For our Environment

Umwelt Bundesamt

CEN/TC 351 Conference, 16-17 October 2019, Vilnius

EU-LCI Values for the Health-related Evaluation of Construction Products Emissions

Ana Maria Scutaru
German Environment Agency (UBA), Berlin, Germany
EU-LCI Secretariat

1

LCI – Lowest Concentration of Interest

Origins:

ECA 18 – European Collaborative Action, Report No. 18 (1997)

„The lowest concentration above which, according to best professional judgment, the pollutant may have some effect on people in the indoor environment."

The LCI concept was integrated into national evaluation systems, updated and improved:

In **Germany** by AgBB since 2001:

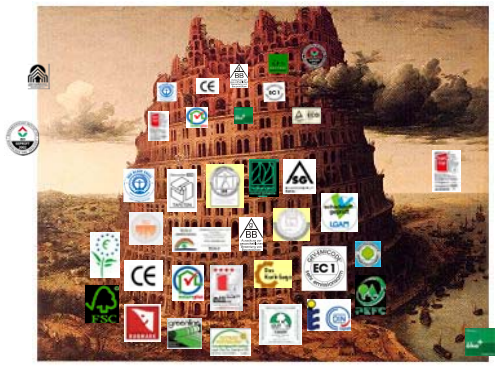
NIK – Niedrigste interessierende Konzentration

In **France** by AFSSET (now ANSES) since 2005:

CLI – Concentration limite d'intérêt

2

Tower to label



Turm von Babel - Pieter Bruegel

3

History of initiatives towards European processes

- **2007: International Conference** "Construction Products and Indoor Air Quality", Berlin, 4-5 June
  German initiative to investigate potential for harmonization
- **2008 - 2009**: Work on **Harmonisation of labelling systems**
  M1 **DICL** **AgBB** **AFSSET ; results in ECA 27**
  + JRC + BREEAM + …

4

Methodical approach of the Preparatory WG

+ JRC + BREEAM + …

Step 1 Practical comparisons of the various test and evaluation systems
Step 2 Joint evaluation of the advantages and disadvantages of individual test criteria and procedures, including all years of experience
Step 3 Development of a consensus on the recommendation of a common European set of criteria
Step 4 Formulate a detailed report on this consensus in ECA activities (European Collaborative Action)
Step 5 Presentation of the results at the Healthy Buildings Conference 2009 (USA)
Step 6 Discussion on how to proceed with DG SANCO and DG ENTR/GROW How can a harmonised assessment of test results be implemented politically in Europe … (Fall 2009)

5

Preparatory WG agreed on Fundamentals in Assessment of Chemical Emissions:

1. assessable single substances
check for toxicological relevance of emissions
- **EU-LCI** values
- **Carcinogens**

2. limit of the total amount of emissions
- **TVOC, TSVOC**

3. limit unassessable substances
(REACH process will help to reduce unassessables)
- **VOC**without LCI

Requirements / Parameter	Consensus
Measuring method / Chamber	Harmonised CEN Standard (based on ISO 16000 series)
Measuring points (days)	3 and 28
Core criteria	
Single VOC evaluation (R = ∑ Ci/LCi, <1)	R < 1 Harmonised list of LCI
Carcinogens EU carcinogens (cl.1 and 2, now 1A and 1B)	Harmonised list
TVOC measured	200-1000 µg/m³
Formaldehyde measured	Value still under discussion
Optional criteria	
Compounds without LCI assessment	Sum < 100 µg/m³
TSVOC measured	Await validation TC 351
Sensory evaluation	Await ISO 16000-28

6

Recommendations of the Preparatory Working Group (ECA 27)

- *"The evaluation criteria should cover all contaminants of concern for health and comfort and be based on scientific evidence when available.*
- *The LCI approach is currently the most feasible strategy to assess the health effects of compounds from buildings products and the harmonisation process of LCI values for around 170 chemicals which has recently started in Europe is fully supported."*

Assessment of combination effects of substances in the mixture via the R-value:

