Raising standards for consumers

POSITION PAPER

Formaldehyde - Proposed requirements for Appendix C of the Toy Safety Directive UPDATED

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Contact Person: Tania Vandenberghe, Senior Programme Manager
(tania.vandenberghe@anec.eu)

Summary

The present paper is an update of the ANEC position paper issued in March 2016 (ANEC-CHILD-2016-G-025). It discusses possible limits for formaldehyde for toys intended for use by children under 36 months or in other toys intended to be placed in the mouth, taking into account food contact material legislation to be inserted in Appendix C (Article 46 of the Toy Safety Directive). In this updated version recommendations for leather components of toys have been included and some text corrections have been made.

It recommends to adopt:

- for **textile components** of toys, a limit of 30 mg/kg when tested in accordance with EN ISO 14184-1 in line with the current requirement included in EN 71-9 unless a REACH restriction is adopted with a similar level (currently subject of discussion);
- for **paper components** of toys, a limit of 30 mg/kg when tested in accordance with EN 645 and EN 1541 in line with the current requirement included in EN 71-9;
- for **leather components** of toys, a limit of 30 mg/kg when tested in accordance with EN ISO 17226-1;
- for formaldehyde as a **preservative** an exclusion based on a LOQ;
- for formaldehyde used as a **monomer** a limit of 1,5 mg/l (expressed as amount of substance per litre of simulant in in the aqueous migrate prepared in accordance with EN 71-10);
- for formaldehyde emissions from **resin-bonded wood components** of toys the requirement to use wood based panels complying with requirements equivalent to the E1 classification of wood-based panels as defined in the relevant European standards.

1. Formaldehyde limits and test methods relating to toys

1.1. Formaldehyde in REACH

At present formaldehyde included in articles for consumers is not restricted in REACH. However, formaldehyde in textiles (including toys) could be restricted in REACH among other CMR cat. 1A and 1B substances based on its Article 68(2) in future. A consultation regarding this issue has been launched by the Commission in October 2015. The suggested limit is 50 mg/kg.

1.2. Formaldehyde limit in the TSD

Formaldehyde (CAS No 50-00-0) has a harmonised classification according to the CLP Regulation. Formaldehyde is classified Carc. 1B, Muta. 2, Acute Tox. 3, Skin Corr. 1B, Skin Sens. 1.

From this follows that the formaldehyde limit in (accessible parts of) toys is 0,1% (= 1000 mg/kg) based on the generic exclusion of CMR substances and applicable thresholds. However, it should be noted that formaldehyde is a gas which is typically released from formaldehyde containing compounds (e.g. resins, polymers, textile or paper products) over time.

1.3. Formaldehyde limits in standards for toys and related test methods

EN 71-9:2005+A1:2007 (organic chemical compounds) contains the following requirements for formaldehyde in clause 4.3:

Accessible **textile components** of toys intended for children under 3 years of age shall not contain free and hydrolysed formaldehyde in excess of 30 mg/kg when tested in accordance with EN ISO 14184-1.

Accessible **paper components** of toys intended for children under 3 years of age shall not contain formaldehyde in excess of 30 mg/kg when tested in accordance with EN 645 and EN 1541.

Accessible **resin-bonded wood components** of toys intended for children under 3 years of age shall not release formaldehyde in excess of 80 mg/kg when tested in accordance with EN 717-3.

In addition, Table 2 D of EN 71-9 addressing **monomers** (migration) gives a limit of 2,5 mg/l formaldehyde (amount of substance per litre of simulant when tested in accordance with EN 71-11).

Finally, Table 2 H of EN 71-9 addressing **preservatives** (other than wood preservatives) gives a limit of 0,05 % for free formaldehyde.

EN 71-7:2014 (finger paints) allows paraformaldehyde as a **preservative** with a limit of 0,1 % for free formaldehyde.

2. Formaldehyde limits and related test methods addressing skin sensitisation

2.1. Regulatory limits for formaldehyde in textiles

Legal requirements in various countries for formaldehyde in textiles from internet sources[1]:

China	Textiles for infants and babies ≤ 20ppm Textiles in direct skin contact ≤ 75ppm Textiles not in direct skin contact ≤ 300ppm
Finland and Norway	Textiles for babies under 2 years: 30ppm Textiles in direct skin contact :100ppm Textiles not in direct skin contact: 300ppm
Austria, Germany	Textiles that normally come into contact with the skin and release more than 1500ppm formaldehyde must bear the label "Contains formaldehyde. Washing this garment is recommended prior to first time use in order to avoid irritation of the skin."
Japan	Textiles for infants: not detectable (20ppm) Textiles in direct skin contact: 75ppm
Netherlands	Textiles in direct skin contact must be labelled "Wash before first use" if they contain more than 120ppm formaldehyde and the product must not contain more than 120ppm after wash.

