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Construction products - Assessment of release of dangerous substances - Guidance on the use of ecotoxicity tests applied to construction products

Bauprodukte - Bewertung der Freisetzung von gefährlichen Stoffen - Leitfaden für die Anwendung von ökotoxikologischen Untersuchungen auf Bauprodukte

Produits de construction □ Evaluation de l'émission de substances dangereuses □ Préconisations concernant l'utilisation des essais visant à évaluer l'écotoxicité des produits de construction

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European foreword

This document (CEN/TR 17105:2017) has been prepared by Technical Committee CEN/TC 351 "Construction Products - Assessment of release of dangerous substances", the secretariat of which is held by NEN.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN shall not be held responsible for identifying any or all such patent rights.

This document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association.

This Technical Report gives guidance for the combination of the recommended horizontal leaching tests harmonized by CEN/TC 351 with existing biological test methods for the assessment of ecotoxicological properties of eluates of construction products.

Guidance regarding biological tests for the effects of construction products on soil organisms is also included. This document takes into account relevant information that had become available by March 2016. This document is intended as easy-to-use guidance especially for the Group of Notified Bodies, test laboratories and EOTA. Technical committees for construction products (product TCs) are expected to benefit from the information given in the report, if they have been mandated to address ecotoxicity in their product standards or if they are interested to include ecotoxicity in a dossier prepared in the context of qualifications for a "without testing" status.

Introduction

Ecotoxicological analysis of construction products and their eluates and biodegradability of the organic substances in eluates belong to the essential characteristics covered by the basic requirement for construction works “hygiene, health and the environment” from Annex 1 of the Construction Products Regulation [1]. Under the European Commission’s mandate M/366 (see mandate database at http://ec.europa.eu/growth/tools-databases/mandates) and according to the Indicative List (see https://www.nen.nl/ under search term CEN/TC 351) which specifies the mandated parameters, CEN/TC 351 has been assigned to deal with these essential characteristics. Now that the mandated leaching tests from CEN/TC 351 (CEN/TS 16637-2, CEN/TS 16637-3) [2], [3] are available and also work on the methods for the chemical analysis of eluates has progressed, CEN/TC 351 has included a Technical Report on ecotoxicity / biodegradability in its active programme of work. The background for the decision to cover this topic was presented in an open expert workshop in Brussels in April 2014. The conclusions and recommendations of the workshop are presented in Annex A.

The regulatory background for the work is explained in Annex B and information on its possible interface with data generated under the REACH Regulation is given in Annex C. In the context of harmonized specifications for construction products currently only Germany requests performance data on ecotoxicity/biodegradability in certain cases, i.e. when and where a chemical analysis and assessment of the eluates of construction products is considered to be too onerous or not possible due to the lack of analytical methods/data. Examples of products addressed are fire protective products and fire stopping and fire sealing products depending on their ingredients. Ecotoxicity assessment is considered to be especially relevant for the building and for the demolition phase in the life cycle of construction works. These life cycle phases have been covered by the framework of the Construction Products Regulation since 2013.

The majority of existing internationally harmonized ecotoxicity tests were developed firstly to assess the ecotoxic potential of chemicals, waste water or contaminated soils. More recently, these tests have been successfully applied to waste and waste eluates [4] to [7]. These methods can be applied with some modifications for the ecotoxicological characterization of construction products and their eluates. Several studies as well as an international round robin test have been conducted to validate some test methods for construction product eluates and the results have been used as background information [8] to [13]. The validation of the methods for construction products is not yet complete. Further validation of the recommended test procedure is needed, if this TR is intended to be further developed into a CEN/TS or EN (to be decided later).

1 Scope

This Technical Report gives information on existing methods to test ecotoxicity of construction products. Information is given on how to combine recommended leaching tests with biological tests for the aquatic environment and how to avoid possible problems, when performing biological tests. Also suitable terrestrial tests on granular construction products diluted with artificial soil are proposed for a minimum test battery.

Reference has been made as far as possible to existing International and European Standards and guidelines.

The test procedure described in this Technical Report is technically suitable for all construction product eluates and for terrestrial tests on granular or paste-like construction products. However, from the point of view of test efficiency it is recommended mainly for products containing organics or polymers in case chemical analysis alone is not deemed to be sufficient. For inorganic products the chemical analysis is seen as straightforward in construction product eluates and therefore the added value of data received through ecotoxicity tests is seen as limited.

2 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

2.1
biodegradation
mineralization of organic compounds by bacteria and fungi to carbon dioxide, water and inorganic compounds

2.2
control
mixture of control medium and organisms used in the test without test sample

2.3
control medium
combination of water and additives (e.g. nutrients, salts) used in the test

2.4
dilution level
D
reciprocal value of the volume fraction of test sample in dilution water in which the test is conducted

EXAMPLE 250 ml of test sample in a total volume of 1 000 ml (volume fraction of 25 %) represents dilution level $D = 4$.

