these substances are contact allergens which are of limited relevance for the product group in question and, on the other hand, that fragrances or their reaction products can trigger quite a variety of different symptoms it seems more appropriate to require the indication of a complete list of fragrances exceeding a certain threshold. Bearing in mind that the concentrations of fragrances in the scented candle can be rather low a threshold of 10 ppm is suggested.

It would be desirable to establish a positive list of fragrances which are allowed to be used in candles (and other products emitting such volatile compounds to the indoor air. This can, of course, only be done involving an independent scientific committee (SCHER or SCCS). We call upon the Commission to initiate such a process.

On this occasion ANEC repeats its call for a comprehensive regulatory approach to cover systematically all the products which may emit substances to the indoor air such as construction products, furniture, indoor textiles (floor coverings, carpets, curtains, etc.), paints, cleaning agents, personal care products and air fresheners (whether combustible or not) rather than addressing this subject in a fragmented patchwork approach.

ANEC suggests the following limits for **fragrances**:

All fragrances exceeding a concentration of 10 ppm shall be indicated on the package or on an accompanying leaflet available at the point of sales

Other emissions – general remarks

The provisions of clause 2.6 Emissions of the draft safety requirements are entirely inadequate. First, because the phrase "For indoor candles hazardous substances, including volatile organic compounds (VOCs), created during the burning process shall be minimised as far as possible" is non-saying and leaves industry a large room for interpretation. The more so as industry is also allowed to determine which limits of the WHO Guidelines for indoor air quality are "relevant for candles". By contrast, ANEC believes that the clause must be considerably strengthened to prevent that we end up with (almost) no chemical requirements in the standard to be prepared.

It is insufficient just to refer to "WHO guidelines for indoor air quality: selected pollutants", World Health Organization, 2010". First, because these guidelines address only a very limited number of pollutants, i.e. benzene, carbon monoxide, formaldehyde, naphthalene, nitrogen dioxide, polycyclic aromatic hydrocarbons (especially benzo[a]pyrene), radon, trichloroethylene and tetrachloroethylene. They do, for instance, not address particulate matter. However, in the introduction of the quoted guidelines it is clarified that "the air quality guidelines for particulate matter recommended by the 2005 global update¹² are also applicable to indoor spaces and a new review of the evidence is not necessary at present". Furthermore, the WHO working group which developed the indoor air quality guidelines "acknowledged the applicability of the existing WHO guidelines for air quality¹³ to indoor air and identified a number of chemical substances for which specific indoor air guidelines should be recommended". Thus not only the mentioned WHO guidelines for indoor air quality must be mentioned but also the "Air quality guidelines for Europe; second edition" published in 2000 and the "Air quality guidelines. Global update 2005. Particulate matter, ozone, nitrogen dioxide and sulphur dioxide".

Further, ANEC proposes to consider existing regulatory schemes like the German AgBB scheme addressing emissions from construction products, as well as relevant French and Belgian laws as well as ongoing efforts to harmonise existing schemes, i.e. the EU-LCI Working Group¹⁴. In addition, we encourage the use of other sources such as published test results or various EU funded projects on indoor air emissions (such as the EPHECT project).

ANEC suggests to take into account the following **air quality limits**:

¹² www.euro.who.int/_data/assets/pdf_file/0005/78638/E90038.pdf

¹³ www.euro.who.int/document/e71922.pdf

¹⁴ http://www.eu-lci.org/EU-LCI_Website/Home.html

The recommended limits laid down in the following WHO air quality guidelines shall be taken into account:

- "WHO Air quality guidelines for Europe, second edition, 2000"
- "WHO Air quality guidelines. Global update 2005. Particulate matter, ozone, nitrogen dioxide and sulphur dioxide"
- "WHO Guidelines for indoor air quality: selected pollutants" shall be taken into account as regards the concentration levels for VOCs and particulate matter.

In addition, limits in relevant national regulations and schemes addressing emissions to the indoor air (such as the German AgBB scheme or the relevant French and Belgian legislation) shall be taken into account.

Relevant research projects (such as the EPHECT project) or test results shall also be considered.

