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

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

Produits de construction - Évaluation de l'émission de substances dangereuses - Utilisation de méthodes d'évaluation horizontales harmonisées

Bauprodukte - Bewertung der Freisetzung von gefährlichen Stoffen - Verwendung harmonisierter horizontaler Bewertungsmethoden

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Foreword

This document (CEN/TR 16496:2013) 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 [and/or CENELEC] 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 selection and integration of the recommended horizontal product testing protocols on dangerous substances harmonised by CEN/TC 351 into hENs and EADs. Since the work in CEN/TC 351 in cooperation with the European Commission and its Expert Group on Dangerous Substances (EGDS) and the product TCs is a work in progress, some subjects and issues remain open for the time being. However, the results of the work of CEN/TC 351 are now mature enough for practical implementation in product standards and EADs.

This document takes into account relevant information that had become available by March 2013 through the activities in the working groups and task groups of CEN/TC 351 as well as the guidance provided by the European Commission.

This document is intended as easy-to-use guidance especially for product TCs and EOTA Working Groups (or equivalent groups under the Construction Products Regulation). Where reference is made to ‘Product TCs’, EOTA WGs are also meant where appropriate.

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1 Introduction

1.1 General

The Construction Products Directive 89/106/EEC (CPD) contained six essential requirements for works that gave rise to a number of 'essential characteristics' for products that had to be covered by European Technical Specifications (ETS) for construction products (harmonised European Standards (CEN) and European Technical Approvals (EOTA)). As derogation from this rule, essential requirement No 3 “Hygiene, health and the environment” (ER3) was dealt with via a convention in the ETS which did not take it directly into account, mainly due to the absence of European harmonised test methods. In order to solve this problem, the European Commission gave CEN, the European Committee for Standardization, a mandate (M/366) in 2005 to develop European harmonised test methods for the assessment of release or emission of dangerous substances from construction products.

From July 2013 the CPD has been replaced by the Construction Products Regulation (Regulation (EU) No 305/2011, CPR). The fundamental principles of the CPR are the same as for the CPD. The CPR now refers to basic requirements for construction works (BRCWs) instead of ERs, but the same six functional requirements as for the CPD are still there, supplemented by a seventh, the “Sustainable use of natural resources”, and BRCW 3 is extended to the construction and demolition phase. However, it is expected that the work in CEN/TC 351 according to mandate M/366 will be carried out under the terms and conditions of the CPD with a focus on release and emission in the use phase of construction works.

Mandate M/366 requires that CEN develops horizontal test methods that, as far as possible, are based on existing test methods. This means that European harmonised test methods will not be developed for each construction product separately. The methods should be preferably applicable to all constructions products as defined in the CPR as far as they are covered by BRCW 3. The intention is to avoid the unnecessary and onerous development of product specific test standards for a multitude of construction products and to minimise the amount of costly testing. The horizontal approach is described in detail in CEN/TR 16098.

Furthermore, according to the guidance of the EC (Decision 192, CEN/TC 351 meeting in Berlin on 2013-02-11/12), CEN/TC 351 is asked to provide horizontal methods reflecting the state of the art. Different test methods or testing options can be considered by CEN/TC 351 when technically justified because of different conditions of use, different end uses or product characteristics, but not because of differences in regulations.

In order to apply the horizontal test methods correctly to individual construction products, some product specific additions remain necessary. For example, aspects such as pre-treatment and preconditioning of test specimens cannot be completely specified horizontally but require product specific additions. The necessary product specific additions to the horizontal test standards must be included in the harmonised product standards for the implementation of BRCW 3.

The European Commission has recently amended ten and is currently amending some further existing construction product mandates issued to CEN to include detailed requirements for BRCW 3. The updated mandates include the requirements for each harmonised product standard. For each hEN or mandated prEN, the relevant release/emission scenarios and the relevant regulated dangerous substances[1)] are listed. The CEN product TCs are obliged to amend their product standards using the mandate amendments as a checklist for including BRCW 3-related requirements.

This Technical Report (TR4 of mandate M/366) gives instructions on which aspects related to the horizontal test methods are important to address when amending product standards. The report is intended as guidance for CEN product TCs for the revision of product standards in regard to dangerous substances. The report focuses on the use of the harmonised test standards. The

1) The term regulated dangerous substances refers to dangerous substances for which performance criteria have been defined in notified regulations in the EEA.