2.2. Formaldehyde limits in the Oeko-Tex® Standard 100 and test methods

The Oeko-Tex® Standard 100 (2016) specifies limits for formaldehyde in textile and leather products as shown in the table below:

[1] http://www.productsafety.gov.au/content/index.phtml/itemId/975834
http://www.keepeek.com/Digital-Asset-Management/oecd/trade/environmental-requirements-and-market-access/limits-on-formaldehyde-in-textiles_9789264013742-5-en#page1
http://ec.europa.eu/DocsRoom/documents/10481/attachments/1/translations/en/renditions/native

Substance	**I** **Baby, mg/kg**	**II** **in direct contact with skin, mg/kg**	**III** **with no direct contact with skin, mg/kg**	**IV** **Decoration material, mg/kg**
Formaldehyde	n.d.(x)	75	300	300
(x) n.d. corresponds according to "Japanese Law 112" test method with an absorbance unit less than 0.05 resp. <16 mg/kg				

2.3. Formaldehyde limits in EU ecolabel criteria and test methods

The EU Ecolabel criteria for **textile products (Commission Decision 2014/350/EU), textile floor coverings (Commission Decision 2009/967/EC) and footwear (Commission Decision (EU) 2016/1349)** include provisions for the free and hydrolysed formaldehyde content as below:

Substance	**Textile prod.** **Baby up to 3 years, mg/kg**	**Textile prod.** **Direct skin contact, mg/kg**	**Textile prod.** **Garments with limited skin contact, interior textiles**	**Textile floor coverings**	**Footwear**
Formaldehyde	16 ppm	16 ppm	75 ppm	30 ppm (or chamber test 0,01mg/m^3)	textile: < 20 mg/kg leather: < 20 mg/kg (children's footwear); 75 mg/kg (linings and socks); 100 mg/kg for other parts of the product.

For textiles, EN ISO 14184-1 "Textiles - Determination of formaldehyde - Part 1: Free and hydrolysed formaldehyde (water extraction method)" is used as a test method with a detection limit of 16 mg/kg (16 ppm). For leather, EN ISO 17226-1 "Leather - Chemical determination of formaldehyde content - Part 1: Method using high performance liquid chromatography" is the relevant test method.

2.4. Formaldehyde limits in the Cosmetics Regulation

The Cosmetics Regulation (Regulation (EC) No 1223/2009) provides that all finished products containing formaldehyde or substances in Annex V (allowed preservatives) which release formaldehyde must be labelled with the warning 'contains formaldehyde' where the concentration of formaldehyde in the finished product exceeds 0,05 %. Limits for free formaldehyde in oral products (0,1%) and other products (0,2%) are also stipulated.

A special limit for nail hardeners applies (5%). This was reviewed by SCCS in view of the reclassification of formaldehyde in October 2014. SCCS considered the further use of formaldehyde containing nail hardeners adequate although the "worst case" estimates (taking into account exposure from other sources) may shortly exceed the WHO (indoor air) guideline value by almost a factor of 2, as formaldehyde levels in ambient air were shown to decrease rapidly to background levels after nail hardener application. SCCS expressed concerns about the sensitisation potential of nail hardeners containing formaldehyde (referring to the OECD publication mentioned below) but considered that the risk can be minimised if the products are used properly (i.e. the skin is not exposed to formaldehyde).

NOTE: It is unclear why only formaldehyde in nail hardeners was re-assessed by SCCS but not the use as preservative given that substances classified CMR 1A and 1B are in principle banned. Exceptions are possible but are subject to conditions and must be adopted within 15 months of the classification as CMR 1A or 1B substance.

2.5. Thresholds for formaldehyde addressing skin sensitisation

An OECD report from 2002[2] reports that: "*The thresholds for elicitation of allergic contact dermatitis in sensitised subjects range from 30 ppm (w/w), aqueous solution, for patch testing to 60 ppm (w/w) for products containing formaldehyde. A threshold for induction has not been clearly established, but it is estimated to be less than 5 % aqueous solution (ACGIH, 1991)*".