[SOURCE: EN ISO 15088:2008 [14], 3.2, modified - "waste water" replaced by "test sample"]

2.5
dilution soil
soil added to the test sample to prepare a series of defined dilutions

Note 1 to entry: The origin and composition of the soil is specified in the specific test.

2.6
dilution water
water added to the test sample to prepare a series of defined dilutions

[SOURCE: EN ISO 20079:2006 [15], 3.7]

Note 1 to entry: The composition of the water is specified in the specific test.

2.7
effective concentration
EC_x
concentration of the test material in water or sediment that causes x % change in response during a specified time interval

[SOURCE: ISO/TS 20281:2006 [16], 3.8.1]

2.8
eluate
aqueous solution recovered from a leaching test

[SOURCE: CEN/TR 16110:2010 [4], 3.2]

2.9
leaching test

laboratory test during which a construction product is put into contact with a leachant under strictly defined conditions for the determination of the release of substances into water

2.10
lowest ineffective dilution
dilution factor
LID

lowest ineffective dilution tested, expressed as dilution level *D* (2.4), at which no inhibition, or only effects not exceeding the test-specific variability, are observed

[SOURCE: EN ISO 15088:2008 [14], 3.5]

2.11
storage time
period of time between filling of the sample container and further treatment of the sample in the laboratory, if stored under predefined conditions

[SOURCE: EN ISO 5667-3:2012 [17], 3.4]

2.12
test material
material to be tested

[SOURCE: ISO 17126:2005 [18], 3.3]

3 General information on ecotoxicity assessment

3.1 Basic approaches for ecotoxicity estimation

Ecotoxicity can be estimated using two approaches: a chemical-specific approach and a toxicity-based approach. In the first situation, results of chemical analyses are compared to quality criteria or threshold values to estimate toxicity. This approach is used, e.g. for the evaluation of biocides and is not covered by this report. In the second case, toxicity is measured directly using biological toxicity tests. These two approaches complement each other. However, determination of individual target substances in complex mixtures of unknown or undisclosed composition does not allow a relevant estimation of toxicity via the chemical-specific approach. For such samples, the toxicity based approach is recognised to be practicable to estimate ecotoxicity.

Ecotoxicity tests integrate the effects of all dangerous or hazardous substances including additive, synergistic and antagonistic effects. They are sensitive to the bioavailable fraction of the substances only and integrate the effects of all dangerous substances, including those, not directly addressed by chemical analyses. In principle there is no organism which can be used to test all possible effects on ecosystems. Only a few ("model" or reference) species representing relevant ecological functions can be tested in practice.

3.2 Principles for ecotoxicity testing

Biological tests are suitable for determining the effect of e.g. eluates or of solid material on test organisms under specific experimental conditions. These effects can be enhancing or inhibiting, and can be determined by the reaction of the organisms (e.g. death, growth, proliferation, morphological and physiological changes). The apparent toxicity measurable in the biological test is the result of the interaction between the constituents of the tested sample and the test organism. The protective potential of the biological system, for instance by metabolic detoxification and excretion, is an integral part of the biological test. Biological tests also include those tests which examine the effect of organisms on substances (e.g. microbial degradation studies).

However, the sample to be tested can pose experimental challenges on biotesting. These challenges should be paid attention to, when testing samples that contain sparingly soluble, volatile, unstable, coloured substances and/or suspended, sometimes colloidal, particles. The complexity and heterogeneity of materials should be taken into account when performing biotests. Special care should be taken, if the test material is instable due to reactions and processes such as photo-degradation or biodegradation. If spectrometric measurements are applied, turbidity and colour of the eluate should be considered.

Ecotoxicity tests can be applied to construction product eluates (aquatic tests) or to test samples of construction products mixed with artificial soil (terrestrial tests) to identify their potential hazardous intrinsic properties with respect to the environment, if the construction product comes into contact with soil or water in its intended use. In general aquatic test are performed with construction product eluates mixed with dilution water but in a few cases liquid construction products could directly be mixed with dilution water. The result of the biological test refers primarily to the organism used in the test and the conditions stipulated in the test procedure. A harmful effect stated by means of standardised tests can justify concern that aquatic or terrestrial organisms and ecosystems might be endangered. The results, however, do not permit direct or extrapolative conclusions as to the occurrence of similar effects in the aquatic or terrestrial environment.

The interpretation of the ecotoxicological testing is related to the purpose of testing and the intended use scenario for the tested product and further criteria when defined in regulations or guidelines. Depending upon the purpose of testing, technical choices can be made to enhance the reliability of the results.

Any construction product that falls under the scope of the leaching tests in the CEN/TS 16637 series may also be assessed with biological tests, when and where desired. Currently biological tests are only requested and applied in certain cases, if a chemical assessment of eluates from the CEN/TS 16637 tests is not considered to cover all organic substances with hazardous properties that may be released from a product [19], [20]. For construction products in direct contact with soil in their intended use also terrestrial tests are a relevant assessment tool.

