TECHNICAL REPORT

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ICS

English Version

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

Produits de construction - Evaluation de la liberation des substances dangereuses - Methodologies applicables aux cas 'Sans essai' (SE) et 'Sans essai supplementaire' (SES)

Bauprodukte - Bewertung der Freisetzung von regulierten gefährlichen Stoffen aus Bauprodukten auf der Grundlage der WT-, WFT- und FT-Verfahren

This Technical Report was approved by CEN on 3 February 2009. It has been drawn up by the Technical Committee CEN/TC 351.

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COMITÉ EUROPÉEN DE NORMALISATION
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Executive summary

Most EU Member States protect their environment by general regulatory requirements not to pollute. Some place requirements on the RDS content within the environment, e.g. within the indoor air, and a few Member States place requirements in notified regulations on the release/emission of RDSs from construction products. As these Member State regulations may be regarded as a barrier to trade in construction products, the European Commission is seeking a way to provide the information these Member States require in a transparent way based on European standard test methods. Consequently, the European Commission will revise the mandates for all construction products to require information on the release/emission of RDSs under the CE marking where this is required by European or Member State regulations. Where there are no specific requirements, manufacturers may use the No Performance Determined declaration when placing their products on those markets.

Where a Member State regulates release from construction products, they identify for each product a set of RDSs and for each one assign a regulatory level, i.e. a maximum level of release. This CEN/TR suggests that the harmonised European Standard (hEN) corresponding to the product provides technical classes for the release/emission of RDSs, referred to as 'RDS classes' that coincide with the different regulatory levels. As different Member State regulations have different sets of RDSs and different regulatory levels, this CEN/TR also proposes to simplify this complexity by providing in the hEN sets of RDS classes. Each set of RDS classes would, in principle, satisfy a particular Member State's regulations, but there may be also a set that satisfies all Member State regulations. As an alternative, this CEN/TR mentions also the possibility to provide in the hEN the declared value concept for each mandated RDS.

Experience has shown that the majority of construction products pose no significant risk to the environment, so this CEN/TR provides two assessment procedures for providing, when required, this information on the release/emission of RDSs. Where there is a dossier of information that has been accepted by the Commission showing the release/emission of all or some of the mandated RDSs remains with time under relevant regulatory levels, these classes can be assigned by the manufacturer without testing (WT). The conditions for applying this procedure will be specified in the product standard. All the other mandated RDSs are subjected to an initial type testing (ITT) as specified in the relevant product standard. Based on the results of the ITT, the release/emission is then either assessed 'Without Further Testing' (WFT) or as requiring 'Further Testing' (FT). The WFT procedure is for the situation where the ITT shows that the release/emission from the product is significantly lower than the RDS class limit and, where this is not the case, the FT procedure is required to show conformity to the RDS class.

Both assessment procedures include ongoing factory production control (FPC) as specified in the relevant hEN and operated by the manufacturer. In the case of the WT procedure, the provisions for the FPC comprise all actions to be taken by the manufacturer, which result from the conditions under which the dossier has been approved by the European Commission.

In the case of the WFT/FT procedure, the FPC may or may not include further testing depending on the results of the ITT assessment.

This CEN Technical Report sets out the framework for the system described above and identifies appropriate supporting standards and guidance documents that should be worked out in CEN/TC 351 for the horizontal approach, and guidance on the provisions that Product TCs should include in their hENs. If the European Commission accepts the principles set out in this CEN Technical Report, it is intended to provide some examples of the application of the system, e.g. in a Part 2 of this document.

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Foreword

This document (CEN/TR 15858:2009) 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.

This document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

This CEN Technical Report describes a technical procedure for providing information on the release/emission of regulated substances in accordance with Essential Requirement No. 3 (ER 3) of the Construction Products Directive (CPD) and in particular the provision of this information using the ‘Without Testing’ and ‘Without Further Testing’ procedures. An overall description of all options for testing construction products with respect to ER3 is given. Within the overall framework and criteria, flexibility is built into the system to permit CEN technical committees (CEN/TCs) and individual manufacturers to select the optimal solutions for their construction products. The system is designed to cope with changes to construction products and to allow for further optimization when there are data to justify such optimization.

This CEN Technical Report applies to construction products under the responsibility of CEN, i.e. those that conform to European product standards. However, many of the principles and concepts described in this report could be applied to construction products covered by a European Technical Approval.

This report describes how Regulated Dangerous Substance classes (RDS classes) for each mandated Regulated Dangerous Substance (RDS) are developed and how sets of these RDS classes may be grouped for user convenience. It introduces the idea of an Initial Type Assessment (ITA) as the first step in the technical process. This Initial Type Assessment brings a more flexible approach to satisfying the requirements of ER3 and may/may not include any testing using a European test method depending on the quality of the product information already available. Where the ITA identifies that the construction product satisfies the criteria set out in the product standard with either no, a limited amount, or in specific cases more extensive testing using European test methods, the construction product may be deemed-to-conform to one or more RDS classes. Where all relevant RDS classes are satisfied by these procedures, the construction product may be deemed-to-conform to a set of RDS classes. The technical procedure(s) for establishing a deemed-to-conform approach to satisfying ER3, and its informational requirements, is described in this CEN Technical Report.

