Health-based evaluation of chemical emissions to indoor air from construction products: Development and application of the EU-LCI harmonisation framework

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SUMMARY
A wide range of organic vapour phase compounds are released from construction products that can have an adverse impact on indoor air quality and be a potential risk to human health. A number of labelling schemes concerning emissions to indoor air exist in Europe and these use different criteria for product assessment. This paper reports on the work of the 'Subgroup on EU-LCI Values' that has a mandate from the European Commission concerning the harmonisation of criteria used in product labelling for assessing the risk to health of organic vapour emissions.

PRACTICAL IMPLICATIONS
The application of equivalent criteria within Europe for the labelling of construction products according to their impact on indoor air quality would enhance users' ability to select appropriate products, encourage free trade and promote the development of lower emitting products. The Subgroup on EU-LCI Values is working towards this objective by seeking agreement between stakeholders on the application of best chemical risk assessment practice for product labelling purposes.

KEYWORDS
Vapour phase organic compounds, VOCs, emission testing, CE marking, toxicity

1 INTRODUCTION
There is common acceptance in the indoor air sciences community that control of sources of indoor air pollution, when combined with the provision of adequate ventilation, is a prime consideration for achieving and maintaining good indoor air quality. This has been recognised for several decades with respect to chemical emissions from construction products and has led to the development of a number of labelling schemes to identify and promote the use of low emitting products. Within Europe a range of national regulatory and voluntary schemes as well as sector specific schemes has evolved (Brown et al., 2013). In 2005 the main labelling schemes in place at that time were described and their characteristics compared. The expert group undertaking this work identified the need for harmonisation of these schemes through sharing and adopting best scientific practice, in order to provide clearer information for users and producers and prevent barriers to trade (ECA, 2005).

During 2007-11, European experts in health-related evaluation of construction products and emission testing developed a framework for harmonising the criteria for product labelling schemes, as described in ECA (2012). The experts concluded that the "Lowest concentration

of Interest" (LCI) approach is a feasible strategy for inclusion in product safety assessments with the ultimate goal of avoiding health risks from long term exposure for the general population. Subsequently, a protocol was developed to establish a harmonised list of compounds and their associated EU-LCI values, i.e. 'health-based reference concentrations for inhalation exposure used to assess emissions after 28 days from a single product during a laboratory test chamber procedure' (ECA, 2013). The approach took into account the existing procedures used in some EU Member States and was based on toxicological and risk assessment principles (and in line with principles developed under REACH). It involves three main steps; compilation of toxicological data, data evaluation and derivation of the EU-LCI value on the basis of a total (combined) assessment factor in a standardised factsheet. The derivation factsheet is prepared independently by two or more members of the expert group and subject to review by the whole group. The process is detailed in ECA (2013) and thereby provides a health-protective, science-based and transparent yet pragmatic approach for the evaluation of chemical emissions from construction products.

One driving force for the harmonisation work is the development of labelling requirements for products with respect to emissions to indoor air under the Construction Products Regulation (305/2011/EU) which superseded the Construction Products Directive. Work within the European Committee for Standardisation has resulted in a voluntary Technical Standard (CEN, 2013) for testing of products in environmental chambers to characterise the types and amounts of compounds released. The emission is expressed as the concentration of the vapour phase organic chemical in a theoretical reference room that contains a defined loading of the product and environmental conditions, including air exchange rate. Work on development of this standard began within European and International standards organisations (CEN and ISO) in the early 1990s. The position in early 2016 is that the responsible CEN working group (TC351/WG2) has prepared a draft EN standard which will be put to formal vote for full EN status. The reporting requirements of the draft EN fulfil the requirements of the the main European labelling schemes including reporting of the concentration of organic phase compounds in a reference room for assessment against LCI values.

This paper presents an update of the work of the expert group responsible for the setting of EU-LCI values and describes the planned activities going forward. It also highlights some of the particular challenges associated with this process.

2 PROGRESS WITH SETTING EU-LCI VALUES

Subsequent to the formulation of the protocol for setting EU-LCI values, the expert group published values for 82 compounds of which 61 were *ascribed* values and 21 were *derived* values (ECA, 2013). Ascribed EU-LCI values are given to those compounds that, for whatever reason, had identical or very similar (within 20%) LCI values in the French, ANSES, list of 2009, and the German, AgBB, list. *Derived* EU-LCI values are de novo values that have been established according to the published protocol and taking account of the most recent toxicological information.

