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Progress with the establishment of harmonised health-based reference values, EU-LCIs

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IEH Consulting
The integrated environment and health consultancy

BS EN 16516: 2017 (European test method for determining emissions from construction products to indoor air)

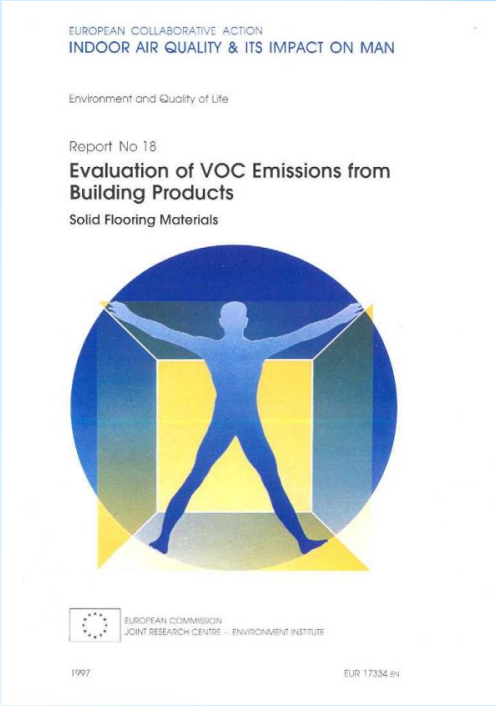
Includes definition of an LCI value

3.1.3.1 Lowest Concentration of Interest; substance-specific value, quoted in terms of mass concentration in the air of the reference room, for health- related evaluation of emission levels from construction products

Note 1 to entry: This term can be used in conjunction with any available list of LCI values.

Origin of LCI

ECA report no. 18 (1997) includes a definition of "lowest concentrations of interest" (LCIs), i.e. the lowest concentration above which, according to best professional judgment, the pollutant may have some effect on people in the indoor environment.



The toxicological evaluation of relevant compounds VOC_i present in the emissions measured on day 28 is performed by comparing their exposure concentration with the "lowest concentrations of interest" (LCIs) defined in section 4.4 and reported in Table 4.2, i.e. calculating the ratios:

$$R_i = \frac{C_i}{LCI_i}.$$

VOCs for which a LCI value is reported in Table 4.2 are called "assessable". A VOC_i is supposed to have no effect if R_i does not exceed the value 1. For more than one relevant compound, additivity of effects is assumed as explained in section 4.3, and it has to be determined if:

$$\mathbf{R} = \sum_i R_i = \sum_i \frac{C_i}{LCI_i} \leq \mathbf{1.} \qquad \mathbf{(6.12)}$$

R is termed "risk index" of assessable emitted compounds.

Harmonisation of Low Emission Product Labelling schemes

- In 2005 a preparatory group published a comparison of existing schemes (ECA report no. 24)
- JRC, Ispra established a steering / consultation group in 2010 to continue the harmonisation process
- ECA report no.27 (2012); a road map to harmonisation; identified LCIs as key factor for achieving greater harmonisation
-

Construction products: Main indoor emission labelling schemes in Europe

Finland, M1 (voluntary)

Denmark, DICL (voluntary)

Germany, AgBB (regulatory)

E class (formaldehyde only)

France, CESAT (Anses) (voluntary (regulatory),

(Belgium (regulatory)**)**

Plus a range of sector schemes such as ecolabel, nature plus, blue angel…

Common features

Environmental chamber test of product to determine emission rate

Also differences

e.g. TVOC threshold, use of sensory tests, *requirements for individual VOCs e.g, AFSSET and AgBB LCI lists*