In the technical procedure, there is a hierarchy of testing using reference test methods for the determination of release/emission, alternative test procedures and screening tests. These may be used in the Initial Type Testing (ITT) and in the further testing (factory production control and evaluation of conformity) to assess the constituents or materials and approve the construction product. The overall objective of this report is to set out a framework for an effective, appropriate and cost effective system for providing when required information on the release/emission of regulated dangerous substances from construction products under ER3. The NPD option is retained for CEN Member States who protect the environment with a different approach.

NOTE As the general CEN/TC 351 document on terminology is still under development, this document has its own clause on terms and definitions. Those are incorporated in the draft general document. It is expected that in the final technical report (after the approval of CEN/TC 351), this clause will be replaced by reference to the general CEN/TC 351 document.

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Abbreviations

CEN	European Committee for Standardization
CEN/TR	European Committee for Standardization Technical Report
CPD	Construction Products Directive
EGDS	European Commission's Expert Group on Dangerous Substances
EN	European Standard
ER3	Essential Requirement No. 3: *Hygiene, health and the environment*
ETA	European Technical Approval
ETS	European Technical Specification, i.e. a hEN or ETA
FT	Further Testing
hEN	Harmonised European standard
ITA	Initial Type Assessment
ITT	Initial Type Testing
NPD	No Performance Determined
REACH	European regulation on the Registration, Evaluation, Authorisation and restriction of Chemicals
RDS	Regulated dangerous substance
RDSs	Regulated dangerous substances
TC	Technical Committee
WFT	Without Further Testing
WT	Without Testing

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1 Introduction

Mandate M/366 EN [1]

Development of horizontal standardized assessment methods for harmonised approaches relating to dangerous substances under the Construction Products Directive (CPD) [2] introduces, with respect to compliance with EU or Member State Regulations, procedures for classification of construction products using a 'Without Testing procedure' (WT procedure) and a 'Without Further Testing procedure' (WFT procedure) in addition to the normal 'Further Testing' approach (FT procedure).

Work Package 1 given in the mandate to CEN requests, amongst other things, that a Technical Report on “Without Testing (WT)” and “Without Further Testing (WFT)” be developed.

Text abstracted from Mandate M/366:
This Technical Report shall develop criteria for classifying products as WT/WFT. It must define the criteria a product or material has to fulfil, in order to be accepted as WT/WFT. The mandated Technical Report will need to make it possible for the European Expert Group on Dangerous Substances to develop a concept, how these products will be selected, and which the European Commission Services intends to use for further measure, with the endorsement of the Standing Committee on Construction.

The TR should consider the viability of two lists, i.e. a) products or materials regarded as WT/WFT based on generally accepted knowledge on the constituents and release behaviour, and b) products regarded as WFT based on verification of their emission or content of regulated dangerous substances (measured/tested in accordance with the harmonised measurement/testing standards).

Mandate M/366 also states in 1.2 sub-clause 5:
It should be possible to demonstrate, for a larger number of products, that they do not contain any regulated dangerous substances or do not have the ability of releasing dangerous substances into soil, ground or surface water, or to indoor air, in quantities above the limits regulated in any Member State of the EU.

During the second half of 2006 and the first months of 2007 there was considerable discussion over various concepts and the evolution of ideas. In order to clarify matters, a delegation from CEN/TC 351 held a meeting with the Construction Unit on the 2 March 2007. The main outcome of this meeting was a confirmation that in the future CEN product standards would have to provide a system for manufacturers to provide information on the release/emission of relevant regulated dangerous substances related to release scenarios, as far as this information is required by EU regulations or MS regulations where the construction product is placed on the market. Where there are no specific regulations with respect to release/emission of regulated dangerous substances, the manufacturer may use the ‘No performance determined (NPD)’ option. At this same meeting, it was also clarified that the WT and WFT procedures are ‘substance based’. This means that each relevant RDS is assessed individually to determine if the WT, WFT or FT procedure applies to the classification of the particular RDS.

NOTE Although European and Member State Regulations require a substance based assessment of the possible leaching/emission from construction products at some fixed distance from the construction works, the corresponding information to be provided under CE marking refers to the construction product as defined in the European Technical Specification (ETS) and determined only on the basis of harmonised European laboratory test procedures.

As requirements for the *regulatory level* of release/emission of RDSs vary between Member States, this report introduces a system for splitting each RDS into RDS classes.

These RDS classes will be established in product standards as ‘technical classes’ under the CPD, as described in Commission Services' Guidance Paper E [3].

The technical experts in CEN/TC 351 believe that this CEN Technical Report should:

a) describe the basis of the normal CPD approach (herein referred to as FT) to providing the information required in the product standard under essential requirement No. 3 (ER 3);

b) describe how the WT and WFT procedures lead to a 'deemed to conform' approach that may reduce the amount of testing needed to supply the informational requirements;

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c) explain the detail how the WT, WFT and FT procedures may be used to determine in which RDS class each relevant substance within a construction product can be declared to lie;

d) include as much of the overall process as possible bearing in mind that matters that are strictly administrative are outside the remit of CEN and this CEN Technical Report.

