PUBLISHED DOCUMENT

PD CEN/TR
15858:2009

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

ICS 91.100.01

BSI
British Standards

National foreword

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The UK participation in its preparation was entrusted to Technical Committee B/557, Construction products - Assessment of dangerous substances.

A list of organizations represented on this committee can be obtained on request to its secretary.

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This Published Document was published under the authority of the Standards Policy and Strategy Committee on 30 April 2009

ISBN 978 0 580 64644 7

Amendments/corrigenda issued since publication

Date	Comments

TECHNICAL REPORT

RAPPORT TECHNIQUE

TECHNISCHER BERICHT

CEN/TR 15858

March 2009

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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EUROPEAN COMMITTEE FOR STANDARDIZATION
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EUROPÄISCHES KOMITEE FÜR NORMUNG

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Ref. No. CEN/TR 15858:2009: E

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.

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

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;

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;

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.

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

3.4
authorized body
expert body that assesses a dossier of information submitted by an applicant and prepares a decision if a deemed-to-conform assessment (WT procedure) is appropriate

3.5
CE marking
standardised European mark affixed to a product, its packaging, or its accompanying documents symbolising the conformity of the product with the relevant national standards transposing the harmonised standards, or with a European technical approval, (...) and that the system of attestation of conformity laid down in the Commission Decision relating to the product has been applied (Guidance Paper D [4])

3.6
class limit
value of release/emission measured in accordance with a European test method and the associated product specific conditions that has a probability agreed at the European level of not being exceeded

NOTE See 5.6, NOTE 1.

3.7
constituent
product conforming to an European standard (EN) used with other constituents to make a material (see 3.26)

NOTE 1 See also definition of 'element'.

NOTE 2 This is a term where there is no common understanding of its meaning and in this report it is used in the narrow way described above.

3.8
constituent approved for use
constituent of a clearly defined material, e.g. by limits on its composition, used to make a construction product that under a given release scenario may lead to the construction product being assessed using the WT procedure

NOTE If all the constituents are 'approved for use', the resulting construction product may be assessed by the WT procedure as conforming to a defined set of RDS classes provided the resulting construction products conforms to all the WT procedure criteria placed on it.

3.9
construction product
any product that is produced for incorporation in a permanent manner in construction works, including buildings and civil engineering works

NOTE A construction product may also be a material (see 3.26) or a constituent (see 3.7).

3.10
construction product harmonised under the CPD
construction product, according to a European Technical Specification as defined by the CPD produced by an individual manufacturer (i.e. the item to which the CE marking applies)

NOTE A construction product under the CPD may also be a material (see 3.26) or a constituent (see 3.7).

3.11
construction product under mandate M/366
product covered by a CPD-product mandate that is produced for incorporation in a permanent manner in construction works, including buildings and civil engineering works and is subject to at least one European Union or Member State regulation limiting the release/emission of one or more regulated dangerous substances

3.12
Construction Products Directive (CPD)
European directive 89/106/EEC to facilitate the free movement of construction products throughout the European Union by removing technical barriers to trade

3.13
dangerous substances (under the CPD)
substances, preparations and radioactive substances, present (either by deliberate use in manufacture or adventitiously) in construction products and possibly released from those products, that may present a danger for man or the environment during normal use of construction products when installed in construction works

NOTE It still has to be decided if and how the potential for microbial growth that may lead to the release of dangerous substances may be taken into account. This topic is not addressed in this report.

3.14
declared class
RDS class as defined in a harmonised product standard and selected and declared by a manufacturer

NOTE These are RDS classes the manufacturer is confident of achieving. However, it is likely that at the European level there will be an agreement on a minimum probability that the class limit will not be exceeded. The manufacturer will be free to use a higher probability, i.e. a lower risk of the class limit being exceeded.

3.15
element (of a construction product or kit)
complete component that is part of a construction product or kit being assessed for the release of RDSs, e.g. a brick in a layered wall system, plasterboard and a complete window used in a prefabricated wall system

3.16
emission
liberation of chemical species (e.g. volatile organic compounds, ionizing radiation) from a construction product into indoor air

NOTE The terms ‘emission’ and ‘release’ have fundamentally the same meaning. However, it is convention to use the term ‘emission’ when describing ‘release’ into indoor air. This report respects these conventions by using the term ‘release/emission’.

3.17
essential requirement
provisions of the CPD that constitute both the general and specific criteria with which construction works must comply, e.g. ER3: Hygiene, health and the environment

3.18
European Technical Specification (ETS) under the CPD
specification contained in either a harmonised European Standard (hEN) or European Technical Approval for a construction product (article 4.1 of the CPD [2])

3.19
evaluation of conformity
test and procedure used to verify that the construction product represented by the tested sample conforms to its specification

3.20
Factory Production Control
permanent internal control of production exercised by the manufacturer

NOTE All the elements, requirements and provisions adopted by the manufacturer shall be documented in a systematic manner in the form of written policies and procedures. This production control system documentation shall ensure a common understanding of quality assurance and enable the achievement of the required product characteristics and the effective operation of the production control system to be checked.

3.21
Further Testing (FT)
assessment procedure where the conformity evaluation requires routine testing by the manufacturer to verify that the given RDS class is being achieved

NOTE Further testing is applied when the initial type testing shows there is a risk that the RDS class limit may be exceeded.

3.22
immission
derived measure of the environmental burdening of soil, groundwater or surface water or air by release/emission of chemical species or radiation from construction products into a specific, limited environment. The derived measure is determined as a quantity per unit of time entering the specified environment

NOTE Immission values are calculated for particular species from data obtained using laboratory leaching tests, using regulatory formulae for comparison with regulatory immission limits.

3.23
Initial Type Assessment (ITA)
assessment of specific products or a group of specific products based on criteria and rules outlined in this CEN/TR and specified in the relevant European standard

NOTE Guidance Paper M [5] sub-clause 4.4 indicates that ITT can be 'Without Testing' but this is very confusing. For the purpose of this report, an additional term 'Initial Type Assessment' has been introduced, with ITT being part of this assessment in some, but not all, cases.