NOTE: ACGIH is the American Conference of Governmental Industrial Hygienists

In a review "Formaldehyde-releasers: relationship to formaldehyde contact allergy. Contact allergy to formaldehyde and inventory of formaldehyde-releasers" conducted by de Groot et al.[3] in 2009 the following concluding statement was

[2] http://www.chem.unep.ch/irptc/sids/OECDSIDS/FORMALDEHYDE.pdf
[3] http://onlinelibrary.wiley.com/doi/10.1111/j.1600-0536.2009.01582.x/epdf

made: "*Levels of 200–300 p.p.m. free formaldehyde in cosmetic products have been shown to induce dermatitis from short-term use on normal skin. It may be assumed that thresholds of elicitation are lower when these or other topical products are used on more sensitive skin (e.g. the axillae), for longer periods of time or on diseased skin. This demonstrates beyond doubt that EU legislation, stipulating that all finished products containing >500 p.p.m. free formaldehyde must be labelled with the warning 'contains formaldehyde', is not strict enough and the concentration required for the labelling should be lowered*".

The review also mentions some studies where very low levels of formaldehyde could elicit reactions. In their classical study Jordan et al. "Threshold responses in formaldehyde-sensitive subjects" (1979) exposed formaldehyde-sensitive subjects to pump-sprayed formaldehyde (30 ppm) into one axilla twice a day for 2 weeks. The vehicle served as a control in the other axilla. Two of the patients developed very mild perifollicular dermatitis to the formaldehyde site but not the control site. Their responses to 30 ppm aqueous formaldehyde indicate that levels below this concentration should be tolerated by sensitive subjects if repeatedly applied to normal skin.

This supports the suspicion that elicitation in sensitised people may occur at levels comparable to the lowest results found in patch testing.

2.6. Conclusions regarding limits for toys addressing skin sensitisation

Formaldehyde limits in limits for textiles or paper products in regulatory or voluntary instruments including EN 71-9 are based on reported thresholds for sensitisation presumably protecting most sensitised individuals. **Hence, the provisions of EN 71-9 concerning formaldehyde in paper and textile products seem suitable for inclusion in Appendix C**.

By contrast, the limit of 0,05% (=500 ppm) for free formaldehyde as a preservative in EN 71-9 (in line with the labelling provisions of the Cosmetics Regulation) seems too high compared to the identified thresholds for induction and even more to elicitation of allergic skin reactions. **It appears that an exclusion of formaldehyde as a preservative based on an appropriate LOQ (about 10 mg/kg) is the preferred option**.

Finally, the 0,05% limit in EN 71-9 mentioned in the previous paragraph covers also leather products. This is questionable as the limit is too high and inconsistent with the provision for textile and paper products. Apart from that it is rather strange to consider formaldehyde as a preservative in leather (in fact, it is a tanning agent). **Therefore, it is advisable to establish a requirement for leather products in line with the provisions of EN 71-9 concerning formaldehyde in paper and textile products (i.e. a limit of 30 mg/kg) using the relevant standard for testing (EN ISO 17226-1).**

3. Formaldehyde limits and test methods addressing oral exposure

3.1. Formaldehyde limit in Food Contact Materials Regulation

According to Table 1 of Annex 1 of the Regulation on plastic materials and articles intended to come into contact with food (Commission Regulation (EU) No 10/2011) formaldehyde is covered by a group restriction and an SML(T) of 15 mg/kg is defined (i.e. 15 mg is allowed to migrate into 1 kg food or food simulant).

This SML corresponds to the maximum allowed intake of a person of a mass of 60 kg (i.e. 0,25 mg/kg body weight per day). The acceptable amount for a child (= 10% of TDI) of 10 kg per day is given by 15*10/60*10 = 0,25 mg per child and day. The limit is identical with the limit given in EN 71-9 (2,5 mg/l = 0,25 mg/100 ml) corresponding to the amount that may migrate from a surface of 10 cm^2 into 100 ml water when subject to extraction in accordance with 6.4 of EN 71-10.

3.2. Thresholds for formaldehyde addressing oral exposure

It is not known on which basis the SML(T) of 15 mg/kg mentioned above was derived. Division by 60 gives a theoretical TDI of 0,25 mg/kg bw per day. This value does not seem to be appropriate.