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possibilities to avoid testing through the use of e.g. descriptive elements like positive or negative lists in product standards are not covered by this report. With respect to this issue, the product TCs may consult the guidance given by the European Commission including the amended product mandates.

The examples described in Annex A and Annex B show how the guidance given in this Technical Report can be adopted in a product standard. They illustrate a possible way to implement the horizontal test standards of CEN/TC 351 into product standards by product TCs. The examples are inspired by work in progress on existing harmonised product standards. Their intention is to provide generic, non-product specific assistance; they are not the only possible solution confirmed by the powers that be.

1.2 Mandate amendment for BRCW 3 and the product TC's answer

The European Commission describes in the amendments to the various product mandates for dangerous substances the tasks the product TCs are expected to carry out, when preparing an answer to the mandate amendment. Hereunder, as an example, the relevant text from mandate M/103 rev.1 on Thermal Insulation Products is cited[2)] the specifications in the other amendments are comparable.

Description of the mandated work

The attached annex provides an overview on national notified regulatory requirements that have been linked by several experts of the Commission's expert group on dangerous substances to products covered under mandate M/103.

CEN/TC 88 has to assess the list and to take it completely into consideration when describing and justifying its selection of substances and their relevance in its work programme, in particular on the following aspects:

- If these substances may be present in products covered by mandate M/103 and in all existing harmonised product standards or harmonised product standards under development;
- If these substances are likely to emit from the above mentioned products and if these emissions are close to existing limit values in regulations referred to in this document[6)];
- If there is available data, particularly where the above mentioned products have been tested in the past on either content or emission of these substances by national authorities/bodies[7)].

NOTE The work programme of the product TC will be used for further discussion in the EGDS between the Commission, national experts and experts of the product TC and CEN/TC 351.

CEN has to provide in existing harmonised product standards or harmonised product standards under development either

- clear and transparent definitions of products[8)] that will make further requirements for testing for dangerous substances obsolete or/and
- a set of clear and transparent requirements for products which will be laid down in product standards for these specific product families or relevant sub-families.

Execution of the mandate

The standards resulting from this amended mandate will have to be delivered by no later than 12 months after the adoption of technical specifications developed under the mandate M/366.

2) See: http://ec.europa.eu/enterprise/standards_policy/mandates/database/index.cfm?fuseaction=search.detail&id=455#

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After formal acceptance of the mandate, CEN will present to the Commission within 2 months a detailed proposal for the Work Programme. Having regard to the scope of this mandate this Work Programme will include

- a selection and clear indication of substances and materials indicated in the annexes of this mandate which are considered as relevant in products covered by mandate M/103, or a justification for excluding substances or materials of the attached annex from standardization work in the relevant product TC;
- a list of all product standards considered to require declaration categories for the potential release or content of regulated dangerous substances to enable fulfilment of regulatory requirements;
- the timetable for the development and the publication of each amended standard; if not all regulated dangerous substances can be dealt with in one phase or generation of the standard, it should be explained how and when to handle the other substances and which steps still need to be taken.

[6)] The possibility of excluding products, components or substances from testing will be dealt with in detail in another document describing a system of defining products "Without Testing" or "Without Further Testing".

[7)] If products have not been subject to testing for dangerous substances (or specific substances now mentioned in this document have not been assessed in the past), it will be helpful to assess the priority given by regulators or the lack of useful technical instruments for the assessment, but does not necessarily indicate that Member State authorities might not insist on these specific requirements during the development of a standard or *after* it has been finalised. Therefore, each substance should be assessed carefully by the TC and in case of doubt clarification should be requested from the Commission.

[8)] If necessary with regard to materials, constituents, admixtures, etc.

1.3 FAQs on mandate amendments for dangerous substances

These questions on mandate amendments were posed in the CEN/TC 351/TG2 workshop on 8 March 2011 by the representatives of product TCs. The answers have been provided by the Commission Services and updated afterwards to reflect the position in June 2012.