3.24
Initial Type Testing (ITT)
complete set of initial tests described in the European standard, determining the performance of samples of products representative of the product type. An ITT verifies that a product is likely to conform to the European standard

NOTE 1 ITT is not an assessment of the fitness for use of a product. ITT is only one element which determines whether a product can be attested to be in conformity with a technical specification.

NOTE 2 ITT includes the collection of data from a number of the same tests to determine variation (ranges) of the investigated property.

3.25
intended use
role(s) that a product is intended to play in the fulfilment of the essential requirements of the construction works. The intended use is thus related to the function of a product in a construction works

3.26
material
substances from which a product or the construction works is made

NOTE 1 Some regulations for the release/emission of RDSs are based on the 'material' itself and a release scenario and so cover all products incorporating the material and the way of use specified in the regulation.

NOTE 2 This is a term where there is no common understanding of its meaning and in this report it is used in the way described above.

3.27
outlier (in a data set)
value that is outside the normal range of expectation, e.g. a value three or more standard deviations from the mean

3.28
pass/fail criterion for release/emission
pan-European limiting value for release/emission of a regulated dangerous substance from a construction product that is not allowed to be exceeded in all of the European Union for all release scenarios

NOTE This is a value that Member States cannot change and which negates the use of the NPD option by manufacturers.

3.29
previously existing data
test data obtained by other test procedures that preceded the publication of a relevant European test method, and test data obtained from these European test methods before the specific ITA/ITT started

3.30
RDS class
technical class, as specified in a hEN, containing the abbreviation of the RDS, the word 'class' followed by a numerical value that is the class limit (see 3.6) for the release/emission of that RDS, a limit declared by the manufacturer or the letters 'NPD' to indicate that the release/emission of the RDS has not been determined

NOTE 1 RDS classes are defined by a single upper class limit (see 3.6) and not by both a specified upper and a specified lower limit. Consequently, the real value for a batch of a construction product will be expected to be between zero and the specified upper class limit.

NOTE 2 The upper class limit has been determined on the basis of measurement using the reference test method, including the material specific provisions.

3.31
regulated dangerous substances (under the CPD)
substances, preparations and radioactive substances that may present a danger for man or the environment during normal use of construction products when installed in works and that are regulated in European Union regulations or national regulations

NOTE 1 The CPD only covers the in-use phase, i.e. the in service ('permanent incorporation') phase, of life and not the construction and end-of-life phases.

NOTE 2 What the REACH Regulation [6] defines as a 'substance' is not the same as a 'substance' in the term 'regulated dangerous substance'. For example, cement clinker is a substance under REACH but not a substance under mandate M/366. To avoid confusion this report avoids using the single term 'substance'.

3.32
regulatory level of an RDS
regulatory limit value of release/emission/content of a regulated dangerous substance when measured in accordance with a European test method

NOTE A construction product that satisfies the RDS class with the same or lower numerical value (see 3.30) than the 'regulatory level' will satisfy the regulatory requirement in the relevant Member State or all of the European Union.

3.33
release
liberation of chemical species (e.g. water-soluble chromium (VI) compounds) from a construction product into soil, groundwater or surface water

NOTE The terms 'release' and 'emission' have fundamentally the same meaning. However, it is convention to use the term 'release' when describing 'emission' into soil, groundwater or surface water. This report respects these conventions by using the term 'release/emission'.

3.34
release/emission scenario
model describing the transfer of RDSs from construction products into their immediate air, soil and water environments and the chemical, physical and geometrical parameters that influence this transfer

3.35
screening test
test used in factory production control that shows performance in a defined release scenario to be on the safe side

3.36
set of RDS classes
group of RDS classes that include all the mandated RDS for a construction product under a given release scenario that satisfy the regulatory levels in a Member State or the whole of the European Union

NOTE These sets of RDS classes are provided for the convenience of users as, for example, they should know that 'Set NL' satisfies the relevant regulations in the Netherlands.

3.37
Without Further Testing (WFT)
deemed-to-conform assessment procedure for determining the RDS class based on initial type assessment and initial type testing alone

NOTE Assessment by the WFT procedure means that an individual producer does not need to determine the release/emission of the relevant RDS in the construction product by further testing.

3.38
Without Testing (WT)
deemed-to-conform assessment procedure for determining the RDS class based on criteria approved by the authorized body and set out in the harmonised product standard

NOTE Assessment by the WT procedure means that an individual producer does not need to carry out initial type testing (but an initial type assessment is needed to establish that the construction product satisfies the conditions applying to the application of the WT procedure for the RDS) and the individual producer does not need to determine the release/emission of the relevant RDS in the construction product by further testing.

4 General procedure

The assessment of the release/emission performance of construction products is based on two major steps (see Figure 1):

a) identification of the necessary information on the mandated performance characteristics to be declared in the CE marking;

b) allowed procedures to assess conformity to the declared information.

The identification of the necessary information includes:

c) definition of the construction product according to an European technical specification;

d) selection of the relevant conventional release scenario related to the intended use (see clause 6);

e) identification of the RDSs relevant for the construction product and related to the release scenarios on the basis of notified European Union /Member State regulations (see 5.2 and clause 7);

f) elaboration of technical classes for each RDS, a group of RDS or all RDS (see 5.6 and clause 8).