The WHO Guidelines for Drinking-water Quality, 4th edition, 2011[4] (based on the background document "Formaldehyde in Drinking-water", 2005[5]) consider a NOEL of 260 mg/l appropriate (concentration of water in a 2-year study in rats). It corresponds to 15 mg/kg of body weight per day. Applying a safety factor of 100 results in a TDI of 0,15 mg/kg bw per day.

This NOAEL was also supported by the Opinion of the Scientific Panel on food additives, flavourings, processing aids and materials in contact with food (AFC) related to "Use of formaldehyde as a preservative during the manufacture and preparation of food additives"[6], 2006.

3.3. Conclusions regarding limits for toys addressing oral exposure

The limit for formaldehyde as a monomer included in EN 71-9 (2,5 mg/l) should be lowered in line with the NOEL accepted by WHO. **It is suggested to include a limit of 1,5 mg/l (expressed as amount of substance per litre of simulant in in the aqueous migrate prepared in accordance with EN 71-10) for formaldehyde used as a monomer.**

[4] http://www.who.int/water_sanitation_health/dwq/guidelines/en/
[5] www.who.int/water_sanitation_health/dwq/chemicals/formaldehyde130605.pdf
[6] http://www.efsa.europa.eu/en/efsajournal/pub/415

4. Formaldehyde limits and test methods addressing inhalation

4.1. Formaldehyde limits for classification wood based panels and test methods

The harmonised standard EN 13986:2004+A1:2015 "Wood-based panels for use in construction - Characteristics, evaluation of conformity and marking" defines wood-based panels for use in construction and specifies the relevant characteristics and the appropriate test methods to determine these characteristics for wood-based panels, unfaced, overlaid, veneered or coated. The standard is the basis for establishing performance declarations and CE marking. It specifies formaldehyde classes E1 and E2 reflecting national legal requirements in Annex B.

Requirements for formaldehyde class E1:

- initial type testing for all boards based on EN 717-1 (chamber method, measured at steady state conditions): release ≤ 0,124 mg/m^3 air (=0,1 ppm)
- factory production control based on EN 120 (perforator, for unfaced particleboard, OSB, MDF) or EN 717-2 (gas analysis, for unfaced plywood, solid wood panels, LVL and coated, overlaid or veneered particleboard, OSB, MDF, plywood, solid wood panels, fibre boards (wet process), cement bonded particleboards, LVL)

In some cases, initial type testing for "established products" may also be done on the basis of "existing data" using EN 120 or EN 717-2.

The most relevant standard EN 717-1 uses test chambers which can be large (minimum net volume 12 m³), a 1 m³ test chamber or a 0,225 m³ test chamber. Test pieces with a loading rate of 1 m²/m³ are used (e.g. 2 pieces of 0,5 x 0,5 m³ in a 1 m³ test chamber). Other test parameters: air exchange rate of 1/h, temperature 23°C, relative humidity 45 %. The minimum duration of the chamber test is fixed to 10 days. The steady-state is reached when the decline of the calculated concentration curve is equal to or lower than 5 % over a testing time of 4 days. If this condition is not reached within 10 days, the test shall be continued. If the steady-state condition is not reached within 28 days (672 h), the value calculated by the complete power function for the 28th day of the test is defined as the steady-state emission value.

4.2. Formaldehyde limits in the Oeko-Tex® Standard 100 and test methods

The Oeko-Tex® Standard 100 specifies a limit for emissions of formaldehyde for textile carpets, mattresses as well as foams and large coated articles not being used for clothing: 0,100 mg/m3 measured in a test chamber (no details given).

4.3. Formaldehyde limits in EU ecolabel criteria and test methods

EU ecolabel criteria for bed mattresses include limits for the emissions of formaldehyde: < 0,060 mg/m^3 measured after 7 days and 28 days. Test according to ISO 16000-3. Testing following the standard CEN/TS 16516 is considered equivalent to those of the ISO 16000 series of standards (see below). A loading factor 'L' of 1 m^2/m^3 and further test details are given.

EU ecolabel criteria for wooden furniture include limits for the emissions of formaldehyde:

- Particleboard: the emission of formaldehyde from particleboards in their raw state, i.e. prior to machining or coating, shall not exceed 50 % of the threshold value that would allow it to be classified as E1 according to standard EN 312.
- Fibreboard: the emission of formaldehyde from fibreboard(s) in their raw state, i.e. prior to machining or coating shall not exceed 50 % of the threshold value that would allow it to be classified as E1 quality according to EN 622-1. However, fibreboard(s) classified as E1 will be accepted if they do not represent more than 50 % of the total wood and wood-based materials used in the product.

