Project Number: 285463 SUS-CON CP-IP

Sustainable, Innovative and Energy-Efficient Concrete, based on the Integration of All-Waste Materials

Deliverable 7.9

Final assessment of the Health & Safety impacts

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Date:	**21/12/2015**
Workpackage:	WP7
Distribution[2]:	PU
Status[3]:	**Final**
Abstract:	This report provides the final assessment of the Health and Safety Impacts of the concrete solutions developed within SUS-CON project
File Name:	Deliverable D7.9_Final assessment of the Health & Safety impacts

[1] Just mention the partner(s) responsible for the Deliverable

[2] PU: Public, RE: restricted to a group specified by the consortium CO: Confidential, only for members of the consortium; Commission services always included.

[3] Draft, Revised, Final

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1. INTRODUCTION

An environmental sustainability evaluation should always start with complete data and knowledge on content and emissions of dangerous substances. They may or may not be dangerous, but if released or emitted from a construction product they could represent a danger for people or the environment during normal use of the construction products when installed in construction works. Information about toxicity and dangerous properties of different substances is, however, constantly updated and revised. Therefore the list of dangerous substances will hardly ever be complete requiring constant follow up from construction producers and other stakeholders.

SUS-CON final products (blocks, facade panels and floor screeds)cannot be considered wastes , according to Directive 2008/98/EC. Indeed Article 6 of this Directive explains that a waste ceases to be such, when it is subjected to a recovery operation, including recycling, and meets specific criteria to be taken under the following conditions:

a) the substance or object is commonly used for specific purposes;
b) a market or demand exists for such substance or object;
c) the substance or object fulfills the technical requirements for the specific purposes and meets the existing legislation and standards applicable to products;
d) the use of the substance or object will not lead to overall adverse environmental or human health impacts.

The Directive also specifies that the criteria shall include limit values for pollutants where necessary and shall take into account any possible adverse environmental effects of the substance or object. SUS-CON products meet the above criteria falling into product categories clearly defined by reference standards (EN 13318:2002 for screed material and floor screeds; EN 14992:2007+A1:2012 for precast concrete products – wall elements; EN 771-3:2011 for aggregate concrete masonry units - dense and lightweight aggregates) and, moreover, characterization tests were performed to define the harmfulness of such products (see D8.4). In the following considerations are made for a final assessment of the health and safety impacts of the developed SUS-CON concrete solutions according to the current standards.

2. ASSESSMENT ON THE HEALTH AND SAFETY IMPACTS OF SUS-CON SOLUTIONS

The third Basic Requirement of CPR (Construction Products Regulation) relating to construction projects is the following:

"Hygiene, health and the environment".

The construction works must be designed and built in such a way that they will, throughout their life cycle, not be a threat to the hygiene or health and safety of workers, occupants or neighbours, nor have an exceedingly high impact, over their entire life cycle, on the environmental quality or on the climate during their construction, use and demolition, in particular as a result of any of the following:

(a) the giving-off of toxic gas;
(b) the emissions of dangerous substances, volatile organic compounds (VOC), greenhouse gases or dangerous particles into indoor or outdoor air;
(c) the emission of dangerous radiation;
(d) the release of dangerous substances into ground water, marine waters, surface waters or soil;
(e) the release of dangerous substances into drinking water or substances which have an otherwise negative impact on drinking water;
(f) faulty discharge of waste water, emission of flue gases or faulty disposal of solid or liquid waste;
(g) dampness in parts of the construction works or on surfaces within the construction works.

Information on the content of hazardous substances in the construction products improves the possibilities for sustainable construction and allows the development of environment-friendly products. This is complicated by the fact that, for many substances, the necessary test methods have yet to be agreed. Initially it should be limited to substances referred under the Registration, Evaluation, Authorisation and Restriction of Chemicals (**REACH**).

Regulation (EC) n.1907/2006 of the European Parliament and of the Council of 18th December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), came into force on 1st June 2007, and its main objective is to improve the knowledge of the hazards and risks from chemicals and at the same time maintain and strengthen the competitiveness and innovative capacity of European chemical industry.