$R_i = C_i / LCI_i$, where C_i = measured chamber concentration

LCI_i = the lowest concentration of interest for substance *i*

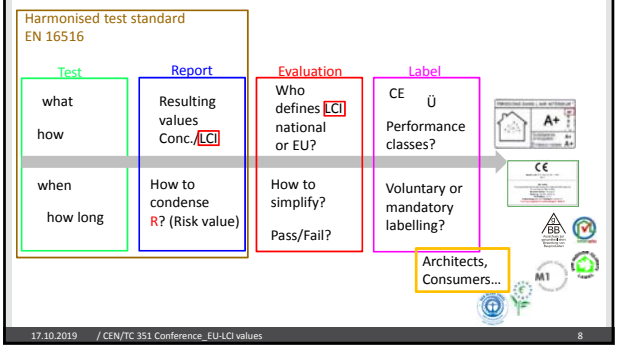
$R_i < 1$ → no adverse health effects

R = sum of all R_i = sum of all ratios $(C_i / LCI_i) \leq 1$

17.10.2019 / CEN/TC 351 Conference_EU-LCI values 7

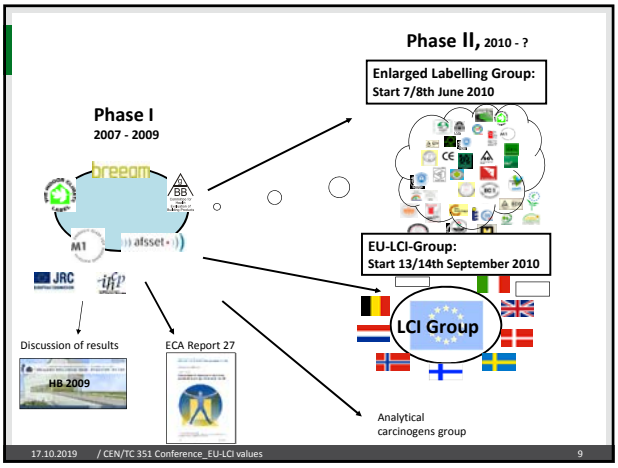
7

The need and key benefits of health-based reference concentrations for building products emissions



17.10.2019 / CEN/TC 351 Conference_EU-LCI values 8

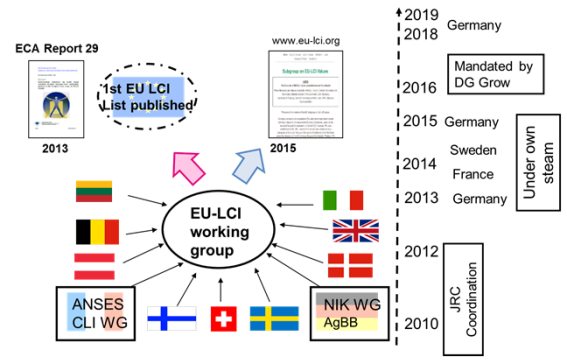
8



17.10.2019 / CEN/TC 351 Conference_EU-LCI values 9

9

Development of harmonised EU-LCI values



Since 2016 results are published at https://ec.europa.eu/growth/sectors/construction/eu-lci_en

17.10.2019 / CEN/TC 351 Conference_EU-LCI values 10

10

Definition and derivation procedure of EU-LCI values

EU-LCI: health-based reference concentrations for inhalation exposure used to assess emissions after 28 days from a single product during a laboratory test chamber procedure (see ECA Report 29).

The Protocol for the *de novo* derivation of EU-LCI values consists of three main steps:

1. compilation of published toxicological data
2. data evaluation and choice of point of departure (POD)
3. derivation of the EU-LCI value on the basis of a total (combined) assessment factor in a standardized factsheet.

Results are published at https://ec.europa.eu/growth/sectors/construction/eu-lci_en.

17.10.2019 / CEN/TC 351 Conference_EU-LCI values 11

11

Toxicological challenges

- The key study and the lowest reasonable point of departure (POD) is chosen after thorough evaluation by the experts of the EU-LCI WG (expert judgement).
- Chronic (long-term) studies are generally preferred, except where a short-term study provides valuable information about an important end point.
- Human studies are preferred to animal studies, provided the study design is robust.
- Inhalation studies are preferred to oral studies, although the latter can be used with an appropriate route-to-route extrapolation factor.
- The use of assessment factors is in accordance with ECHA guidance for REACH.