At this stage (April 2008), this report focuses on the main points, main procedures and the structure of the system. The criteria cannot be finalised until there is a fundamental decision on the *level of risk* acceptable with each of the procedures. This report notes that CEN/TC 351 has agreed to hold a Workshop on the 27 October 2008 to review this issue and makes a recommendation via CEN/TC 351 to the European Commission. Once the *level of risk* is agreed by the European Commission, this report should be revised to reflect that decision and to provide further elaboration and examples. It would be helpful to users if the technical procedures described in this document and the complementary administrative procedures to be developed by the European Commission were to be combined into a single document.

This CEN Technical Report is for the European Commission Services and their expert bodies (DG Enterprise and the *Expert Group on Dangerous Substances*), the Standing Committee for Construction, construction product technical committees and all mirror groups including environmental legislators, representatives of manufacturers organisations, notified bodies and laboratories concerned with the development and use of test methods for measuring the release/emission of regulated dangerous substances into soil, groundwater, surface water and indoor air in harmonised construction product standards. Guidance is provided for other CEN/TC 351 Working Groups and Task Groups showing how their specific activities fit within the overall framework. This Technical Report is also aimed at construction product technical committees to provide guidance on how ER3 with respect to the release/emission of RDSs should be addressed in future revisions of their product standards.

This CEN Technical Report is not aimed at individual manufacturers of construction products.

2 Scope

This CEN Technical Report describes a procedure for assessing construction products with regards to their release/emission of regulated dangerous substances (RDS) into the environment in accordance with Essential Requirement Number 3 of the Construction Products Directive (CPD), as far as these construction products fall under the responsibility of CEN.

NOTE 1 For the purpose of this document and mandate M/366, the release of regulated dangerous substances from construction products is limited to two main environmental compartments:

1) soil, groundwater and surface water;
2) indoor air.

NOTE 2 It should be noted that construction products falling under the CPD and these environmental compartments are the subject of other European Union regulations, e.g. REACH, and they may also be the subject of Member State regulations.

This Technical Report defines how the mandated characteristics expressed in terms of mandated RDSs for each construction product can be assessed by an individual manufacturer using the 'Without Testing' (WT) procedure and/or the 'Without Further Testing' (WFT) and 'Further Testing' (FT) procedures after an initial type assessment and how the corresponding information accompanying the CE marking can be expressed in terms of declared values or RDS classes.

This report describes:

a) under which conditions a RDS class for a construction product may be declared by the individual manufacturer using the 'Without Testing (WT)' assessment procedure;

b) if all relevant mandated RDSs are assessed by this Without Testing procedure, how a set of RDS classes for a construction product may also be declared by the manufacturer without the need for testing of their specific products;

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c) how to establish RDS classes for a construction product using a Without Further Testing procedure once sufficient information has been obtained from initial type testing;

d) when and how to undertake Further Testing as part of factory production control;

e) how to evaluate conformity of the construction product to one or more RDS classes;

f) how to create and declare a set of RDS classes using one or a combination of the WT, WFT and FT procedures.

For construction products that have to be tested, horizontal European release/emission test methods are the reference methods, but this report also describes under which conditions screening tests may be used. The use of alternative tests is part of the standard CPD procedure and therefore the use of alternative tests is not described in this report.

NOTE A manufacturer is free to use an alternative test calibrated against the reference method. However, data based on the reference method has precedence if there is conflicting information.

The procedures described in this CEN Technical Report are intended to be applied for placing products on the market; it includes the 'no performance determined' option (NPD) for application where compliance to a regulation related to ER 3 of the CPD is not required.

This report does not cover European Technical Approvals.

This CEN Technical Report is limited to the scope of the CPD and mandate M/366. Consequently, release/emission during the construction and end-of-life phases are not covered.

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3 Terms and definitions

In the field of European driven activity, some terms are used in different ways. This report uses terms that have a common European understanding of their meaning. Where there is not this common understanding, the following list of definitions defines the way the term is used within the context of this report.

NOTE As the general CEN/TC 351 document on terminology is still under development, this document has its own clause on terms and definitions. Those are incorporated in the draft general document. It is expected that in the final technical report (after the approval of CEN/TC 351), this clause will be replaced by reference to the general CEN/TC 351 document.

3.1
alternative test method (for determining the release/emission of RDSs)
test method calibrated against the reference method used either to determine a value of release/emission or to support evaluation of conformity to one or more RDS classes

NOTE The RDS classes, and any regulatory levels are based on the reference method and in cases of dispute, the reference method will have precedence over an alternative method.

3.2
applicant (applying for approval of a WT procedure)
person or body that prepares and submits a proposal to the authorized body for the application of the WT procedure together with a dossier of information to justify the use of this procedure

NOTE It is anticipated that in most cases a CEN Product Technical Committee or a European manufacturers association will be the applicant.

3.3
assessment
process by which RDS classes are assigned to a construction product