<table>
<tr><td colspan="2">1. Definition of the construction product(s) according to one or more hENs</td></tr>
<tr><td colspan="2">2. Definition of the intended use (contact with soil, groundwater, surface water or indoor air) and selection of the relevant release scenarios from the corresponding hEN</td></tr>
<tr><td colspan="2">3. List of mandated RDSs related to the relevant release scenarios and the Member States to which the construction product will be supplied
(The EU Commission will mandate the RDSs and they will be listed by CEN in the relevant hENs)</td></tr>
<tr><td colspan="2">4. Identification and elaboration of mandated RDSs and sets of RDS classes in the corresponding hEN</td></tr>
<tr><td colspan="2">Conformity assessment where the classification is based on using the</td></tr>
<tr><td>WT procedure
Step 1: Initial type assessment
Step 2: Dossier preparation and assessment</td><td>WFT/FT procedure
Step 1: Initial type assessment
Step 2: Initial type testing</td></tr>
<tr><td colspan="2">Conformity evaluation</td></tr>
<tr><td>Step 3: Factory production control to show conformity to the conditions for the WT procedure</td><td>Step 3: Factory production control, including, where needed, further testing</td></tr>
</table>

Figure 1 — Identification and conformity assessment of the information to be declared in the CE marking

For the conformity assessment of the construction product, this CEN Technical Report distinguishes between RDSs that were classified by:

— WT procedure (see 5.7 and clause 10);

— WFT/FT procedure (see 5.7, clause 11 and clause 12).

5 Basic principles

5.1 Introduction

From the viewpoint of human health and protecting the environment, it is the release/emission of regulated dangerous substances (RDSs) into the environment from the construction works that matters. In recent years,

the European Union has been very active in instigating environmental regulations and directives, but Member States still retain control over levels of safety and have many differing national regulations related to the environment. The national approaches vary widely from a general requirement not to pollute the environment without specifying exactly what this means to a prescriptive approach where immission limits are placed on a number of RDSs.

It has been agreed that at the European level it would be helpful to standardize test methods for the release/emission of RDSs (Mandate M/366), but that limits on release/emission would remain in, mainly, national provisions. In a parallel activity, it is anticipated that CEN will be mandated by the Commission to address ER3: *Hygiene, health and the environment*, in harmonised product standards in a more complete way by providing information on the release/emission of RDSs when required by notified regulations. For this, some standardized form of presentation is needed.

Environmental regulations are all aimed at protecting the environment but the European and notified national regulations approach this objective in different ways. For example, the Water Framework Directive [7] and the Groundwater Directive [8] place direct requirements on changes to the existing quality of the groundwater. On the other hand, the Austrian regulation on ionizing radiations into indoor air [9] places requirements directly on the construction products and their constituents. The Finnish [10] and German [11] schemes for emission of volatile organic compounds place requirements on the emission into the air within a test chamber. With many current regulatory systems, an immission limit is placed on changes to the environment. This is compared with a derived value based on calculation using data obtained by testing in accordance with national standards. If the calculated immission value is below the regulatory immission limit, the construction product is approved for use. Member States use different models and criteria for calculating the immission value. The calculated immission value will depend upon the site-specific conditions that are unknown to the manufacturer of the construction product.

All a manufacturer can provide to the user under CE marking is product information based on standardized testing using a European test procedure, i.e. the starting point for calculating an immission value. As there will be variations in release/emission performance between batches of the same construction product, the most practical way in which the manufacturer can provide this information to users is by using RDS classes.

To enable manufacturers to provide appropriate information relating to Essential Requirement 3: *Hygiene, health and the environment,* of the CPD, it would be very helpful if European Union and Member State Environmental Regulators transpose their immission limits into ‘regulatory limits’ based directly on testing using the European test methods. CEN/TC 351 could then develop RDS classes with the class limits being identical to the regulatory limits. This means that users, on the basis of the information on RDS classes provided by the manufacturer of the construction product, could easily in most situations determine whether the construction product will satisfy the regulatory requirements in the place of use.

There is a benefit to regulators by following this approach as they remain free to set the immission model parameters and in particular, the period over which release is determined. As construction products are under the CPD, the harmonised provisions in these standards only apply to the in-use phase of life. This means that release/emission should only be determined for the intended working life (i.e. the planned in-use phase of life) which is either defined in the product standard or selected and declared by the manufacturer. For example, normal building structures are typically assumed to have an intended working life of 50 years and civil engineering structures 100 years (see EN 1990). The ‘intended working life’ is being treated as meaning ‘at least’, but the expected average life is not defined. On the other hand, national regulators may determine life on a completely different basis, using a fixed period of time, the expected life or the time at which the product is expected to be removed from the environment. Leaving the regulators free to determine how the ‘regulatory levels’ are determined avoids all these complications. How the regulators arrive at their regulatory levels stays their business and not a matter for the European Commission or CEN.

The requirements for information on RDSs provided under CE marking are linked directly to notified regulations. It is recognised that there are many environmental requirements arising from, for example, planning consents/approvals, that are not notified regulations. These cannot be addressed directly by CEN. However, it should be noted that the user may use the information on RDS classes provided by the manufacturer to show compliance with some or all of these environmental requirements.

5.2 Construction Product Directive

Under the CPD, as elaborated in Commission Services' Guidance Paper H [12], the function of a harmonised European product standard is to set out rules by which information is given by the manufacturer to the user in a standardized (i.e. uniform, transparent and robust) way for every mandated (performance) characteristic linked to the intended use via the relevant release scenario.

In line with the CPD, the product performance may be expressed in three ways:

1) declared physical or chemical value;

2) technical classes;

3) pass/fail criteria.

Any measurement of a physical or chemical value should be based on a European or International test procedure. CEN/TC 351 recommends no limit for a class is created that is below the limit of detection of the test method plus an allowance for test precision, i.e. no requirements that cannot be verified.

The declared value could be the measured value from a single test, a value that the manufacturer will guarantee or a value declared following rules set out in the hEN. A reported single measured value is of limited use to the user, as they will not know where this falls within the population of all possible values. As the Commission cannot force a level of risk on a manufacturer, the use of the 'guaranteed' declared value will be outside the control of CEN and driven by market forces. Each manufacturer will have their own set of declared values with differences between products often being illusionary rather than real differences, i.e. just reflecting the risk the manufacturer is prepared to accept and not real differences in the potential release/emission of RDSs. If the declared value is to follow rules given in the hEN, the user will want to know if the construction product conforms to the local regulations for the release/emission of RDSs. Declaring a mean value and standard deviation is of little help to the user and, in effect, the user will want the manufacturer to declare a 'value' (class) with the same or a lower value than required by the regulatory limit. This option is provided for in this Technical Report as a 'declared class', see 5.6. It has to be recognised that such an option may be used for marketing purposes, but at least the rules will be transparent and enforceable.