REACH is the biggest and most important regulation on chemicals ever produced in Europe and, to achieve its ambitious goals, it replaces most of the previous rules of the EU by introducing an integrated system based on four key elements (recording, evaluation, authorization and restrictions). All processes of REACH are governed by the European Chemicals Agency (ECHA), based in Helsinki (Finland), whose aim is to ensure the consistency of the application of REACH across the European Union. REACH aims to ensure a high level of protection of human health and the environment by improving the knowledge of the hazards and risks from chemicals, the promotion of alternative methods for assessment of hazards of substances, while enhancing free movement of substances in the internal market, competitiveness and innovative capacity of European chemical industry.

About 30,000 substances and chemicals are in fact subject to an examination for their dangerousness and placed into a database common to all Member States. Through REACH it is possible to get more and complete information on:

- the hazardous properties of the products handled;
- the risks of exposure;
- the security measures to be applied.

One of the main requirements of REACH is the **registration** of chemicals. This means that each manufacturer or importer, whether he handles or imports the substance in quantities at or above 1 ton per year, must provide to the European Chemicals Agency (ECHA) a range of information in the form of a recording dossier. This information includes the hazards and exposure expected regarding the use of the substance. If a substance is manufactured or imported in quantities at or above 10 tons per year it is required a chemical safety assessment (CSA). At first the dangers arising from the intrinsic properties of the substance have been evaluated (hazard assessment). If the substance meets certain criteria of danger it is also required an evaluation of the nature and extent of exposure (exposure assessment and risk characterization). The purpose is to demonstrate that the risks related to exposure can be controlled through a range of Operational Conditions (OC) and Risk Management Measures (RMM), intended for the use in question. The CSA and its results are documented in a Chemical Safety Report (CSR),

which is a part of the registration dossier. This must be updated whenever new information becomes available.

In accordance with REACH, the compliance of the registration dossier of each substance can be **evaluated** by the authorities. Two types of evaluation are carried out: the dossier evaluation and the substance evaluation. ECHA is required to assess at least 5% of the registration dossiers in each tonnage band to confirm if the information they contain comply with the requirements laid by REACH. If ECHA considers that the dossier does not comply with REACH requirements, it will ask an update. Substance evaluation considers all registration dossiers related to a specific substance and it is a task carried out by the competent authorities of the Member States. This assessment is carried out if the substance may be a risk to human health or the environment.

Substances of Very High Concern (SVHC) included in the candidate list and subsequently included in Annex XIV of REACH will require **authorization** before their use. The authorization is intended to adequately control the risks related to these substances and progressively replace them with less hazardous alternatives or appropriate technologies, where these are economically and technically viable, and ensure the efficient functioning of the internal market.

Finally, **restrictions** may be imposed at EU level on certain substances in order to protect human health and the environment from unacceptable risks posed by chemical substances. Restrictions may limit or prohibit the manufacture, placing on the market or use of a substance and, therefore, may also affect the use of a substance by a downstream user.

REACH has reversed the charge of evidence regarding the safety of chemicals: now it is up to manufacturers, importers and downstream users to ensure that the way they produce and use chemicals not adversely affect human health or the environment. As before the implementation of REACH, downstream users receive information on dangerous substances and mixtures using the safety data sheets. Currently, with the entry into force of REACH, in the case of dangerous substances registered in quantities above 10 tons per year, the safety data sheets can be accompanied by exposure scenarios as annexes. The exposure scenario provides specific information on how to use the

substance safely and the measures through which employees, customers, consumers and the environment can be protected from risks. The table below is an overview of the obligations regarding the reporting under Regulation REACH for registered substances:

Table 1: Obligations of REACH regulation.

TYPE OF COMMUNICATION	SUBSTANCE IS NOT DANGEROUS	SUBSTANCE IS DANGEROUS
Safety Data Sheet (SDS)	• SDS is not required • SDS can be provided voluntarily • Information must be provided in accordance with Article 32	SDS is required (for hazardous substances in accordance with Article 31, paragraph 1)
Exposure Scenario (ES)	ES is not required	ES is required if the manufacturer/importer has made a registration of more than 10 tons/year (for hazardous substances in accordance with Article 14, paragraph 1).