Point of departure values:
NOAEL/LOAEL/BMD/PBPK

Assessments factors:
Adjustment for exposure duration
Study length
Route-to-route extrapolation factor
Dose-response
Severity of effect
Interspecies differences
Intraspecies differences
Sensitive population
Quality of database

Read-across approach

17.10.2019 / CEN/TC 351 Conference_EU-LCI values 12

12

Compound	TRIMETHYLBENZENES		*Factsheet*
Parameter	**Note**	**Comments**	**Value / descriptor**
EU-LCI Value and Status			
EU-LCI value	1	Mass/volume [µg/m³]	450
EU-LCI status	2	Interim / Confirmed	Interim
EU-LCI year of issue	3	Year when the EU-LCI value has been issued	22 November 2012
General Information			
CLP-INDEX-Nr.	4	INDEX	601-025-00-5 601-043-00-3 601-025-00-5
EC-Nr.	5	EINECS – ELINCS - NLP	247-099-9 202-436-9 203-604-4 208-394-8
CAS-Nr.	6	Chemical Abstracts Service number	25551-13-7 95-63-6 108-67-8 526-73-8
Harmonised CLP classification	7	Human Health Risk related classification	Not harmonised
Molar mass	8	[g/mol]	120.19
Key Data / Database			
Key study, Author(s), Year	9	Critical study with lowest relevant effect level	Korsak and Rydzynski, 1996, 1997, 2000a, 2000b
Read across compound	10	Where applicable	
Species	11	Rat,... human	Rat
Route/type of study	12	Inhalation, oral feed, ...	Inhalation
Study length	13	Days, subchronic, chronic	Subchronic
Exposure duration	14	Hrs/day, days/week	6h/24h / 5d/7d
Critical endpoint	15	Effect(s), site of	Neurotoxicity and local effects on lungs
Point of departure (POD)	16	LOAEC*L, NOAEC*L, NOEC*L, Benchmark dose, ...	NOAEC
POD Value	17	[mg/m³] or [ppm]	123 mg/m³
Assessment Factors (AF)	**18**		
Adjustment for exposure duration	19	Study exposure hrs/day, days/week	5.6
AF Study Length	20	sa→ sc→ c *(R8-5)*	2
Route-to-route extrapolation factor	21		
AF Dose-response	22 a	Reliability of dose-response, LOAEL → NOAEL	
	22 b	Severity of effect *(R 8-6d)*	
Interspecies differences	23 a	Allometric Metabolic rate *(R8-3)*	
	23 b	Kinetic + dynamic	2.5
Intraspecies differences	24	Kinetic + dynamic Worker - General population	10
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)	280
POD/TAF	28	Calculated value (µg/m³ and ppb)	......439.29 µg/m³ ..... 88.84 ppb
Molar adjustment factor	29	Used in read-across	
Rounded value	30	[µg/m³]	450
Additional Comments	31		
Rationale Section	32		

Trimethylbenzene (CAS 25551-13-7) has three isomers:
1,3,5-trimethylbenzene (synonym: mesitylene; CAS 108-67-8)
1,2,4-trimethylbenzene (synonym: pseudocumene; CAS 95-63-6)
1,2,3-trimethylbenzene (synonym: hemimellitene; CAS 526-73-8)

None of the agencies WHO, EPA, ATDSR, EU RAR, INDEX) provide a human health risk assessment for TMB exposure in indoor environments, but the Ontario Ministry of Environment [2007] and RIVM [Dusseldorp et al. 2007] reviewed the compound and derived a 24-hour Ambient Air Quality Criterion (AAQC) of 220 µg/m³ for trimethylbenzenes and a chronic air limit value (TCA) of 870 µg/m³ respectively. An industry sponsored study [Firt 2007] derived an RfD of 3 mg/m³ using standard USEPA methods.

POD

The LCI derivation is based mainly on the key studies by Korsak et al. [1996, 2000a, b] and Wiaderma et al. [2002], In accordance with Ontarion Ministry of Environment [2007] CNS effects were chosen as the critical effect observed in 5 subchronic inhalation studies on rats. In subchronic inhalation studies of 1,2,3 and 1,2,4-trimethylbenzene (Korsak et al., 2000a and 2000b; Korsak and Rydzynski, 1996) rats were exposed to 123 mg/m³, 492 mg/m³ and 1230 mg/m³, 6 h/day, 5 days/week for 3 months. The same neurotoxic effects were observed as in the subacute studies. A NOAEC of 123 mg/m³ and a LOAEC of 492 mg/m³ was identified for TMB which includes also local effects in the lung and is below the exposure concentration (1476 mg/m³) at which reprotoxic effects were observed [Sallenfait et al. 2005]. A comparison of the available toxicity data for 1,2,4-TMB and 1,3,5-TMB suggests similar toxicity.