If a declared class option is used, there can be no WT procedure.

The pass/fail approach is of limited applicability since it must not be used to introduce a pass/fail requirement that is more demanding than is applicable in any Member State. Since most Member States, apart from implementing European Union regulations with specified substances, do not have their own specific requirements with respect to release/emission of RDSs, establishing any pass/fail criterion generally contravenes the principle of not introducing requirements above those currently required in a Member State.

NOTE The placing of common pass/fail criteria in European Technical Specifications (ETSs) has been explicitly ruled out by the Construction Unit for use in the environmental compartment known as 'drinking water' because …"*a pass-fail approach would be binding in all Member States and also force all Member States to demand testing for the (highest) performance criteria that have not regulated in their own country before.*" (CONSTRUCT 06/768 (Rev1) [13]. All environmental compartments come under ER3 therefore the same principles must apply to all.

However, the pass/fail approach could be applied to the European list of fully banned substances (there are some that have restricted use, but are not fully banned) to define the meaning of 'not used' (see clause 11). It might also be usable in cases where there is a European Union regulation with only one regulatory limit value that covers all the ways of use and all locations of use falling under the scope of the 'intended use', as defined in the hEN.

It is not permitted under the CPD to exclude products from CE marking that are legitimately placed on the market (see clause 8). Some Member States do not have specific regulations that require the measurement of release/emission of RDSs and it is not permissible for CEN to introduce requirements where none have been needed by the Member State. Therefore, a No performance determined (NPD) class should be established for each RDS.

Thus for a harmonised product standard to cover CPD ER3 with respect to RDSs, it will need to contain:

a) list of mandated RDSs linked to the relevant release scenario;

b) assessment procedure for each RDS, i.e. WT or WFT/FT;

c) conditions that apply to an assessment by the WT procedure, e.g. RDS Z may be assessed by the WT procedure provided the construction product comprises;

d) requirements for WFT/FT;

e) a No Performance Determined option;

f) where relevant, a list of appropriate test methods and instructions/guidance on the use of the test methods;

g) requirements for factory production control;

h) rules for the evaluation of conformity;

i) level of attestation of conformity.

NOTE At present harmonised European standards and mandates for construction products do not address in detail ER 3: *Hygiene, health and the environment.*

Thus for each harmonised product standard, there will be for each relevant release scenario a list of mandated RDSs that have to be addressed in the information accompanying the CE marking, even if the declarations are 'No performance determined'. If the construction product can be made with different materials, e.g. concrete, ceramic or plastic, there will be lists in the product standard specific to each material. If a construction product is made with more than one material, the information accompanying the CE marking relates to the construction product and the individual or combined effects of the different materials depending on the requirements in regulations.

The technical criteria and rules apply to construction products mandated under the CPD and to affects on the immediate environment, generally by being in contact with it, (see clause 6 for further explanation).

The overriding principle under the CPD is that a manufacturer of a construction product uses the European technical specification procedures to declare the performance of the product in the form of mandated information accompanying the CE marking. The CE mark attests the product performance but it is not a proof of conformity of the product to regulations. It is a matter for the user of the product to determine, on the basis of the information provided, whether the RDS classes for the construction product will satisfy the European Union or Member State regulatory levels and by implication the regulations for the construction works in the place of use.

A 'Declaration of Conformity' for a product and the information accompanying the CE marking relates to all mandated characteristics, including release/emission performance. Whether the level of attestation of conformity that already applies to the other technical characteristics of each product will also apply to release/emission performance is not a matter for CEN/TC 351.

5.3 Scope of Mandate M/366

Mandate M/366 applies to construction products that are both:

a) subject of a harmonised ETS;

b) subject of a barrier to trade.

The prime purpose of mandate M/366 is to provide horizontal test methods to measure the release/emission of RDSs. The development of test methods for enforcement purposes, i.e. to detect the presence of a banned substance, is not part of the present scope, but should moves be made in this direction, the meaning of 'not containing a banned substance' has to be quantified and agreed by regulators, the European Commission and CEN.

NOTE The present system where the manufacturer and regulator agree a local interpretation is not appropriate for a transparent European market. A manufacturer must be able to verify conformity without having to involve a regulator.

As mandate M/366 is a mandate under the CPD, the same limitation of scope applies, namely it is limited to the in-service phase of life. The construction and end-of-life phases are covered by REACH [6] and other European Union and Member State regulations, but not by the CPD. It is also limited to release/emission into soil, groundwater, surface water and indoor air. However, for the selection, development and use of horizontal test methods it is important to harmonize as much as possible with the needs for the other regulations and available methods covering the other phases of product life.

Consequently, the task of CEN product technical committees is to amend their product standards to facilitate the provision of information on the release/emission of RDSs into soil, groundwater, surface water and indoor air that are subject to notified regulations in one or more Member States. How this is to be achieved is the subject of this CEN Technical Report.

5.4 Constituents, materials, products

The range of construction products include:

a) construction products made of one or more materials, e.g. masonry, pipes, windows;

b) materials forming a product and representative for its release, e.g. bricks, ceramic roofing tiles, walls made of preserved wood, or materials used even directly in the construction works, e.g. concrete, unbound aggregates in embankments and road foundation, wood as beams;

c) constituents used to make a material, e.g. cement, lime, aggregates for concrete, bitumen;

d) elements of a construction product, e.g. plasterboard and a complete window used in a prefabricated wall system, frame and double glazed panel used in a window unit.