Assessment and verification: wood-based materials are required to emit less than 4 mg/100 g according to EN 120 (perforation method) or less than 0,062 mg/m^3 according to EN 717-1 (chamber method, measured at steady-state conditions).

EU ecolabel criteria for wooden floor coverings includes an additional requirement for cork and bamboo (also 0,062 mg/m^3).

4.4. Formaldehyde coverage in the context of the Construction Products Regulation

Dangerous substances in construction products are subject of work mandated by the EU Commission. Emission to indoor air were initially addressed by the Technical Specification CEN/TS 16516: 2013 "Construction products - Assessment of release of dangerous substances - Determination of emissions into indoor air". The horizontal specification was subject of further evaluation of repeatability and reproducibility. The draft standard prEN 16516 "Construction products - Assessment of release of dangerous substances - Determination of emissions into indoor air" was published in May 2015 and received broad support from the CEN membership. The publication of the standard can be expected later in 2016. Its key provisions are as follows:

As pointed out in a note to the scope of the draft standard it describes the overall procedure and makes use of existing standards mainly by normative reference, complemented when necessary with additional or modified normative requirements.

It defines among other a European reference room corresponding to a small normal living room and emission scenarios taking into account intended conditions of use of the construction products. The reference room is 3 m x 4 m and has a height of 2,5 m. The total air volume is 30 m^3.

From these dimensions, load factors are derived as follows:

— 1,0 m^2/m^3 – walls;

— 0,4 m^2/m^3 – floor, ceiling;

— 0,05 m^2/m^3 – small surfaces, e.g. door, window, heating system;

— 0,007 m^2/m^3 – very small surfaces, e.g. sealants.

Technical Committees establishing product standards shall use these dimensions and load factors unless they do not represent the intended conditions of use for a specific product. In such case the establishment of product specific alterations are allowed.

Other test parameters: rate of ventilation 0,5 air changes per hour, 23 °C and 50 % relative humidity. Measurements are performed after day 3 and day 28.

The time schedule specified in EN ISO 16000-9 shall be used for emissions evaluation, i.e. short-term emissions shall be tested at 3 days and long-term emissions shall be tested at 28 days after installation of the product. However, steady-state emissions may be reached much earlier for some products. In such cases, an optional shorter testing duration may be defined in the relevant product standards provided the 28-day requirements can be shown to be reliably met at that earlier time.

Formaldehyde shall be measured according to ISO 16000-3 including additional requirements. The draft prEN 16516 has not been evaluated for the determination of 'steady-state' concentration of formaldehyde. Formaldehyde specific methods including the ones listed above are also mentioned.

4.5. Thresholds for formaldehyde addressing inhalation

The "WHO guidelines for indoor air quality: selected pollutants", (World Health Organization, 2010) establishes among other a short-term (30-minute) threshold preventing sensory irritation in the general population is 0.1 mg/m^3, i.e. the threshold should not be exceeded at any 30-minute interval during a day. The use of this limit is considered also to prevent long-term health effects, including cancer. The value is generally accepted.

It should be noted that the WHO guideline value is an indoor air concentration which must not be exceeded. There may be, however, several sources for formaldehyde emissions. This means that thresholds for the releases from ALL sources must be chosen in such way to ensure that the value can be complied with.

In the framework of the "European Collaborative Action - Urban Air, Indoor Environment and Human Exposure", co-ordinated by the EC Joint Research Centre in Ispra (Italy), a series of 29 reports on indoor quality issues have been published since 1988. ECA Report No 29 " Harmonisation framework for health based evaluation of indoor emissions from construction products in the European Union using the EU-LCI concept"[7] describes a harmonised procedure for establishing a list of compounds and their associated LCI (Lowest Concentration of Interest) values for the evaluation of emissions from construction products (EU-LCI) taking into account existing procedures used in some Member States (in particular, from ANSES in France and AgBB in Germany). Among other it addresses the issue of exposure from several sources and recommends to adjust the limits by application of a 'multiple sources factor', i.e. to use 20% – 50% of the LCI depending on the likelihood of the presence of other sources. Where other sources can be excluded no correction is considered to be necessary.

According to the WHO guidelines for indoor air quality formaldehyde may be also formed through chemical reactions between, for example, ozone and terpenes.