In order to carry out the chemical safety assessment for substances they intend to register, manufactures need to first understand how the substance is used in its life cycle. This analysis is complicated by the fact that, in real life, most of the substances are in the form of component of mixtures, while REACH requires following the life cycle of a substance. The life cycle of a substance begins at the time of manufacture and ends when the substance is transformed into another substance, given in the form of emission into the air or waste water or becomes waste. There are few substances that follow a simple life cycle, in which the substance is manufactured, used as such and issued/transformed into waste. More generally a substance is manufactured and then mixed with other substances in the formulation process. These mixtures are then used as the basis for the formulation of other mixtures, or used as such. Finally, if not emitted, the substances become waste that need to be manipulated safely. REACH expected that registrants collect from downstream user's information regarding the uses of the substance. These information include a list of the uses of the substance during its life cycle, the use of products containing the substance and the waste stage, as well as information on the actual conditions of use, i.e. what are the operating conditions for each use and what measures of risk management have been implemented for each use. Registrants make use of this

information as a starting point for their chemical safety assessment. All chemicals produced or imported in the European Economic Area (EEA), in a range between 1 and 100 tons per year, must be registered by 31 May 2018 at the European Chemicals Agency (ECHA).

Many provisions of **CLP** (Regulation n° 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures) are closely linked to those of REACH. One of the main aims of CLP is to determine whether a substance or mixture presents properties that lead to classify it as hazardous. Once such properties are identified and the substance or mixture is classified accordingly, manufacturers, importers, downstream users and distributors of substances and mixtures should communicate the hazards identified. The labelling of danger allows to communicate the hazard classification to the user of a substance or mixture as well as to report the presence of a hazard and the need to manage the risks associated. The classification of a substance or mixture reflects the type and severity of the intrinsic hazards of a substance or mixture.

CLP Regulation entered into force in January 20th, 2009. However, not all the disposals of the Regulation involve immediate obligations. The transitional arrangements in CLP define two deadlines for classification, hazard communication and packaging of substances and mixtures, namely 1st December 2010 and 1st June 2015. Since June 1st, 2015, before putting them on the market, mixtures must be classified, labelled and packaged in accordance with CLP. Regarding substances, the obligation to classify, labelling and packaging according to CLP applies from 1st December 2010.

The classifications of substances and mixtures according to CLP must be provided in the Safety Data Sheet (SDS) both for substances and for mixtures.

A substance or mixture contained in packaging should be labelled according to the CLP rules:

- if the substance or mixture is classified as hazardous; or
- if it is a mixture containing one or more substances classified as hazardous in concentrations higher than those referred to in Annex II, Part 2 of CLP, even if the overall mixture is not classified as hazardous; or

- if it is an explosive article as set out in Annex I, Section 2.1 of CLP.

Both substances and mixtures are labelled in accordance with the requirements of CLP. It applies a transitional period only to mixtures labelled in accordance with the DPD (Dangerous Products Directive) and already placed on the market before 1st June 2015. These mixtures must be relabelled before 1st June 2017. Labels should be firmly affixed to one or more surfaces of the packaging immediately containing the substance or mixture (Article 31 of CLP). They should be readable horizontally when the package is set down normally. Labels should have a minimum size in relation to the volume of packaging as defined in Annex I Section 1.2.1 of CLP:

Table 2: Prescriptions for labels and pictograms.

Capacity of the package	Dimensions of the label (in millimetres) for the information required by Article 17	Dimensions of each pictogram (in millimetres)
Not exceeding 3 litres:	If possible, at least 52 × 74	Not smaller than 10 × 10 If possible, at least 16 × 16
Greater than 3 litres but not exceeding 50 litres:	At least 74 × 105	At least 23 × 23
Greater than 50 litres but not exceeding 500 litres:	At least 105 × 148	At least 32 × 32
Greater than 500 litres:	At least 148 × 210	At least 46 × 46

It is possible to display the labelling information on the packaging itself rather than set up a label. The label must be in the official language of the Member State where the substance or mixture is placed on the market. It is possible to use more languages than those required by the Member States, as long as the same information is given in all languages and the label is still easily readable.

The elements that the label must contain according to Article 17 of CLP are:

- name, address and phone number of the supplier of the substance or mixture;
- the amount of the substance or mixture in the package made available to the public, unless this quantity is specified in another part of the same package;
- product identifiers and, if appropriate:
  - hazard pictograms;
  - warnings;
  - indications of danger;
  - the appropriate safety advice;
  - additional information.

The labelling elements described above should be reported clearly and indelibly on the labels. Also ensure that these elements are clearly distinguishable from its background and easy readable for size and spacing.