It should be noted that WHO air quality guidelines for carcinogens do not indicate a single value. As an example, the concentrations of airborne benzene are indicated which are associated with an excess lifetime risk of 1/10 000, 1/100 000 and 1/1000 000. Hence, it must be stated that the concentrations associated with an excess lifetime risk of 1/1000 000 must be used.

ANEC suggests with respect to **non-threshold compounds**:

Where different concentrations for different cancer risks are indicated the concentration corresponding to an excess lifetime risk of 1×10^{-6} must be used.

In view of the fact that multiple sources may contribute to indoor pollution the emissions of candles must not exceed 10% of the relevant air quality threshold.

It is important to make clear that any air quality limits established by WHO or others are to be complied with taking into account all sources of indoor air pollution including outdoor sources. Hence, only a fraction of the allowed emissions can be allocated to candles. The suggested approach is similar to the one applied in other areas, e.g. to toys where only 5% or 10% of the relevant limit is allocated to exposure from toys. We suggest that this portion is set to 10% (in line with the BfR calculation for a nickel limit).

ANEC suggests the following **allocation of air quality limits to candles**:

In view of the fact that multiple sources may contribute to indoor pollution the emissions of candles must not exceed 10% of the relevant air quality threshold.

An appropriate emission scenario must be defined. ANEC cannot support the use scenario given in clause 4.1.2.1 of FprEN 16739 "Emission safety of combustible air fresheners - Methodology for the assessment of test results and application of recommended emission limits" for scented candles, i.e. 1 combustible air freshener

used 4 days per week, 4 h per day. First, the scenario assumes the use of just 1 product at a time. However, the EPHECT study (WP7, Survey on indoor use and use patterns of consumer products in the EU member states) pointed out that 39% had two or more candles burning at the same time. An even higher percentage was determined for users in Denmark (68%). 7% of the Danish survey participants indicated to use more than 6 candles simultaneously! Second, the above mentioned survey included only combustible air fresheners rather than all candles. From this follows that the scenario must include at least 4 candles.

Further, we strongly disagree with the provision in the standard that the "default" scenario may be replaced by another one based on "reliable specific data". One defined scenario must be used.

A time weighted average concentration can be calculated using a room size of 30 m³ and an air exchange rate of 0,5 h⁻¹. However, for formaldehyde the WHO has defined a short-term (30-minute) threshold. In this case, the emission scenario must use the short term peak concentration.

ANEC suggests the following **emission scenario**:

The following emission scenario shall be used:

Number of candles: 4 at a time

Frequency of use: 4 days per week

Exposure time: 4 h per day

Room size: 30 m³

Air exchange rate: 0,5 h⁻¹

Where limits are expressed as short-term thresholds the emission scenario must use the short term peak concentration.

Other emissions – particles

Candles are a major contributor to residential particle exposure. A Danish study published in 2013 (Bekö et al., Ultrafine Particles: Exposure and Source Apportionment in 56 Danish Homes)¹⁵ found that "candle burning occurred in half of the homes where, on average, it was responsible for almost 60% of the integrated exposure". Attention was drawn to the fact that "extensive candle burning (on average ~140 min per day) occurred in 50% of the homes" and that "several hours of candle burning nearly every day during the winter months are not unusual in Scandinavia".

¹⁵ <http://pubs.acs.org/doi/abs/10.1021/es402429h>

Several studies are available which have identified candles as sources of ultrafine (or nano) particles. For instance, Pagels et al. (Chemical composition and mass emission factors of candle smoke particles)¹⁶ measured up to 2.400 µg PM_{2.5} per hour during steady burn (mainly inorganic compounds), and up to 25.000 µg PM_{2.5} per hour under sooting conditions (mainly elemental carbon). Assuming a single candle burning (10 g) just for 1 hour in an unventilated room of 20 m³ we end up with a concentration of 120 µg/m³. This exceeds the WHO 24-hour mean threshold for PM_{2.5} of 25 µg/m³ by a factor of almost 5! As stated above, only a tenth of this value is acceptable from a consumer protection perspective (i.e. the threshold would be exceeded by a factor of 50). This is a clear indication that a limit for particulate matter is needed. A soot index limit is by no means a replacement for a PM_{2.5} threshold (the soot number does not correlate with the particle emission factors).