Assessment factors

Standard default assessment factors for adjustment for exposure duration (note 19), study length (note 22), interspecies AF (note 23b) and intraspecies AF (note 24) were applied.
No additional factor for combined effects was introduced, because according to Clark et al. (1989), the NOAEL for a mixture of high aromatic naphtha was without systemic toxicity with a NOAEC of 1800 mg/m³ in a 12 month rat study.

References

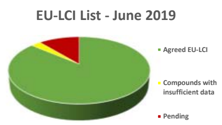
Trimethylbenzenes: 1,2,3-Trimethylbenzene, 1,2,4-Trimethylbenzene, 1,3,5-Trimethylbenzene. Standards, Development Branch, Ontario Ministry of the Environment. http://www.ene.gov.on.ca/envision/env_reg/er/documents/2007/PA05E0031-f.pdf

Dusseldorp A., M. van Bruggen, J. Douwes, P.J.C.M. Janssen, G. Kelfkens. Health-based guideline values for the indoor environment. RIVM report 609021044/2007. RIVM, Bilthoven, the Netherlands. 2007

Korsak, Z. and Rydzynski, K. 1996. Neurotoxic effects of acute and subchronic inhalation exposure to trimethylbenzene isomers (pseudocumene, mesitylene, hemimellitene) in rats. J Occup Med Env Health 9(4):341-349

13

EU-LCI List: State of the art after last meeting in June 2019



EU-LCI master list: 181 compounds

- 156 agreed EU-LCI values
- 5 compounds: no EU-LCI value due to insufficient toxicity data
- 20 listed as pending

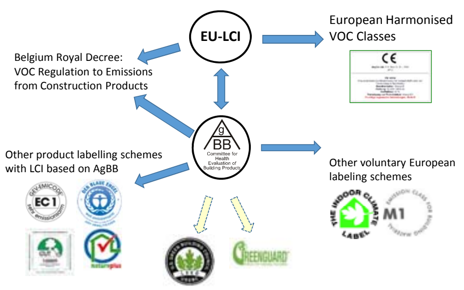
Additional support is provided through funding of technical dossiers for

- 25 substances by UBA (2015-2019)
- 21 substances by the European Commission (2016-2019)

17.10.2019 / CEN/TC 351 Conference_EU-LCI values 14

14

Spreading uses of harmonised EU-LCI values



17.10.2019 / CEN/TC 351 Conference_EU-LCI values 15

15

Conclusions

- Harmonisation of health requirements for construction products is a common objective for all parties involved.
- A complete harmonised EU-LCI list is needed to develop European classes for assessing and controlling health risks from indoor product emissions.
- The EU-LCI Working Group developed a health-protective, science-based and transparent procedure for assessing chemical emissions from construction products.
- In November 2015 the European Commission mandated the EU-LCI WG to continue this work and finalise a common EU-LCI list.
- Possible future challenges: consideration of acute and sensory effects, total exposure to the compounds, multiple sources and ozone-initiated chemistry.

17.10.2019 / CEN/TC 351 Conference_EU-LCI values 16

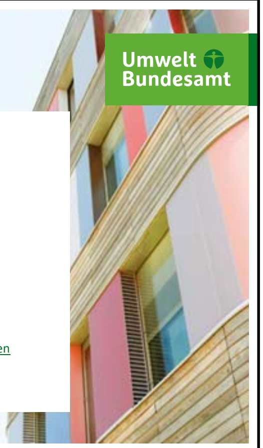
16

Umwelt Bundesamt

Thank You! Questions?

Dr. Ana Maria Scutaru
anamaria.scutaru@uba.de
http://www.umweltbundesamt.de

The EU-LCI Working Group:
https://ec.europa.eu/growth/sectors/construction/eu-lci_en



17