It is the materials and the constituents that contain the RDSs, but it is the way the material/element is used in the construction product and intended conditions of use of the construction product that will determine if and at what rate RDSs are released/emitted. Information on release/emission from a construction product under standardized test conditions linked to intended release scenarios is provided in the information accompanying CE marking. Where a construction product covered by a European standard has no mandated requirement to provide information, the same approach as described in this report could be followed albeit without mandated RDSs and CE marking.

There is nothing stopping an individual manufacturer providing whatever information they wish as part of their customer service, but in this case, there will be no classes in the standard to follow or rules on how this information should be created.

5.5 Regulations and Directives placing requirements on the environment

The Water Framework Directive [7] and the Groundwater Directive [8] place requirements directly on changes to the groundwater quality. CEN product committees do not have to take these Directives into account until the requirements have been transposed at the European Union or Member State level into requirements for release/emission from construction products. However such requirements may be formalised in individual, local or regional permits and there is no obligation for these requirements to be notified. It would be very helpful if those specifying requirements in individual, local or regional permits would use for their requirements the RDS classification being developed by CEN. The user can then use the RDS classes for specifying contract specific provisions to their suppliers if different to the information already provided under ER3.

NOTE Certain regulations and directives contain lists of substances for which there can be no release or are banned. A true zero release/content is both impractical and unenforceable, e.g. many foods contain trace amounts of banned substances such as dioxins. It would be very helpful if there was a European understanding of the meaning of 'no release' and 'when a product is regarded as not containing a banned substance'.

Where there is Member State requirements placed on the environment, all the manufacturer will provide is the RDS classes for their product and it is up to the user to determine if the product is suitable.

5.6 Regulatory levels, RDS classes and sets of RDS classes

The following concepts are proposed as being a practical basis for dealing with RDSs under ER3. These concepts may require further refinement and they will need to be accepted and adopted by the European Union and its Member States.

This report introduces the concept of 'regulatory levels' (see 3.31). These are set by the European Union or Member State regulators and are based on measurements using harmonised European test procedures. The test methods will be selected and developed under CEN/TC 351.

However, CEN may not introduce 'levels' under its own responsibility. The term '(threshold) level' (GP-E, 'Levels and Classes in the CPD' [3]) has a particular meaning under the CPD and the use of this term would mean that the highest 'level' of release/emission would become a threshold value and products that exceed this value would no longer be permitted on the European market. CEN has no power to impose requirements above those deemed necessary by Member State regulators and therefore this report is proposing that product committees introduce technical classes, called 'RDS classes'. In practice these 'RDS classes' will be aligned to the regulatory levels required by Member State regulators.

The details of creating RDS classes are given in clause 8, but some principles are introduced in this section. For each product, there will be lists of mandated RDS (see clause 7), one for each material and one for each release scenario (see clause 6). Construction products that are made with a composite of materials will have a single list reflecting the product as it is placed on the market. The classes are presented as the abbreviation for the RDS follows by the word 'class' and the class limit, e.g. Pb class 0.01. The probability that the class limit will not be exceeded is to be set at a European level, e.g. x%

NOTE 1 CEN/TC 351 has agreed to hold a Workshop on the 27 October 2008 to make a recommendation to CEN/TC 351 and then the European Commission on what this probability should be.

Each relevant RDS should allow for the following different classes:

a) a class with a manufacturer's declared limit. This facilitates the provision of information by manufacturers with products that do not meet the provided RDS class limits but their products are currently legitimately placed on the market. This is an option a manufacturer may wish to use as an alternative to using the NPD option. The declared class is also useful when a new regulation is introduced with a regulatory level that is not the same as the existing RDS class limits or to show conformity to a contract specific requirement to satisfy some local or regional requirement;

b) NPD class;

c) one or more classes with a numerical value linked to Regulations. These may be classes to suit different Member State Regulations with different levels.

No RDS class should be created that is below the limit of detection by the corresponding harmonized European test method.

For ease of application, it is proposed to group the RDS classes into sets linked to the regulations in one Member State (see Figure 4 for an example). A set of RDS classes would contain all the RDS classes that are required by a particular European Union or Member State regulation for a particular release/emission scenario. CEN/TC 351 would like to label these sets with the Member State abbreviation to make life easier for users. If a Member State has more than one option or level for a construction product under the same release/emission scenario, a sub-heading will be needed. With certain construction products, it may be

practical to have one set for a particular release scenario that satisfies **all** the European Union and Member State regulations for all relevant substances and this should be labelled 'Set EU'. At present it is not permitted to label a 'Set' with a Member State abbreviation but CEN/TC 351 seeks derogation from the European Commission.

NOTE 2 Any 'Set EU' would have to be modified if the European Union or a Member State introduces a new notified regulation that is more onerous than the existing regulations.

NOTE 3 For sets of RDS classes there should be found a solution to make it easy to find the information on the RDS classes that comprise a 'Set' without having to refer to the product standard, e.g. available for free downloading from the internet.

For each construction product there should also be a 'NPD set' to save the manufacturer having to list all the mandated RDSs where he has not determined a performance.

A construction product with a given RDS class automatically satisfies the requirements for less stringent RDS classes and less stringent regulatory levels. Clearly, this generalisation does not apply to a Set of classes, as any particular set may contain a mixture of higher and lower values than another set of classes.

5.7 Assessment procedures

The provision of the information on the RDS classes may be based on the normal CPD approach of testing (the FT procedure). However, experience has shown that results for release/emission of most RDSs are lower than and not close to the regulatory levels required by Member State regulations and therefore it is appropriate to introduce systems that reduce the amount of testing needed to determine the RDS classes. These are called the WT procedure (see clause 10) and the WFT procedure (see clause 11 and clause 12). The procedures for assessing the potential release of RDSs in a construction product are outlined in Figure 2.

For the WT procedure, the applicant, usually a CEN product technical committee or a European manufacturers' association, will prepare a dossier of information to justify why clearly defined construction product(s) may be deemed-to-conform always to RDS classes. If the dossier of information is accepted by the authorized body, any manufacturer may declare the RDS classes without testing of their specific products provided their construction products fully conform to the criteria for applying the WT procedure.