A hazard pictogram is a graphical representation of a particular hazard. Consequently, the classification of the substance or mixture determines the hazard pictograms that should be reported on the label, as defined in Annex I, parts 2 (physical hazards), 3 (health hazards) and 4 (hazards the environment) of CLP. Annex V of CLP shows also the applicability of hazard pictograms according to the specific class and hazard category. The hazard pictograms have the shape of a square set at a point with a black symbol on a white background and a red border (Annex I, section 1.2.1 of CLP).

A warning indicates the reader if a hazard is more or less severe. The label shall include the relevant signal word in accordance with the classification of the dangerous substance or mixture. When the substance or mixture presents a danger more serious, the label should bear the warning "danger" and in case of less severe hazards must bear the warning 'attention" (Article 20 of CLP). The signal word relevant for each specific classification is set out in the tables of Annex I, Parts 2 to 5 of CLP, which show the label elements required for each hazard class.

The hazard statements and precautionary statements shall be encoded with a unique alphanumeric code comprising a letter and three numbers, as specified below:

- the letter "H" (for the hazard) or "P" (for the *precautionary statements*);

- a number designating the type of hazard, e.g. "2" for physical hazards;
- two numbers corresponding to the sequential numbering of hazards such as explosivity (codes from 200 to 210), flammability (codes 220 to 230) and so on.

The number of codes provided for the hazard and precautionary statements under CLP are set out below:

Table 3: Types of hazard and precautionary statements.

Hazard statements: H	Precautionary statements: P
200-299 Physical hazard	1 00 General
300-399 Health hazard	2 00 Prevention
400-499 Environmental hazard	3 00 Reaction
	4 00 Storage
	5 00 Disposal

The label should be updated after each change to the classification and labelling of the substance or mixture when the new hazard is more severe or when the new supplemental labelling elements are required under Article 25 (Article 30 of CLP). If other labelling elements are required, for example if the revised classification is less severe or the phone number changed, the supplier of the substance or mixture shall ensure that the label is updated within 18 months.

Where the classification of a substance or mixture would result in the presence of more than one pictogram on the label, rules of precedence shall be applied in order to reduce the number of pictograms required (Article 26 of CLP). As a general rule, pictograms which indicate the most severe hazard category for each hazard class should be included. An example of the rule of precedence relating to hazard pictograms is the follow:

If it applies the pictogram GHS05 (corrosion), it should not be used GHS07 (exclamation mark) for skin or eye irritation.

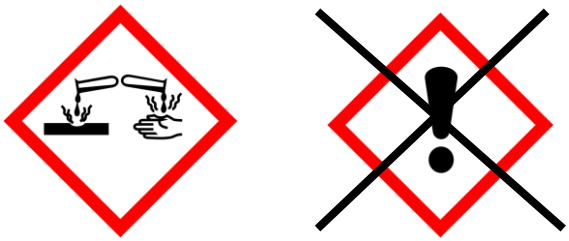


Figure 1: Rules of precedence for pictograms on the label.

The **safety data sheets** are an important communication tool in the supply chain, as they help the actors of the chain to fulfil their responsibilities in relation to management of risks arising from the use of substances and mixtures. The obligation to provide a safety data sheet is stated in Article 31 and Annex II of REACH.

In order to provide information to manufacturers and standards bodies and in order to contain the difficulties arising from the diversity of national rules, in this period in which it's in development the evaluation of European standard methods, the Commission has created a database available at *http://ec.europa.eu/growth/tools-databases/cp-ds/*. The database contains the regulatory requirements of the Member States, who have contributed to this practice and it should help the manufacturers, who have to declare the performance of their products in these States. Germany, for example, has established a system of approvals for health and environmental protection aspects for a number of construction products used indoors and for some construction products with contact to the ground. German building law requires that these products bear the German Ü-mark in addition to the CE mark. Approval is granted by the Deutsches Institut für Bautechnik (DIBt). As a result, construction products with the CE marking from other Member States are often denied access to the German market. The European Commission has requested that Germany to change current rules and practices because it creates a barrier to trade: the court confirmed that it is not allowed to establish a national approval system for properties of products that are dealt with in CE marking and the related harmonized EN standard. At the moment most decisions still are unclear, but DIBt considers to stop the national technical approvals during 2016, and to substitute these with requirements on the construction work (meaning on the building, not on the individual construction product).

In order to develop European evaluation methods for hazardous substances, in 2005 the Commission issued Mandate M/366 to CEN/CENELEC (under Directive 89/106/EEC) asking the development of horizontal evaluation methods for hazardous substances.