3.3 Information on the biological test battery

Sensitivity of animal and plant communities to toxicants may vary significantly from one species to another. If testing is performed on one species or function only, the high diversity in the sensitivity between species results in a high level of uncertainty. Only a combination of several ecotoxicity tests can give a clear view of the toxic effects of product samples. The recommended approach for the ecotoxicological characterisation of the toxicity of construction products and eluates is therefore to use a battery of tests with several species belonging to different taxonomic groups and trophic levels.

Two approaches can be applied for selecting bioassays in order to establish a test battery: (i) an "a priori" method, in which the selection is made, independently of the results, according to decision criteria such as standardization of the method, ecological relevance of test organisms, or cost, (ii) an "a posteriori" method, in which the selection is made after analysing test results obtained on a large series of bioassays. Regarding the "a priori" approach, there is a good overall agreement on the criteria to be considered to establish a test battery. These are: robustness, relevance, reproducibility, sensitivity, endpoints (chronic, acute), standardisation status, discriminative power, cost, ease of use. The importance of each individual criterion is clearly related to the aim of the ecotoxicological assessment.

These criteria fall into three main categories (see Table 1 below).

Table 1 — Relevant criteria for establishing a test battery for construction products

Decision categories	Criteria
General criteria	— Good ratio cost efficiency of selected tests — Lack of test results redundancy — Ability of discrimination between samples
Test battery organization	— Combination of different trophic levels — Combination of assessment endpoints (e.g. acute, chronic, genotox) — Are the most important exposure pathways related to construction products (soil, groundwater, surface water) covered?
Test methods included in the test battery	— Ecological relevance: e.g. the species dominance in terms of abundance or biomass, representation of trophic level — Ecological tolerance: degree of sensitivity of the species to changes in environmental conditions — Keeping/breeding: the easiness and quickness of the species to be bred in the laboratory — Practicability: Are a plenty of or few resources (costs, staff, and time) required to perform the test? — Reproducibility of the results obtained — Sensitivity of the species — Standardization: Is the method published as a validated (international) guideline, preferably ISO?

In ecotoxicology the measured endpoints are intended to be indicative for potential negative effects on the survival of the populations (not of the individuals). Relevant endpoints therefore are mortality and reproduction impairment. Next to these direct endpoints also the presence of genotoxic substances

(inducing DNA damage) and hormone disturbing compounds (inducing reproductive impairment) are considered as relevant for interfering with normal population survival.

Due to general reasons of practicability, an ecotoxicological test battery usually consists of three tests for each medium considered (aquatic, terrestrial), often each divided into three trophic/taxonomical groups. The current approaches for the evaluation of test results are described in Annex E.

4 Sampling and transport of construction products

In addition to the relevant product standards guidance on sampling of construction products is given in CEN/TR 16220 [21]. Also guidance given in EN 15002 [22] on how to produce representative test portions from laboratory samples can be applied to construction products before biological tests are carried out.

In the case of aquatic tests and in order to generate suitable eluates for ecotoxicological testing, it is recommended additionally to use the guidance for taking laboratory samples of products and for transport, storage and product sample pre-treatment for leaching tests given in CEN/TS 16637 [23], [2] and [3], EN 14735 [24] or EN 16105 [25] and in relevant product standards or specifications.

5 Leaching procedures for ecotoxicological testing

5.1 Suitable leaching tests and selection of fractions from leaching tests

5.1.1 General

A leaching method should be selected using guidance given in CEN/TS 16637-1 [21]. Eluates from the DSLT (CEN/TS 16637-2) and column test (CEN/TS 16637-3) are considered to be basically suitable for ecotoxicological tests on the basis of current experience.

Products that come into contact with water only occasionally in their intended use may not be stable in a test set up with long time immersion in water. For these products a leaching test with short immersion phases — EN 16105 Laboratory method for determination of release of substances from coatings in intermittent contact with water [25] — is recommended instead.

The results of biological tests with the same product, but using a different leaching test are not comparable due to the different test conditions.

The selection of fractions from leaching tests for biological tests depends on the purpose of the testing approach. Generally, for many construction products the maximum effect is expected to occur with the first elution steps. It is often also practicable to test the first two fractions, because organic substances are not always stable during long immersion periods.

An alternative option for the selection of fractions is to define an indicative parameter (e.g. TOC or substances of interest) which is analysed in each eluate fraction. The two fractions with the highest amount of the indicative parameter are combined and tested.

For construction products with continuously releasing compounds, those fractions with the longest contact time may exhibit higher effects and the fractions should be taken from an advanced stage of the leaching procedure. By comparison of effects from different fractions, the longer term behaviour of the construction products may be assessed. The use of this option should be justified with an indicative parameter.

5.1.2 Dynamic Surface Leaching Test (DSLT) CEN/TS 16637-2

The test describes a tank test for monolithic construction products of > 40 mm edge length in all directions and for plates or sheets with a surface area exposed to the eluate of > 100 cm2. In the standard procedure, this test is carried out for 64 days, while the eluate water is replaced at distinct time intervals (after 6 h, 24 h, 2,25 d, 4 d, 9 d, 16 d, 36 d and 64 d).