1. *Can a product TC incorporate the forthcoming TS test methods from CEN/TC 351 into its harmonised product standard(s) or should the product TC wait until a fully validated EN test method from CEN/TC 351 is available?*

The mandate amendments ask for the technical specifications of CEN/TC 351 to be incorporated within one year of their availability (i.e. until end of 2014 at the latest according to the current time table of CEN/TC 351). All product TCs with relevant mandate amendments are expected to incorporate the TS test methods into their hEN, where relevant, after acceptance by the European Commission of the work programme to the mandate amendment. The TS test methods can first be added to the voluntary part of the standard if the product TC wishes to wait for fully validated EN test methods before incorporating clauses on the new test methods into Annex ZA. Conversely, the product TC may incorporate clauses into Annex ZA which directly refer to the TS methods, if it wishes to do so.

If the fully validated EN test methods of CEN/TC 351 should not become available until the second half of 2016, the TS methods are considered established enough to be called up by Annex ZAs as a mandatory basis for declaring the performance of a product in regard to dangerous substances. This deadline is intended to ensure that a potential delay of the full validation of the CEN/TC 351 test methods does not further delay the implementation of the mandate amendments. As soon as the EN test methods become available, they must be used. For the change from TS to EN test method in a hEN product standard, a corrigendum is adequate and a full revision of the hEN is not necessary.

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2. *Which system of attestation of conformity/assessment and verification of constancy of performance will be applied to BRCW 3?*

The AoC/AVCP system(s) will remain the same as in the original product mandate. Member States may ask the Commission to introduce another AoC/AVCP system via a Commission Decision (legal act). So far such requests have not been made.

3. *When will notified bodies become available for the new test methods for dangerous substances?*

A sector group for dangerous substances has been set up in the Group of Notified Bodies. It is expected that member states will be able to nominate notified bodies for the new test methods as soon as they are available as CEN/TS (from end of 2013). According to Annex V of the CPR a reference to a harmonised product standard is not necessary when nominating notified bodies for horizontal characteristics such as dangerous substances.

4. *What should the product TC do, when new national regulations for dangerous substances concerning its products emerge after the TC has received its mandate amendment?*

The product TC may deal with any additional requirement in its draft answer (work programme) to the mandate amendment. Furthermore, a product TC could inform the Commission about new national requirements that come to its attention at a later stage. However, the product TC is not obliged to take any new requirements into account formally before the Commission Services have revised the mandate amendment for dangerous substances accordingly.

5. *Is it foreseen that a TC may create its own classes or levels for the declaration of test results according to the new CEN/TC 351 methods?*

For the performance declaration of emissions into indoor air the Commission Services have already provided a framework for classification, which is expected to be finalised in the course of 2013. A supporting activity is currently being carried out by the DG JRC with the aim of providing harmonised reference values for VOC emissions from construction products (so called Lowest Concentrations of Interest, LCI). As soon as the harmonised LCI become available, they will form the basis for the classification of emission performance within the technical framework provided by the DG ENTR Construction Unit. For release into soil and water, the possibility of creating horizontal declaration formats is currently being scrutinised by the Commission. The classes of convenience for indoor air or other declaration formats of convenience for release into soil and water that reflect the relevant national requirements are a possible future addition to the horizontal tool kit provided by CEN/TC 351, which may become available e.g. as informative annexes in the CEN/TS or EN test methods. If a product TC has identified the need for specific classes or levels, it should contact the European Commission for further guidance and a decision.

6. *The scope of BRCW 3 (under the CPR) is wider than the scope of ER 3 (under the CPD). Has this been taken into consideration in the amendments of the product mandates? If not, how should a product TC address any additional requirements under BRCW 3?*

The amendments of the product mandates are based on the requirements under the CPD and each product TC is expected to start work under the framework of the CPD. The Commission (with the input of the EGDS) will assess in the course of 2013 if there is any need for additional testing under BRCW 3 for each product group. Only if the Commission concludes that additional requirements have to be fulfilled, the relevant product mandates will be amended, which would require additional work within specific product TCs. In this case, the methods developed for assessment of the in use phase by CEN/TC 351 may also be suitable to assess other phases of the life cycle, if considered necessary.

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2 Harmonised horizontal test methods for the assessment of the release of regulated dangerous substances and the possibilities and limitations of their use

2.1 Release into soil, groundwater and surface water

2.1.1 Horizontal test methods

CEN/TC 351/WG 1 has drafted two generic horizontal testing standards for release of substances: a dynamic surface leaching test (DSLT) for leaching from monolithic, plate-like or sheet-like construction products (WI 00351009, prCEN/TS 16637-2) and an up-flow percolation test for the release of substances from granular construction products (WI 00351010, expected as prCEN/TS 16637-3).