Paragraph IV.7 of the Mandate expects that the development of the horizontal measurement/test standards "shall identify and cover all products or product families for which the three following conditions are fulfilled:

- European or national regulations are limiting or banning the emission or content (see IV.8) of dangerous substances;
- existing or potential barriers to trade have been identified;
- measurement/test methods for these specified regulated dangerous substances have already been developed and are used on a national or EU level.

Paragraph IV.9 also expects "Due to regulatory requirements (e.g. the content of restricted and banned substances in construction products), …, it is also intended to consider content measurement/test standards."

The Commission has therefore requested to CEN/CENELEC to develop evaluation methods for hazardous substances regulated by national or European standards. CEN Technical Committee TC/351 carried out the activities required by the Mandate M/366 and has been divided into 5 working groups:

- WG1: Release from construction products into soil, ground water and surface water
- WG2: Emissions from construction products into indoor air
- WG3: Radiation from construction products
- WG4: Terminology
- WG5: Content and eluate analysis in construction products

TC/351, at the moment, adopted the following documents:

CEN/TR 15855:2009 Construction products - Assessment of release of dangerous substances - Barriers to trade

CEN/TR 15858:2009

Construction products - Assessment of the release of regulated dangerous substances from construction products based on the WT, WFT/FT procedures

CEN/TR 16045:2010

Construction Products - Assessment of release of dangerous substances - Content of regulated dangerous substances - Selection of analytical methods

CEN/TR 16098:2010

Construction products: Assessment of release of dangerous substances - Concept of horizontal testing procedures in support of requirements under the CPD

CEN/TR 16220:2011

Construction products - Assessment of release of dangerous substances - Complement to sampling

CEN/TR 16410:2012

Construction products - Assessment of release of dangerous substances - Barriers to use - Extension to CEN/TR 15855 Barriers to trade

CEN/TR 16496:2013

Construction Products - Assessment of release of dangerous substances - Use of harmonised horizontal assessment methods

CEN/TR 16797-1:2015

Construction products: Assessment of release of dangerous substances - Guidance on the statistical assessment of declared values - Part 1: Principles and rules of application

CEN/TR 16797-2:2015

Construction products: Assessment of release of dangerous substances - Guidance on the statistical assessment of declared values - Part 2: Technical and statistical background

CEN/TS 16516:2013

Construction products - Assessment of release of dangerous substances - Determination of emissions into indoor air

CEN/TS 16637-1:2014

Construction products - Assessment of release of dangerous substances - Part 1: Guidance for the determination of leaching tests and additional testing steps

CEN/TS 16637-2:2014

Construction products - Assessment of release of dangerous substances - Part 2: Horizontal dynamic surface leaching test

EN 16687:2015

Construction products - Assessment of release of dangerous substances – Terminology

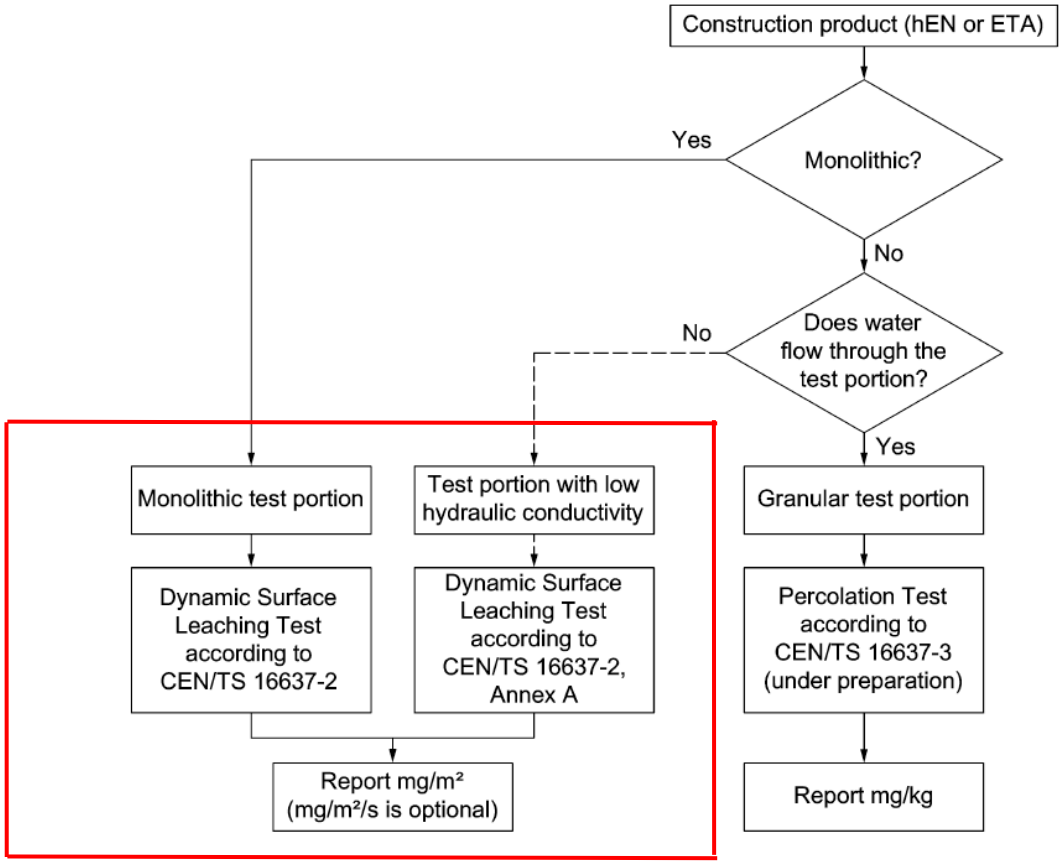
Others documents are under approval or under drafting and their list is available at *http://standards.cen.eu/dyn/www/f?p=204:22:0::::FSP_ORG_ID,FSP_LANG_ID:510793,25&cs=135BD767027D4B4E081006EF46B5E957C.*