ANEC suggests the following **limit for PM_{2.5}**:

The calculated indoor concentration of PM_{2.5} using the standard emission parameters shall not exceed a tenth of the WHO 24-hour mean threshold for PM_{2.5}, i.e. 2.5 µg/m³

Other emissions – VOCs

According to the literature review conducted in the EPHECT project funded by the Commission (WP4, September 2010 (rev. March 2012))¹⁷ a number of substances were identified in candle emissions. The most relevant ones are summarised below.

Benzene concentrations resulting from candle emissions were are quoted in the SCHER "Opinion on the report "Emission of chemicals by air fresheners Tests on 74 consumer products sold in Europe" (BEUC report January 2005)", January 2006¹⁸). One study found up to 30 µg/m³, another one up to 3.9 µg/m³. The relevant WHO threshold associated with an excess lifetime risk of 1/1 000 000 is 170 ng/m³, a tenth of this value is 17 ng/m³. This limit would be exceeded by the max. values mentioned above by factors of 1765 and, respectively, 229. Hence, it appears reasonable to require that a limit for Benzene shall be included.

Formaldehyde concentrations of more than 300 µg/m³ for scented candles were also reported in the above mentioned SCHER document. Another study (Maupetit et al., Caractérisation des émissions de benzène et de formaldéhyde lors de la combustion d'encens et de bougies d'intérieur: élaboration de scénarios d'exposition et conseils

¹⁶

http://www.researchgate.net/publication/223827610_Chemical_composition_and_mass_emission_factors_of_candle_smoke_particles

¹⁷ <https://sites.vito.be/sites/ephect/Pages/home.aspx>

¹⁸ http://ec.europa.eu/health/archive/ph_risk/committees/04_scher/docs/scher_o_026.pdf

d'utilisation¹⁹) measured up to 50 µg/m³. The relevant WHO short-term (30-minute) threshold preventing sensory irritation in the general population is 0.1 mg/m³, a tenth of this value is 10 µg/m³. This limit would be exceeded by factors of 30 and, respectively, 5 by the concentrations mentioned above. Hence, it appears reasonable to require that a limit for Formaldehyde shall be included.

Further, it should be noted that this limit relates to short term exposure. Hence, the standard emission scenario (averaging an exposure of 4 days and 4 hours (the time weighted average (TWA)) does not fit. The short term peak concentration (STPC) must be used instead.

Styrene concentrations of up to 70 µg/m³ and, respectively, up to 112 µg/m³ were measured in studies quoted in the SCHER opinion. The relevant WHO threshold is 260 µg/m³ (weekly average), a tenth of this value is 26 µg/m³. This limit would be exceeded by factors of 2.6 and, respectively, 4.3 by the concentrations mentioned above. Hence, it appears reasonable to require that a limit for Styrene shall be included.

Benzo(a)pyrene concentrations of up to 7.5 ng/m³ were reported (Orechi, Polycyclic aromatic hydrocarbons (PAHs) in indoor emission from decorative candles²⁰). The relevant WHO threshold associated with an excess lifetime risk of 1/1 000 000 is 0.012 ng/m³, a tenth of this value is 0.0012 ng/m³. This limit would be exceeded by the max. value mentioned above by a factor of 6250. Hence, it appears reasonable to require that a limit for Benzo(a)pyrene (and possibly other PAHs shall be included.

ANEC suggests the following **minimum list of emissions to be restricted**: PM2.5, Benzene, Formaldehyde, Styrene, Benzo(a)pyrene (and possibly other PAHs).

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¹⁹ http://www.jle.com/fr/revues/ers/e-docs/caracterisation_des_emissions_de_benzene_et_de_formaldehyde_lors_de_la_combustion_dence_ns_et_de_bougies_dinterieur_elaborat_280754/article.phtml

²⁰ <http://www.sciencedirect.com/science/article/pii/S1352231010010502>

About ANEC

ANEC is the European consumer voice in standardisation, defending consumer interests in the processes of technical standardisation and conformity assessment, as well as related legislation and public policies.

ANEC was established in 1995 as an international non-profit association under Belgian law and is open to the representation of national consumer organisations in 33 countries.

ANEC is funded by the European Union and EFTA, with national consumer organisations contributing in kind. Its Secretariat is based in Brussels.



Raising standards for consumers

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