In early 2013, the technical work on prCEN/TS 16637-2 was completed and this draft standard submitted for TC Approval. It is foreseen to be published as a Technical Specification at the beginning of 2014. It then will be subject to round robin validation. In March 2013, prCEN/TS 16637-3 was still under development.[3)]

In addition, CEN/TC 351/WG 1 is drafting a Technical Specification for CEN Product TCs and EOTA experts for selection of the appropriate release tests for their product(s) (WI 00351008, prCEN/TS 16637-1). PrCEN/TS 16637-1 gives background information on release scenarios and specific influencing factors. The general part of this Technical Specification and its content regarding prCEN/TS 16637-2 have been completed, including robustness validation, and submitted for TC Approval. Once prCEN/TS 16637-3 becomes available, prCEN/TS 16637-1 will be updated with the remaining part and the revision will be submitted for TC Approval.

PrCEN/TS 16637-2 (DSLT) determines the surface dependent leaching behaviour of monolithic or plate-like or sheet-like construction products under dynamic conditions (as a function of time). The test (DSLT) produces eluates, which can subsequently be characterised by physical, chemical and ecotoxicological methods. Organic coatings for metals are not included in the scope of the DSLT, but the validation work may lead to modifications and additional scope for use of the method. Metals and metallic coatings are so far excluded from the scope and this Technical Report (CEN/TR 16496) cannot therefore provide any guidance on this subject.[4)] A special case of the DSLT is a test for “Granular construction products with Low Hydraulic Conductivity" (GLHC). The test for GLHC is specified in an Annex of prCEN/TS 16637-2.

The prCEN/TS 16637-3 (up-flow percolation test) determines the leaching behaviour of non-volatile inorganic and organic substances from granular construction products (with or without size reduction). Granular construction products are subjected to percolation with water as a function of liquid to solid ratio under specified percolation conditions. The resulting eluates can subsequently be characterised by physical, chemical and ecotoxicological methods. Results are presented as a function of the liquid to solid ratio. The test is not suitable for substances that are volatile under ambient conditions.

These test procedures can be used for assessing release from construction products in different release scenarios. To compare test results expressed e.g. as concentrations in eluates with regulatory requirements expressed e.g. as concentrations in soil or groundwater under construction works, a modelling step is necessary. This modelling step may be different in different regulations and is not covered in the CEN/TC 351 test methods. Therefore, the test results are unlikely to be directly comparable to limit values. However, it is expected that the national regulations will evolve to express criteria which accord with the CEN/TC 351 methods.

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3) Details on the availability of the standards and reports of CEN/TC 351 can be found in the CEN/TC 351 secretary's report which is updated regularly (latest version N0465. 2013-01-10).

4) Guidance could be offered if the regulatory requirements linked to BRCW 3 make it necessary. So far, no European or notified national provisions that require the determination of the leaching performance of metal products have been identified. CEN/TC 351/WG 1 has not yet harmonised any test methods for metals and metallic coatings, because mandate M/366 covers only test methods required by existing regulations.

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In prCEN/TS 16637-2 and prCEN/TS 16637-3 all aspects for determining release from construction products are specified. These cover:

a) general aspects of taking laboratory samples for testing;

b) general aspects of preparing test specimens from the laboratory sample;

c) general aspects of equipment and apparatus;

d) general aspects of the leaching procedure (e.g. type of leachant, temperature, L/A ratio; collection of eluates and total duration of the test);

e) expression of test results and calculation of release;

f) general aspects of taking product laboratory samples for testing;

g) general aspects of making test specimens from the laboratory sample.

The methods for the analysis of eluates are under development in CEN/TC 351 WG 5 (see 2.4).

2.1.2 Implementation of TSs in harmonised technical specifications

It is foreseen that all relevant harmonised Technical Specifications (hEN and EADs) specify the most appropriate of the two test methods according to the rules given in prCEN/TS 16637-1 and then provide product-specific detail such as:

a) taking product laboratory samples for testing;

b) making test specimens from the laboratory sample.