The expert group has continued with the derivation of EU-LCI values and has published, as of December 2015, a total of 38 *derived* values. 85 compounds are listed as *pending* with 19 of these as under active review. It is intended, in due course, to re-evaluate all the compounds with *ascribed* EU-LCIs, using the protocol to produce 'derived' values. Table 1 lists the compounds under review in early 2016. These are largely de novo derivations of compounds without EU-LCI values but include seven compounds given *ascribed* EU-LCI values in 2013. Table 2 lists all derived EU-LCI values and the date of adoption. Further information about

the expert group and including the master list of derived, ascribed and pending EU-LCI values is available at www.EU-LCI.org.

Table 1. Compounds under review by the Subgroup on EU-LCI Values in early 2016

No.	CAS no.	Compound	Status of EU-LCI value
1-4	98-82-8	Isopropylbenzene (Cumene)	Derivation pending
1-13	104-72-3	Phenyl decane and isomers	Derivation pending
1-14	6742-54-7	Phenyl undecane and isomers	Derivation pending
2-1	110-54-3	n-Hexane	Derivation pending
4-2	78-83-1	2-Methyl-1-propanol	Derivation pending
4-8	111-87-5	1-Octanol	Derivation pending
5-1	108-95-2	Phenol	Derivation pending
6-1	107-21-1	Ethandiol (Ethyleneglycol)	Derivation pending
6-4	111-46-6	Diethylene glycol	Ascribed EU-LCI under review
6-5	57-55-6	Propylene glycol (1,2-Dihydroxypropane)	Derivation pending
6-9	110-63-4	1,4-Butanediol	Ascribed EU-LCI under review
6-11	6846-50-0	2,2,4-Trimethylpentanediol diisobutyrate	Ascribed EU-LCI under review
6-16	25265-77-4	2,2,4-Trimethyl-1,3-pentanediol monoisobutyrate	Ascribed EU-LCI under review
6-19	110-80-5	Ethylene glycol monoethyl ether (2-Ethoxyethanol)	Derivation pending
6-20	111-15-9	2-Ethoxyethyl acetate	Derivation pending
6-25	112-07-2	2-Butoxyethyl acetate	Derivation pending
6-28	122-99-6	2-Phenoxyethanol	Ascribed EU-LCI under review
7-1	50-00-0	Formaldehyde	Derivation pending
9-1	64-19-7	Acetic acid	Derivation pending
9-2	79-09-4	Propionic acid	Ascribed EU-LCI under review
12-3	872-50-4	N-methyl-2-pyrrolidon	Derivation pending
12-4	556-67-2	Octamethylcyclotetrasiloxane (D4)	Ascribed EU-LCI under review
12-5	541-02-6	Decamethylcyclopentasiloxane (D5)	Derivation pending
12-6	540-97-6	Dodecamethylcyclohexasiloxane (D6)	Derivation pending
12-16	107-50-6	Tetradecamethylcycloheptasiloxane (D7)	Derivation pending
12-17	2687-91-4	N-Ethyl-2-pyrrolidone	Derivation pending

Table 2. List of *derived* EU-LCI Values in early 2016

No.	CAS no.	Compound	EU-LCI (µg/m³)	Year of adoption
1		*Aromatic hydrocarbons*		
1-1	108-88-3	Toluene	2900	2013
1-2	100-41-4	Ethylbenzene	850	2013
1-3	1330-20-7 106-42-3 108-38-3 95-47-6	Xylene (o-, m-, p-) and mix of o-, m- and p-xylene isomers	500	2013
1-5	103-65-1	n-Propylbenzene	950	2013
1-6	108-67-8 95-63-6 526-73-8	Trimethylbenzene (1,2,3-,1,2,4-,1,3,5-)	450	2013
1-7	611-14-3	2-Ethyltoluene	550	2014
1-9	95-93-2	1,2,4,5-Tetramethylbenzene	500	2014
1-10	104-51-8	n-Butylbenzene	1100	2014
1-11	99-62-7 100-18-5	Diisopropylbenzene (1,3-, 1,4-)	750	2013
1-12	2189-60-8	Phenyl octane and isomers	1100	2013
1-16	100-42-5	Styrene	250	2013
1-23	91-20-3	Naphthalene	10	2015
3		*Terpenes*		
3-2	80-56-8	α-Pinene	2500	2013
3-4	138-86-3	Limonene	5000	2014
4		*Aliphatic alcohols*		
4-7	104-76-7	2-Ethyl-1-hexanol	300	2014
6		*Glycols, Glycolethers*		
6-24	111-76-2	Ethylene glycol monobutylether (2-butoxyethanol)	1100	2013
7		*Aldehydes*		
7-2	75-07-0	Acetaldehyde	1200	2013
7-4	123-72-8	Butanal	650	2013
7-5	110-62-3	Pentanal	800	2013
7-6	66-25-1	Hexanal	900	2013
7-7	111-71-7	Heptanal	900	2013
7-8	123-05-7	2-Ethyl-hexanal	900	2013
7-9	124-13-0	Octanal	900	2013
7-10	124-19-6	Nonanal	900	2013
7-11	112-31-2	Decanal	900	2013
7-12	4170-30-3 123-73-9 15798-64-8	2-Butenal (Crotonaldehyde)	5	2015
7-13	1576-87-0 764-39-6 31424-04-1	2-Pentenal	7	2015