The construction product has to be well-defined including the boundaries for the assessment based on the WT procedure, e.g. by defining its composition. For certain products composition may be sufficient. For instance, assessment of release/emission of RDSs from construction products obtained exclusively by mixing constituents themselves covered by hENs under the CPD should be based on the WT procedure subject to prior 'approval for use' of these constituents. 'Approval for use' has to be established for the constituent being used in the end product taking into account any adverse interactions. Example 1 gives a framework of how assessment based on the use of approved constituents may be used.

The 'approval' procedure for constituents is to some extent comparable to the procedure for the assessment of release applied to construction products. It should be opened to constituents for which it is possible to demonstrate that their contribution to the release of RDSs from the products in which they are incorporated is negligible. Such a demonstration may be based on a dossier prepared by the applicant, e.g. a CEN/TC or a European manufacturer association, or on the results of the ITT, depending on the available information related to the intended use. This information may or may not include everything that is covered by the hEN dealing with the constituent. The 'approval' procedure should be based on the evaluation and acceptance of the dossier or of the results of the ITT by the authorized body, and should result in the introduction of the product into a list established and maintained by the EC.

NOTE 1 In the drinking water field, this approach has been called the 'Approved Constituents List' for concrete and the 'Composition List' for metals.

EXAMPLE 1 A prefabricated concrete product standard may state in the normative part of the document that concrete made only with:

1) 'approved' cement conforming to EN 197-1, EN 197-4, EN 14216, or EN 14647;
2) 'approved' additions conforming to EN 450-1, EN 13263-1 or EN 15167-1;

3) ‘approved’ normal weight aggregates conforming to EN 12620;
4) ‘approved’ lightweight aggregates conforming to EN 13055-1;
5) ‘approved’ admixtures conforming to EN 934-2;
6) ‘approved’ mixing water conforming to EN 1008;

is deemed-to-conform to ‘Set EU’.

NOTE 2 In Example 1 note that all constituents have been approved for use. This ‘approval for use’ may result in some sources of constituents that conform to the basic requirements of their corresponding hENs being excluded.

The WFT procedure lies between the FT procedure and the WT procedure. On the basis of data obtained during the initial type testing from the reference test methods, alternative test methods (as permitted by the CPD) and/or screening tests (see 3.35), a RDS class is determined for each relevant mandated substance that is not assessed using the WT procedure.

If these tests satisfy criteria defined in the product standard (using principles set out in this CEN/TR), the substance may be put into a RDS class without further testing. If the tests fail to satisfy these criteria, further testing is required.

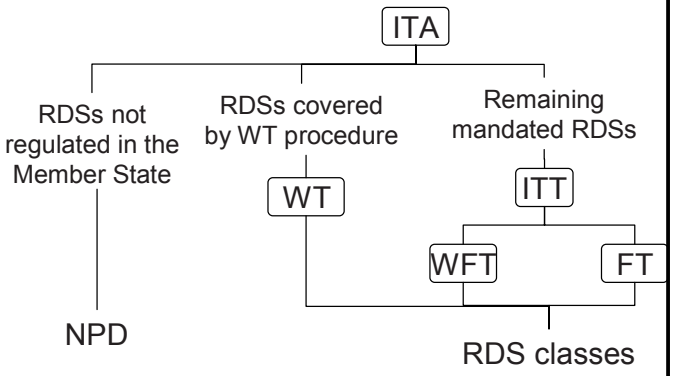
Product TC	Preparation of a dossier of assessment of conformity to ER3 via the WT procedure for the intended use with respect to the leaching/release of some or all mandated regulated dangerous substances (RDSs)
European Commission and Member States	Decision based on evaluation of authorized expert body National regulatory limits for each RDS and each intended use
CEN/TC 351	Recommended RDS Classes
Product TC	Specification in hEN of : • Initial type assessment (ITA) based on the dossier • Initial type testing (ITT) for remaining mandated RDSs • Routine testing for RDSs that require further testing (FT)
Manufacturer or Notified Body	Factory Production Control: 

Figure 2 — General procedures for assessment of construction products with respect to the release/emission of RDSs

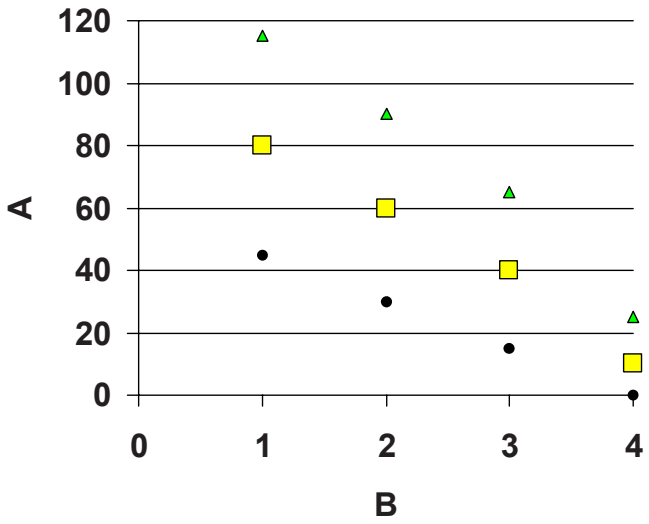
There must be an established and documented link between performance established by the reference method and any use of alternative or screening tests. This relationship may be established by an individual manufacturer, a group of manufacturers or a CEN product technical committee. If the relationship is established or accepted by a CEN product committee, it may be included in the product standard and used by all manufacturers.

EXAMPLE 2 It may not be appropriate to assess a RDS for a construction product by the WT procedure due to the difficulty in defining a borderline excluding sources of raw materials that give a high level of release, yet within the overall group of raw materials there are some sources that give a construction product with consistently low release of that RDS. Release testing under the initial type testing may establish that a particular manufacturer has a source of raw material that give a consistently low release and thus they are able to use the WFT procedure to assess this RDS.