The WHO document reports measured formaldehyde concentrations in homes. For instance, in a large indoor air survey carried out in homes by the Building Research Establishment (BRE) in the United Kingdom in 1997–1999, the geometric mean, 95th percentile and maximum value of three-day samples of formaldehyde in bedrooms (n = 833) were, respectively, 22.2, 61.2 and 171 µg/m^3. In a German longitudinal environmental survey 2003–2006 (GerES IV), formaldehyde was measured through passive samplers for one week in bedrooms of a randomly selected population of children and teen agers. The geometric mean, 95th percentile and maximum concentration (n = 586) were, respectively, 23.3, 47.7 and 68.9 µg/m^3.

4.6. Measurement of formaldehyde emissions from toys

As stated above EN 71-9 includes a limit for formaldehyde emissions from accessible resin-bonded wood components of toys intended for children under 3 years of age. The limit is 80 mg/kg when tested in accordance with EN 717-3 " Wood-based panels - Determination of formaldehyde release - Part 3: Formaldehyde release by the flask method".

The method relies on the determination of formaldehyde by suspending test pieces of known mass (test pieces of 25 mm x 25 mm x board thickness, approximately 20 g in total) over (50 ml) water in a closed container (of 500 ml volume), maintained at a constant temperature (40°C). Formaldehyde released from the test pieces during a defined period of time (3 h) is absorbed by the water. The formaldehyde content of the water is determined photometrically by the acetylacetone method, and the result is expressed in milligrams formaldehyde per kilogram of dry board.

[7] http://publications.jrc.ec.europa.eu/repository/bitstream/JRC83683/eca%20report%2029_final.pdf

The usefulness of the method for the purpose of compliance measurement in general, and for toys in particular, has been questioned.

As stated above the chamber method is considered as the reference method for determining the release of formaldehyde from wood panels to ensure compliance with the classification scheme and national legal provisions. Derived methods have been used where correlations could be established between the results of the reference method and the results of the derived method.

According to specialists for this kind of test (such as the Fraunhofer Institute for Wood Research - Wilhelm-Klauditz-Institut, Braunschweig, Germany) EN 717-3 is suitable only for internal production control of wood based panels[8]. In their review "Formaldehyde in the Indoor Environment" Salthammer et al.[9] state: "*Disadvantages of the method are the small quantity of material which can be tested and the unrealistic ratio of open edges to surfaces of the tested specimens. In spite of these limitations, the method is most suitable for production control of panels with a similar structure*".

The German BfR expressed concern about the requirements for formaldehyde emissions in EN 71-9 as well as the related test methods[10]. The applicable requirements in Germany at the time ("Chemikalienverbotsverordnung") included a limit of 110 mg/kg measured after 24 hours of testing and 30 mg/kg measured after 5 hours of testing using also a flask method similar to the one described in EN 717-3 ("WKI-Flaschenmethode"). These limits (considered safe by BfR) are considerably more stringent than the requirements in EN 71-9, i.e. 80 mg/kg measured after 3 hours. Consequently, the rate of non-compliance using both requirements was quite different as shown in a comparative test (15 % non-compliance for the former, 3 % non-compliance for the latter). The opinion by BfR published in November 2007 led to a research project looking more closely at the test method in EN 717-3 and its relation to indoor air concentrations.

The results were published by Maciej et al. in "Deutsche Lebensmittelrundschau 107, April 2011, 169-176 (not accessible free of charge). Test were performed using 6 uncoated boards and 1 coated board (plywood, MDF boards, chipboard) of various thicknesses (3 to 12 mm). A major result was that chamber test results did not correspond to measurements in accordance with EN 717-3.

Several factors were identified contributing to the non-correlating measurement results. The samples have different thicknesses and, therefore, several pieces needed to be combined to achieve "approximately" 20 g total mass (in the study 2-5 pieces). The consequence was that not only a different total mass (with deviations of up to 20% from the desired value of 20 g) but also quite different volume/surface

[8] http://owic.oregonstate.edu/sites/default/files/pubs/Schwab.pdf
[9] http://pubs.acs.org/doi/abs/10.1021/cr800399g
[10] http://www.bfr.bund.de/cm/343/bfr_schlaegt_die_ueberpruefung_des_grenzwertes_der_din_norm_fuer_die_formaldehydausgasung_aus_holzspielzeug_vor.pdf

ratios. With increasing number of sample pieces, the volume/surface ratios increase and, as a consequence, the formaldehyde release (per mass unit of wood) decreases. Also there is a difference in terms of conditioning: the measurement in accordance with EN 717-1 takes place when steady-state is reached (see above). This can be after 10 days or after 28 days (i.e. the sample is conditioned for more or less days). By contrast, samples are tested according to EN 717-3 without conditioning.