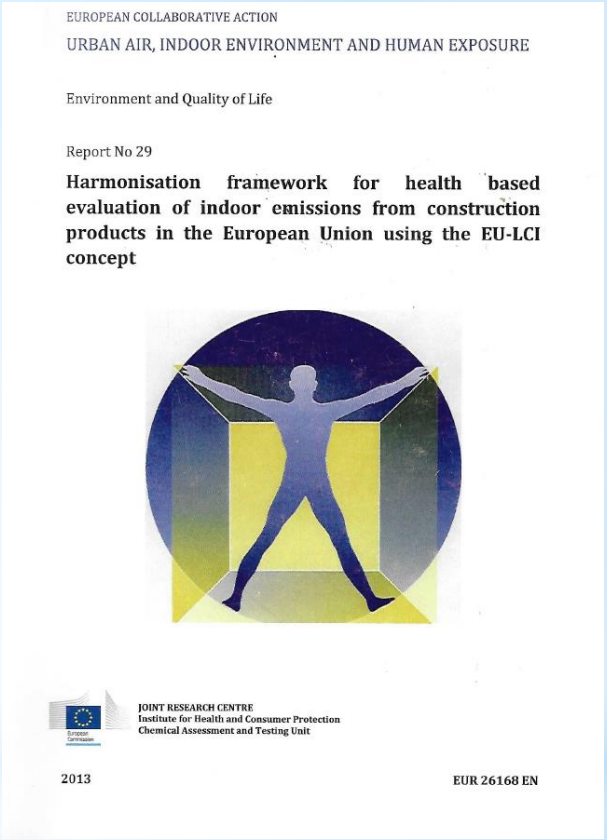
Gradual harmonisation of approaches in Europe facilitated by a ***European Collaborative Action, CEN (TC351 WG2)*** *and* ***European Commission***

Harmonisation of LCI values

- EU-LCI values are derived according to a protocol developed by an expert (ECA) group and since 2015 they are working under a mandate from DG Growth (ECA report no. 29)

- EU-LCIs are health-based values used to evaluate emissions after 28 days from a *single product* during a laboratory test chamber procedure (as defined in the EN 16516 standard)

- EU-LCIs are applied in product safety assessment with the ultimate goal to avoid health risks from *long-term* exposure for the general population


EUROPEAN COLLABORATIVE ACTION

URBAN AIR, INDOOR ENVIRONMENT AND HUMAN EXPOSURE

Environment and Quality of Life

Report No 29

Harmonisation framework for health based evaluation of indoor emissions from construction products in the European Union using the EU-LCI concept

JOINT RESEARCH CENTRE
Institute for Health and Consumer Protection
Chemical Assessment and Testing Unit

2013

EUR 26168 EN

EU-LCI Protocol; properties

- Authoritative; A standard protocol prepared by 24 scientists within the European Collaborative Action on Urban Air, Indoor Environment and Human Exposure facilitated by JRC, Ispra.

- Consensus; a protocol developed by scientists drawn from 10 Member States of the European Union. Takes account of REACH Chemical Safety Reports.

- Robust; Has been applied for 8 years to a wide range of organic compounds and results presented at international conferences and journal papers.

- Transparency; technical documents supporting all derivations are published (EC website) and freely available.

EU - LCI Features

- Only values derived by application of the process established by the EU-LCI WG (i.e. ECA report no. 29) and ratified by the EU-LCI WG shall be called EU-LCIs.
- Since primary emissions decline with time, the 28-day timescale is considered a ‘worst case’ assumption for the long-term indoor air VOC emission scenario in the absence of oxidants.
- The test procedure (using chambers and correction factors relating to a ‘reference’ room) provides only an approximation to the situation in a real indoor environment; concentrations in actual rooms will depend on many factors including temperature, ventilation and the presence of other sources.
- EU-LCI values are usually expressed as $\mu g/m^3$.

Protocol for the de novo derivation of EU-LCIs

- The procedure consists of three main steps:
  - toxicity data compilation,
  - toxicity data evaluation, and
  - derivation of the EU-LCI on the basis of a standardised factsheet generated for each substance.

- The protocol also provides instructions on how to deal with rounding of values, read-across for data poor substances and molar adjustment.

- In the absence of sufficient toxicity data a value is not set.

Protocol - Data evaluation: Standardised Summary Fact Sheet

A summary fact-sheet with a standardised format is generated for each substance. This comprises four main sections:

- General information
- Toxicological database (values derived from the data compilation process)
- Assessment factors used
- Rationale for the derivation of the EU-LCI value.

Example fact sheet for toluene

	TOLUENE		
Parameter	**Note**	**Comments**	**Value / descriptor**
EU-LCI Value and Status			
EU-LCI value	1	Mass/volume [µg/m^3]	2900
EU-LCI status	2	Interim / Confirmed	Interim
EU-LCI year of issue	3	Year when the EU-LCI value has been issued	29 August 2012
General Information			
CLP-INDEX-Nr.	4	INDEX	R2B
EC-Nr.	5	EINECS – ELINCS - NLP	203-625-9
CAS-Nr.	6	Chemical Abstracts Service number	108-88-3
Harmonised CLP classification	7	Human Health Risk related classification	Flam. Liq. 2 Asp. Tox. 1 Skin. Irrit. 2 STOT SE 3 Rep. 2 STOT RE 2
Molar mass	8	[g/mol]	92.14
Key Data / Database			
Key study, Author(s), Year	9	Critical study with lowest relevant effect level	Zavalic et al., 1998
Read across compound	10	Where applicable	
Species	11	Rat,… human	Human
Route/type of study	12	Inhalation, oral feed,…	Inhalation, occupational
Study length	13	Days, subchronic, chronic	17 years
Exposure duration	14	Hrs/day, days/week	
Critical endpoint	15	Effect(s), site of	Neurological effects (color vision impairment)
Point of departure (POD)	16	LOAEC*L, NOAEC*L, NOEC*L, Benchmark dose,….	LOAEC
POD Value	17	[mg/m^3] or [ppm]	123 mg/m^3