Where further testing has been undertaken for a period of time and all the data are sufficiently below the class limit for the RDS, the rate of testing may be reduced. The testing may be stopped completely if the data from this further testing together with other relevant information are used to go successfully through a new WFT procedure for the RDS. Where further testing shows values close to the class limit, a higher rate of testing is applied.

NOTE Further general specifications and instructions for such a flexible approach should be worked out in a special project by a special group as mentioned above, taking into account all relevant statistical and other aspects.

Figure 3 gives an indication of where the different procedures may apply. Product 1 for RDS Z is likely to require further testing, product 2 could follow a WFT/FT procedure and products 3 and 4 could follow the WT procedure. The FT and WFT procedures are linked to a specific manufacturer's products and therefore it is only the variability of their product that has to be taken into account. On the other hand, the WT procedure can only be applied if all construction products conforming to the specification and the conditions applied to the procedure are satisfied with a sufficient margin of safety.



Key

A Percentage RDS class limit
B Construction product
• **Lowest**
□ **Average**
▲ **Highest**

Figure 3 — Indicative uses of assessment procedures for RDS *Z* in construction products

5.8 Combining construction products into a single assessment

To reduce the costs of assessment, a range of construction products may be combined into a single assessment. This could be all construction products made with a particular material or group of materials. Groups of manufacturers may also combine together for a single worst-case assessment. Later in this report, where procedures for assessing a construction product are described, these procedures also apply to construction products grouped together for assessment.

Guidance paper M [5] permits the use of shared ITT. This is where a single ITT covers products of a particular defined type produced by different manufacturers.

5.9 Construction Products covered by Member State Regulations but not covered under CPD-ETS

There are a number of construction products (see 3.9) that are covered by Member State regulations for the release/emission of RDSs that are not construction products covered under the CPD-ETS (see 3.10) e.g. ready-mixed and site-mixed concrete, aggregates for several forms of use, materials used as soil, products that are not used according to intended uses of an European Technical Specification. There can be no mandated list of RDSs and CE marking for such construction products and alternative solutions need to be found. For example when such a construction product is covered by a voluntary European standard, this standard could contain a list of relevant RDSs and have a requirement for the manufacturer to provide information on release/emission of RDS. It would be useful if European Union and Member State regulations would use the same methods and procedures for products that do not fall under the scope of the existing CPD-ETS.

EXAMPLE The voluntary European standard for concrete could contain a list of RDSs and RDS classes that are identical to those in a harmonised pre-cast product standard for the same release scenario. Manufacturers of concrete would provide information on the RDS classes in the same way as a manufacturer of pre-cast concrete, the difference being that for pre-cast concrete this information is part of CE marking and subject to the agreed level of attestation of conformity and for ready-mixed and in-situ concrete, it would only be covered by third party certification where the production is under a certification scheme, e.g. most ready-mixed concrete.

6 Release/emission scenarios

The release/emission scenarios are linked to the following intended use:

a) soil, groundwater or surface water;

b) indoor air.

In CEN/TC 351, a limited number of conventional (model) release/emission scenarios will be selected and defined. These scenarios will be linked to appropriate test methods and other relevant procedures. From these default scenarios, product technical committees should select one or more scenarios that are representative of the intended use of their construction product and check that the selected release/emission scenarios align with the existing Member State or European Union regulations that give rise to the ER3-related informational requirements for the construction product. CEN/TC 351 considers it necessary and desirable to have a reduced number of conventional scenarios to keep the evaluation of construction products and the development and use of tests methods manageable and transparent. CEN hopes that European Union and Member State regulators will align their requirements to use this set of conventional release scenarios.

Every European standard covering construction products that may affect the immediate environment will contain for each appropriate release scenario a list of mandated RDSs to be addressed in the information accompanying the CE marking.

While the Interpretive Document No. 3 [15] states that it is in general important to evaluate the whole life cycle of a construction product, mandate M/366 has been issued under the Construction Products Directive, which

only covers the in-use/in-service phase of life. Therefore, release/emission during the construction and end of life phases is not within the present scope of CEN/TC 351 (see Guidance Paper H, 2.2 (ii) [12]). These phases of life fall within the scope of REACH.

Interpretive Document No. 3 [15] states:

"The construction work shall not release pollutants in quantities which may impair the health and hygiene of occupants, users and neighbours. The requirement is concerned with the protection of people and with the prevention of any impact on the immediate environment by pollution of the air, the soil and the water."

Guidance Paper H explains that only the immediate environment falls under the scope of the CPD and while this is not defined in the Interpretive Document No. 3, Guidance Paper H states that 'this can be taken to mean those parts of the environment that are influenced by direct effects of the products or works in question'.

Clearly, products that may be in contact with the environment and may release/emit RDSs into that environment fall under the scope of ER3. This includes construction products that will never be in direct contact with the environment, but release/emit RDSs through a layer in contact with the environment.

EXAMPLE In a wall system, the source of any ionizing radiation into indoor air may be the structural wall product and not the surface-finish product.

7 Identification of relevant regulated dangerous substances

For relevant construction products and release scenarios, Member State regulations may have set for products placed and/or used on their markets maximum (regulatory) levels for the release/emission of a defined number of RDSs. Where it has been impracticable to regulate on the basis of release or emission, regulations may rely on determination of the content of an RDS. CEN/TC 351 is proceeding on the basis that for construction products there will be for each relevant release scenario a composite list of RDSs covered by European Union and notified Member State regulations that is mandated by the Commission Services. These mandated lists of RDSs will not contain the regulatory levels of release/emission. Harmonised product standards are expected to be revised to include these lists and require manufacturers to provide information on release/emission. However, if a product TC can demonstrate that some of the mandated RDSs are not detectable for a particular group of products, these RDSs need not be listed in the product standard.