No.	CAS no.	Compound	EU-LCI (µg/m³)	Year of adoption
7-14	6728-26-3 505-57-7 16635-54-4 1335-39-3 73543-95-0	Hexenal	7	2015
7-15	2463-63-0 18829-55-5 57266-86-1	2-Heptenal	7	2015
7-16	29381-66-6 2363-89-5 2548-87-0 25447-69-2	2-Octenal	7	2015
7-17	20664-46-4 2463-53-8 18829-56-6 60784-31-8	2-Nonenal	7	2015
7-18	3913-71-1 2497-25-8 3913-81-3	2-Decenal	7	2015
7-19	2463-77-6 53448-07-0 1337-83-3	2-Undecenal	7	2015
9		*Acids*		
9-10	149-57-5	2-Ethylhexanoic acid	150	2014
11				
11-3	106-46-7	1,4-Dichlorobenzene	150	2013
12		*Others*		
12-1	123-91-1	1,4-Dioxane	400	2015
12-2	105-60-2	Caprolactame	300	2013
12-8	96-29-7	2-Butanonoxime	15	2015

An important development with the work of the expert group was the agreement of a mandate in November 2015 to undertake further work on behalf of the European Commission. Originally established as the 'EU-LCI Working Group', the expert group is now known as the 'Subgroup on EU-LCI Values' and reports to DG Growth.

Currently the main task of the Subgroup is to continue with the evaluation of compounds classed as *pending* according to the protocol. This is being undertaken according to the priority list of compounds maintained by the Subgroup secretariat and involves:

- undertaking and facilitating reviews of toxicological data required to inform the derivation of EU-LCI values,
- establishing EU-LCI values for the compounds in the master list that can be viewed at www.EU-LCI.org,
- online publication of EU-LCI values and the rationale applied for their derivation to ensure transparency of the process.

The mandate also requires periodic review of EU-LCI values and consideration of new compounds. In addition the Subgroup has an advisory role with regard to harmonisation of labelling criteria and the requirements for controlling emissions into indoor air. The work is envisaged to be undertaken over a 3-year period primarily for addressing the compounds

described as *pending* in the EU-LCI master list, with further time required to address those remaining with *ascribed* values.

For many of the compounds under review there is limited evidence concerning their toxicity to human health. Therefore appropriate expert judgement and use of published guidance supporting REACH (as described in ECA, 2013) is applied for this chemical risk assessment process. For some compounds the level of data quality is deemed insufficient to establish an EU-LCI even after consideration of a read across approach (www.EU-LCI.org). This highlights an urgent need for further toxicity data on compounds that may be present in products with the potential for emission into indoor air. However the setting of EU-LCI values for many compounds present in products demonstrates how the protection of human health can be improved through consideration of individual compounds and the advantages of progressing beyond the historic reliance on total volatile organic compound (TVOC) values that take no account of toxicity of components of the VOC mixture (Molhave, 2009) and excludes consideration of very volatile and semi-volatile emissions.

3 CONCLUSIONS

EU-LCI values relating to a defined reference room scenario provide a scientific and transparent basis for assessing and controlling health risks from indoor product emissions on the basis of life-long exposure. Their application for product labelling provides a more robust basis for the protection of health than the use only of TVOC values. However establishing EU-LCI values has a number of technical challenges, particularly in cases where there is limited data on the toxicity of a compound. Future challenges for further development of labelling schemes are developing harmonised approaches to take account of sensory effects, acute effects, total exposure to the compounds, multiple source assessment, and ozone-initiated chemistry.

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All members of the EU-LCI group listed at: http://www.eu-lci.org/EU-LCI_Website/Members.html.

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