NOTE 1. All this is not really surprising as the flask method was always considered to be suitable for internal production control only (see above) suggesting that correlations with chamber tests can only be established for specific products (i.e. must be established for every individual product).

NOTE 2. The authors did not discuss the possible influence on the release of formaldehyde related to the different proportions of board surfaces (top and base) compared to the cut areas using the flask method (see also above).

NOTE 3. The study was performed using various boards, i.e. objects differing only in thickness as regards dimensions. For other objects things are even more complicated and efforts to establish "correlations" are presumably almost impossible (except for individual products).

As an alternative, the authors suggest a modified chamber method based on the following principles:

- model room size 20 m^3
- chamber minimum size 0,02 m^3, air exchange rate 0,4/h
- 3 size classes of toys and related number of toys per room are defined:
  - Class 1 (large): > 0,1 m^3, 1 piece/room (e.g. doll kitchen)
  - Class 2 (medium): 0,001– 0,1 m^3, size dependent number of pieces (e.g. wood car)
  - Class 3 (small): < 0,001 m^3, 20 pieces (e.g. wooden figure)
- the volume is the volume of the thought minimum cuboid needed to circumscribe the article
- the number of pieces in Class 2 is calculated by the formula: N_{KZ} = –192 x volume + 20,2
- an individual threshold (in the chamber) is calculated for each article
- sets of small parts (e.g. building bricks) are considered as single article
- 0,1 ppm is considered an acceptable indoor threshold in line with an assessment by BfR (and WHO)
- toys should contribute only 5% to this concentration bearing in mind other emission sources, i.e. formaldehyde from toys may lead to an additional concentration RW_{MR} of 0,005 ppm in the model room
- the acceptable threshold for an article in the chamber $[c_{HCHO}]_{lim}$ is determined following the formula $[c_{HCHO}]_{lim} = RW_{MR} \times F1 \times F2$ whereby
  - F1 = N_{PK}/N_{KZ} (N_{PK} = number of items in the test chamber, N_{KZ} = number of items in the children's room) and

- F2 = V_{KZ}/V_{PZ} (V_{KZ} = volume of children's room, V_{PK} = volume of test chamber)

— to shorten the test period, it is suggested that an article may pass if the concentration in the test chamber on 4 consecutive measurements on 4 days declines and the last measurement is below the threshold. Measurements can already start on day 1 after 6 hours (the maximum test period is 28 days)

Example 1: toy chest, 40 x 60 x 40 cm

The volume is 0,096 m^3. Using the formula "N_{KZ} = −192 x volume + 20,2" gives a value of 1,768, rounded up gives 2, i.e. 2 items need to be tested.

The surface (one sided) is 1,28 m^2. Taking inside and outside area combined gives about 2,56 m^2. Using a model room of 20 m^2 this gives a load factor of 1,28/20 (one sided) 0,064 m^2/m^3 or 2,56/20 = 0,128 m^2/m^3 (both sides)

Example 2: wood puzzle, 16 pieces, 5 x 5 x 0,5 cm

The volume of a piece is 12,5 cm^3 = 0,0000125 m^3. The number of items to be tested is 20. The surface of 1 piece is 60 cm^2, the total surface of 20 pieces is 1200 cm^2 which is 0,12 m^2. The dimensions of the box: 12,1 x 3,8 x 12,2 cm

4.7. Conclusions regarding limits for toys addressing inhalation

Several options for measuring the formaldehyde emissions from toys made of resin-bonded wood are discussed below.

Option 1

The method by Maciej et al. could be a departure point for establishing an emission limit for formaldehyde from wood based toys. An obvious advantage of the method is that complete toys can be tested without cutting.

However, the suggested method for loading of the test chamber seems to pose some significant problems.

As a consequence of the method different limits apply per area (or volume) unit of the material. The bigger the article, the more demanding is the limit. This may lead to the consequence that a material found suitable to produce a small puzzle of a total area of, say, a tenth of a square meter may not be appropriate to produce a large item with an area of e.g. more than one square meter. This is a rather uncommon approach as limits are typically independent of the size of objects (i.e. every area unit of an object is allowed to emit the same amount of a volatile compound).