Assessment Factors (AF)	**18**		
Adjustment for exposure duration	19	Study exposure hrs/day, days/week	4.2
AF Study Length	20	sa→ sc→ c *(R8-5)*	
Route-to-route extrapolation factor	21		
AF Dose-response	22 a	Reliability of dose-response, LOAEL → NOAEL	2
	22 b	Severity of effect *(R 8-6d)*	
Interspecies differences	23 a	Allometric Metabolic rate *(R8-3)*	
	23 b	Kinetic + dynamic	
Intraspecies differences	24	Kinetic + dynamic Worker - General population	5
AF (sensitive population)	25	Children or other sensitive groups	
Other adjustment factors Quality of whole database	26	Completeness and consistency Reliability of alternative data *(R8-6 d,e)*	
Result			
Summary of assessment factors	27	Total Assessment Factor (TAF)	42
POD/TAF	28	Calculated value (µg/m^3 and ppb)	.....2928.57 µg/m^3 ..... 772.58 ppb
Molar adjustment factor	29	Used in read-across	
Rounded value	30	[µg/m^3]	2900
Additional Comments	31		

Example fact sheet for toluene; rationale

Rationale Section	32	•	

Rationale for critical effects

Neurological effects have been demonstrated in rodents and in humans exposed by the respiratory route during chronic exposure. Toluene like many other organic solvents can impair color vision, even at concentrations below 50 ppm. Reprotoxic and developmental effects have also been shown, particularly in animals; however, the neurological effects were reported at lower concentrations than those for effects on fertility or development.

WHO, RIVM, ATSDR, US-EPA, Anses, German IAQ, Austria IAQ, based their values on human studies showing neurologic effects (could be neurobehavioural, vision impairment ...).

Rationale for key study

The reference value is based on the Zavalic´et al. (1998) study. In this study, color vision was examined in two groups of workers occupationally exposed to toluene and in a control group. The autors referenced standard methods for measuring both ambient air concentrations and individual blood toluene levels. Significantly higher values of color confusion index and alcohol intake-adjusted color confusion index in exposed groups in comparison to the non-exposed group were reported. The color confusion index scores were adjusted for alcohol consumption. A LOAEC of 134 mg/m³ (35 ppm) could be derived from this study.

ATSDR (2000) and Anses (2010) also based their toxicological reference value on this study. US-EPA (2005) considered several human studies as key studies, including the Zavalic´et al. (1998). An average NOAEC from these studies was used.

The study from Zavalic´was selected as the key study as it is an epidemiological study on workers exposed for many years and a dose-response relationship for neurological effects was observed in this study.

Rationale for starting point

In the study of Zavalic´ et al. (1998), two groups of exposed workers to toluene and a control group have been evaluated:

- the first exposed group, Group E1, comprised 41 workers (toluene exposure ranged from 11.3 to 49.3 ppm; median 32.0)
- the second exposed group, Group E2, comprised 32 workers (toluene exposure ranged from 66.00 to 250.00 ppm; median 132.00).
- the non-exposed group, Group NE, comprised 83 subjects.

Each group was divided into two subgroups; alcohol consumers and non-consumers. Color vision loss was expressed as a color confusion index (CCI) and as an age and alcohol intake-adjusted colour confusion index (AACCI).

The AACCI value was significantly higher in Group E2 compared to Group NE (t-test, P <0.0001) and Group E1 (t-test; P <0.05), and in Group E1 compared to Group NE (t-test; P < 0.05). Difference was not established in CCI value between groups E1 and NE. No statistically significant correlation was established between AACCI and any marker of toluene exposure in Group E1, or in the subgroups of alcohol consumers and non-consumers. Significant correlation was established between the AACCI value and toluene in air, between AACCI and orthocresol in urine and between AACCI and hippuric acid in urine in this Group.