For products not covered or not fully covered by harmonized standards, the manufacturer can, according to CPR, submit an application to obtain an European Technical Assessment (ETA). ETA is issued by one of the Technical Assessment Body (TAB) designated for that purpose by the Member States. To establish the necessary assessments for products not covered by harmonized standards, EOTA (the organization gathering the TABs) collected the national provisions concerning the content of harmful substances and has also used the data available from CEN. This has led to the development of a checklist that EOTA organisms apply to evaluate the product for the purpose of issuing an European Technical Assessment. This checklist is available on the website *www.eota.eu*: EOTA TR034: General BWR3 Checklist for EADs/ETAs - Content and/or release of dangerous substances in construction products.

3. CONCLUSIONS

SUS-CON final concrete products were tested, according to currently available standards, in order to ensure their safety for human health and the environment. For specific details as well as for test results annexes of Deliverable D.8.4 can be considered. More specifically, in order to define the potential risk of release of substances, upon contact with water during the intended use of the construction product, leaching tests have been performed. The intent of the test is to identify the leaching behaviour of the product, thereby allowing assessments of the release of dangerous substances from the product to soil, surface water and ground water under intended conditions of use in relation to CE marking and assessment and verification of constancy of performance. CEN/TS 16637-1 is intended to provide clear procedures to determine which test method is appropriate for a given product. From the scheme below, reported in CEN/TS 16637-1, it is possible to define the appropriate method to determine the release of dangerous substances from a construction product to soil and water.

Table 4: Scheme for the determination of leaching tests for construction products.



The dynamic surface leaching test (DSLT) can be applied to SUS-CON products, since it determines, as a function of time, the release of substances from granular construction products with low hydraulic conductivity with a leachant in contact with its surface. A test portion of the product is placed in a reactor/leaching vessel and the exposed surface is completely submerged in the leachant. The leachant is introduced in the reactor up to a given volume of liquid to surface area ratio (L/A ratio), at a given temperature. The concentration of the relevant regulated substances is analysed in the individual fractions of the eluate.

Horizontal standardized assessment procedures have been developed by CEN/TC 351 for the measurement of emissions to indoor air and for the release of substances to soil and groundwater. These methods can be used for assessing the properties of Basic Work Requirement 3, such as the emission and release of dangerous substances from construction products relating to the CE marking. The tests can be used as guideline for SUS-CON products relating to the release of dangerous substances: even if these standards are not mandatory, they provide a guidance to determine values and limits equal throughout Europe.

4. REFERENCES

[1] Regulation n° 1272/2008 (CLP)

[2] Regulation n°1907/2006 (REACH)

[3] http://standards.cen.eu

[4] http://ec.europa.eu

[5] https://osha.europa.eu

[6] www.eota.eu

[7] https://www.dibt.de/