A further complication arises from the fact that the number of items changes depending on their volumes. In the example of the toy chest above, a small dimensional increase of the width of just one cm (e.g. 41 cm instead of 40 cm) leads to the need to test only one items rather than two which means that a

significantly decreased area would be exposed. Consequently, the area specific demand would change abruptly at this point.

The draft standard prEN 16516 (7.3) accepts that the loading factor in the test chamber may deviate from the loading factors for the reference room. However, it shall not be below 50 % or above 200 % of the specified loading factor (in the room). This condition is not fulfilled by the method. As an example, a large toy (class 1) would have to be tested in a large chamber unless the requirement is ignored or modified. The draft standard accepts deviations in principle. However, it is uncertain whether the emissions measured in the chamber actually correspond to the emissions in the (model) room, i.e. whether mathematical corrections for different air volumes and/or numbers of items in the chamber and model room give correct results. This would have to be demonstrated.

The suggested number of 20 pieces in class 3 (small) could also be questioned, given that a single wood puzzle for children can already include many more pieces.

In addition, there may be several toys of that kind available to the child.

Apart from that the determination of the size class faces some difficulties: the toy may contain items of different size which raises the question which and how many items of each size should be selected for the test. The statement by Maciej et al. that sets of small parts (e.g. building bricks) are considered as single article in the classification raises several questions, e.g. how the volume of the set is determined (how the items should be allocated to determine the (total) volume), whether then individual pieces are tested or (several) complete sets. When puzzles consist of stamped parts to be broken out of their template – is the volume determined using the set as delivered including the template or are the puzzle pieces to be broken out first. The authors themselves have stated that their method needs to be tested in practice. It is unclear whether further research has been done and what the results were.

Option 2

An alternative would be to modify the above test method by defining an area specific emission rate or a test load (rather than specifying numbers of toys) and to calculate an indoor concentration taking into account the assumed loading factor in the reference room. This would require to measure the surfaces of the toys (which may be difficult for certain toys). However, the problem with associated with test loads not corresponding to the load factors in the (model) room remains (at least for larger items) as in option1. Also for this option further work including testing would be required.

Option 3

Yet another option would be to test only a part of the article. In this case also a load factor would have to be defined (e.g. assuming 3 m^2 toy surface in the European model room of 30 m^3 would give a load of 0,1 m^2/m^3 in the room and in the test

chamber). Using the above toy chest as example one would test slightly less than a third of the side board of the toy chest in a 1 m^3 chamber. The limit value would be – as in the above options – 5-10% of the allowed threshold of 0,1 ppm, i.e. 0,01-0,005 ppm. In case of the puzzle example around 17 pieces would have to be tested. Cut areas need to be sealed, of course.

Option 4

The simplest solution, however, would be just to require that any resin-bonded wood components of toys comply with requirements corresponding to the ones leading to E1 classification in accordance with the relevant specifications mentioned above, i.e. using a test chamber load of 1 m^2/m^3 as usual for wood based panels and a limit of 0,1 ppm. In this case both the test load and the limit would be about an order of magnitude higher compared to option 3. Assuming that the total area of toys made of resin-bonded wood will normally be only a small fraction of the total load of wood panels on which the E1 specification is based (i.e. 30 m^2 in the model room) it can be assured that the contribution of formaldehyde emissions from toys to the total indoor air concentration of formaldehyde will be normally small. This holds true even though the air exchange rate in EN 717-1 is considerably higher than the one used by Maciej et al. (0,4/h) or prEN 16516 (0,5/h). This option is also the most practical one for industry as manufacturers of toys can simply order panels conforming to E1 (or equivalent).

In conclusion the last option seems the most promising one, i.e. to require that resin-bonded wood materials used in toys shall comply with a limit of 0,1 ppm when tested in accordance with EN 717-1 (corresponding to the E1 classification) or equivalent. Some additional details should be given when testing toys (e.g. on sample preparation including sealing of cut surfaces).

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About ANEC

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European association for the coordination of consumer representation in standardisation aisbl

Avenue de Tervuren 32, box 27, B-1040 Brussels, Belgium
Tel.: +32 2 743 24 70 / Fax: +32 2 706 54 30
E-mail: anec@anec.eu

EC Register of Interest Representatives:
Identification number 507800799-30

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