The authors concluded that age and alcohol intake play a role in color vision impairment. Alcohol intake play a role as an additive cofactor with toluene.

Based on the evidence that the AACCI value was significantly higher in Group E1 (median toluene exposure 32.0 ppm) compared to Group NE, 32 ppm could be considered as a LOAEC.

Rationale for Uncertainty factors

- AF Dose response: An assessment factor of 2 is applied to account for extrapolating from a LOAEC to a NOAEC. This low factor is justified by the fact that numerous human studies have identified NOAELs in the range of 25-50 ppm toluene for individual neurological effects and also by the fact that US-EPA considered 34 ppm as a NOAEC (US-EPA, 2005).
- Adjusted study length factor: an assessment factor to account for extrapolating from less than chronic results was not necessary. Most of the studies used in the analysis were of chronic duration.
- Adjusted exposure duration factor: The LOAEL (average) of 32 ppm (123 mg/m³) was adjusted from an occupational exposure scenario to continuous exposure conditions as follows:

NOAEL (adj) = NOAEL (average) x 8 hours /24 hours x 5 days/7 days = 123 mg/m³ x 10m³/20m³ x 5 days/7 days = 30 mg/m³

- Interspecies differences: an assessment factor to account for laboratory animal-to-human interspecies differences was not necessary because the point of departure is based on human exposure data.
- Intraspecies differences: a 5-fold assessment factor for was used to account for potentially susceptible human subpopulations and life stages. Differences in human susceptibility may also be due to life stage (e.g., childhood or advanced age), differences among the adult population, genetic polymorphisms, decreased renal clearance in disease states, and unknown pharmacodynamic variations in response to toluene exposure.

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EU - LCI progress and dissemination

- Full information about the EU Sub Group on EU-LCI Values and the current list of EU-LCI values is available at https://ec.europa.eu/growth/sectors/construction/eu-lci_en.
- Currently there are 159 EU-LCIs with a further 11 pending; plus 5 ‘insufficient data’ (December 2020 update).
- EU-LCIs form an integral part of the harmonisation framework for EU indoor products labelling schemes.

Acknowledgements

All past and present members of the Sub Group on EU-LCI Values;

Carolin Bischoff (since 2019), BASF, Germany
Guillaume Boulanger (since 2014), French Agency for Food, Environmental and Occupational Health and Safety (ANSES), France
Paolo Carrer (since 2011) University of Milan, Dept. of Biomedical and Clinical Sciences, Italy
Derrick Crump (since 2011, Chair since 2015) IEH Consulting Ltd, UK
Christine Däumling (since 2011) Senior consultant, formerly German Environment Agency (UBA), Germany
Katleen De Brouwere (since 2011) VITO, Belgium
Dieter De Lathauwer (since 2011) Belgian Federal Public Services, DG5 Environment, Belgium
Nicole Dommaschk (since 2012) Deutsches Institut für Bautechnik, Germany
Martin Glöckner (since 2011) Deutsche Bauchemie e.V., Germany
Stylianos Kephalpoulos (since 2011) European Commission, Joint Research Centre, Ispra, Italy
Dainius Martuzevičius (since 2015) Kaunas University of Technology, Lithuania
Claudia Röhl (since 2016) Landesamt für soziale Dienste (LasD), Germany
Jorma Säteri (since 2011) Helsinki Metropolia University of Applied Sciences, Finland

Acknowledgements (continued)

Linda Schenk (since 2019) Karolinska Institutet, Institute of Environmental Medicine, Sweden
Armin Schuster (since 2011) Universitätsklinikum, Germany
Ana Maria Scutaru (since 2011, technical secretary) German Environment Agency (UBA), Germany
Cornelia Tietz (since 2019) The European Chemical Industry Council (CEFIC), Belgium
Ilse Mauritz (since 2011) Environment Agency, Austria
Thomas Witterseh (since 2011) Danish Technological Institute, Denmark
Peder Wolkoff (since 2011) National Research Centre for the Working Environment, Denmark

Acknowledgements (continued)

Members of the former subgroups
Rudolf Jäckh (2011-2015)
Paul Harrison (formerly chair 2011-2015)
Birger Heinzow (2011-2015)
Ruth Bevan (2016-2017)
Otmar Geiss (2011-2016)
Christophe Rousselle (2011-2014)
Erwin Annys (2011-2019)
Colin Ehnes (2013-2019)
Gunnar Johanson (2011-2019)
Maria Uhl (2011-2015)

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