2.2 Emission into indoor air

2.2.1 Horizontal test method

CEN/TC 351/WG 2 has drafted a harmonised horizontal test method for emission into indoor air (CEN/TS 16516). This method has gone through robustness validation and will be published as a Technical Specification in 2013. Based on another validation step (statistical evaluation of already performed round robin intercomparison test), the TS is expected to become a fully validated EN in 2016.

The method specifies all aspects of emission into indoor air testing that are generic. It is not expected that product specific deviations from the generic specifications will be necessary. The following aspects are covered:

a) general aspects of taking product laboratory samples for testing;

b) general aspects of making test specimens from the laboratory sample;

c) European Reference Room for which all test results are calculated, including a selection of four different product loading factors (walls, flooring or ceiling, small surfaces such as doors, very small surfaces such as sealants and sealings; see also 3.3.3);

d) operation of test chamber;

e) taking air samples from test chamber, and analysis;

f) reporting;

g) quality requirements.

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2.2.2 Implementation of TS in harmonised technical specifications

It is foreseen that all relevant harmonised Technical Specifications (hEN and EADs) specify this method and then provide product specific details such as:

a) taking product laboratory samples for testing;

b) making test specimens from the laboratory sample;

c) selection of the most appropriate loading scenario.

Deviations from the generic parts of the method are not expected unless its direct application would not be meaningful with respect to the intended conditions of use for a specific product.

2.3 Radiation from construction products

CEN/TC 351/WG 3 “Radiation from construction products” is developing, as its main task, a standardized measurement method for determining the activity concentrations of three relevant naturally occurring radionuclides (gamma spectrometry). A specific convention for expressing results in the form of an activity concentration index (I), as defined in EC guidance Radiation Protection RP 112, is included in the re-cast version of the ”Council Directive laying down basic safety standards for protection against the danger arising from exposure to ionising radiation” (Basic Safety Standards, BSS) [5)] and in Austrian, Czech, Finnish and Polish regulations. This index is a screening tool for identifying materials that might be of concern. For the calculation of the activity concentration index (I) measurements for Radium-226, Thorium-232 and Potassium-40 will be required.

Work on a TS "Construction products — Assessment of release of dangerous substances — Determination of activity concentrations of Radium-226, Thorium-232 and Potassium-40 using gamma spectrometry" was approved as an active work item in the CEN/TC 351 plenary meeting in June 2011. The title clearly describes the objective but the method will also specify sampling, test sample preparation, and the execution of the test. It includes background subtraction, energy and efficiency calibration, analysis of the spectrum, calculation of the activity concentrations with the associated uncertainties, the decision thresholds and detection limits, and reporting of the results. The method described in the standard is applicable to samples from products consisting of single and multiple material increments.[6)]

In the CEN/TC 351 Workshop of 30 October 2009[7)] possible work on radon exhalation was also discussed. Radon exhalation is currently addressed only by the Austrian regulation by an indirect determination. As it’s not addressed by the other identified regulations on radiation under the scope of the CPD, it was decided not to start developing a radon exhalation measurement and dose assessment method at this stage. However, CEN/TC 351/WG 3 has been asked to deliver a state of

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5) The draft of the revised version of Basic Safety Standard Directive (BSS) was published by the European Commission in September 2011 (COM(2011) 593 fin). The draft will be discussed in the Council's Atomic Questions Group in 2013. Considering the complexity of the issues, implementation of the Directive is expected to take place not earlier than 2014-2015.

6) From the CEN/TC 351 document on Terminology, prEN 16687:
3.1.2
increment
individual portion of product collected by a single operation of a sampling device which will not be tested as a single entity, but will be mixed with other increments in a composite sample

7) The CEN/TC 351 Workshop on Radiation from Construction Products was held on 30 October 2009 in Brussels to discuss how to implement the mandated work on radiation from Mandate M/366 and to clarify how the revision of the European Basic Safety Standards Directive for radiation protection (BSS) by EURATOM interfaces with CEN/TC 351 work. Some 25 experts attended including authorities from the member states that regulate in this field, experts on construction products and on the technical aspects of radiation as well as civil servants from DG Enterprise and DG TREN. This resulted in five recommendations that were adopted by CEN/TC 351 Plenary and by the EGDS in 2010 and into the establishment of CEN/TC 351/WG 3 “Radiation from construction products”.

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