As 'regulatory levels' are a regulatory matter they are not a subject for CEN/TC 351. It may be expected that European Union and Member States will need time to transfer their regulations to the new European reference test methods, and that they will not start the formal transformation procedures before the new methods are formally adopted on the European Union level. It must be expected that the changes of regulation might be at different speeds in different countries. But once a new procedure including such new methods is formally accepted under the scope of the CPD, Member States should make room for it in their legislation and should start the transformation process. It might be expected that CEN product committees would not want to start creating RDS classes until the requirements of regulators are known (prior to this time any RDS classes would have no role as the manufacturer has to comply with the existing national regulation using the current test methods). This would mean that the whole process is likely to take at least a decade. This may be regarded as being an unacceptably long period. A possible transitional solution may be to include only the declared and NPD classes into a product standard. Declared classes are not possible until the relevant European test method is published, as a CEN standard should not contain a requirement without a method of verification.

NOTE 1 As the WT procedure does not only depend upon European horizontal test methods, work might commence on developing dossiers of information (see clause 10) even if the intended RDS classes are not finalised.

This is based on the assumption that regulators will simply convert their existing requirements into equivalent requirements based on the new test procedures. However it should be discussed by the European Commission if this is acceptable from a legal point of view (to fulfil existing European Union and national legislation) and deliverable (e.g. different options for the same products, may lead to confusion).

The Commission has been using the EGDS to produce lists of RDSs to mandate. The Commission is expected to invite the relevant product technical committee to comment on the proposed list before it is

finalised and mandated. Such lists should only contain RDSs that are specifically regulated at the European level or in notified national regulations for the product itself: RDSs only listed in general requirements, e.g. for groundwater, should not be included.

NOTE 2 Experience to date has indicated that the lists produced by the Commission contain errors and it would be prudent for product technical committee to prepare their own lists and use these to check the list from the Commission.

On completion of this process, the Commission Services are expected to initiate amendments to current product mandates to require the provision of information on the cited RDSs, always allowing for the NPD option. Construction products implicated by such mandates will be only those that are subject to at least one European Union or Member State regulation limiting the release/emission of one or more regulated dangerous substances. The Commission Services will also recommend to the Standing Committee for Construction the level of attestation of conformity required for this performance characteristic.

Once a list of mandated RDSs for a product has been issued by the Commission Services to CEN, product committees will not be permitted to add additional RDSs as extra performance characteristics without new permission/mandating by the European Commission.

Since European Union and national legislation are setting the regulations and there will be a time gap between a new regulation and its reflection in a product standard, the system proposed in this report allows the use of RDS declared classes. This will enable the manufacturer to respond immediately to changes in legislation

NOTE 3 It is recognised that there may be environmental requirements placed on construction products that do not come from notified regulations. For example, requirements for products that fall under a permitting system for water protection or under a legal duty for care provision do not have to be notified to the European Union. These requirements may contain RDSs that are not covered by a product's CE marking.

While an individual manufacturer has to comply with other relevant product specific environmental regulations, e.g. REACH [6], and has a general duty of care, it is the task of the user to identify any additional requirements in the contract specification above those already placed on the manufacturer.

8 Setting of RDS classes by Product TCs

Guidance Paper E [3] envisaged technical classes to have both an upper and lower limit. To avoid gaps in a product range where classes are used for classification it is necessary to have overlapping ranges. Without such an overlap, there will be a range of performance that fits neither into one class or into the next.

The objective of using RDS classes is for the user to be able to see if a construction product will satisfy the regulatory levels where the product is to be used. How far the construction product is below the regulatory level is not a matter for concern. Therefore, RDS classes will only have a single upper limit. This simplifies matters and avoids the problems and confusing caused when there are overlapping ranges.

This report also proposes that serious attention is paid to the statistics of conformity and testing, taking into account the level of uncertainty that should be taken into account when identifying whether a construction product falls within a class. CEN/TC 351 has agreed that these statistical criteria are worked out at a Workshop to be held on the 27 October 2008. While the majority of RDS classes will be based on the measurements of release/emission using the reference test method, the possibility of using content is not excluded where it is not possible or practical to measure release/emission.

The present position in Europe is that most Member States do not have generally regulated specific requirements for the release/emission of regulated dangerous substances. There is however a European list of banned substances that is sometimes supplemented with national lists. CEN is a standard writing body that does not have, nor should have, the power to introduce requirements into Member States above those currently in operation or to exclude construction products that are currently legally placed on their markets. Therefore when the product committee is setting RDS classes great care is needed to avoid excluding construction products that are legitimately placed on the European market. If the highest RDS class is defined as 'not greater than (…..)', this in effect excludes any product with a higher level of release from the European

market. Such a descriptor would negate the NPD option and this is not permissible. There are at least two possible solutions to this issue. The first is to have an 'open' upper class (greater than), but this provides no useful information to users. A better solution is to have a class with a manufacturer's declaration (declared class) where the declared value has the same probability as the RDS class with a numerical limit linked to regulations of not being exceeded. This implies that a manufacturer will have to undertake sufficient investigations to have the data to justify such a declared value.

A RDS class with a manufacturer's declared limit should always be included as well as an NPD class. For example for the RDS 'lead', the classes could take the pattern:

a) Pb class with a numerical value linked to regulations e.g.:

   1) Pb class 0.xx linked to Member State 1;

   2) Pb class 0.yy linked to Member State 2;

b) Pb class with a manufacturer's declaration;

c) Pb class NPD.

It is expected that the CEN/TC 351 will use the 'regulatory levels' supplied from national regulators, together with its own considerations on how to take relevant European Union regulations into account, to develop horizontal sets of RDS classes in a way that a specifier may select a release/emission class knowing it will satisfy the regulations in their intended place of use. However, the RDS classes are not being allowed to contain in their identification the name of a European Union Member State.

Guidance Paper H [12] allows CEN product committees to set technical classes (RDS classes). When elaborating such classes, product committees should select the most practical system and the most easily understood form of information to accompany CE marking in order to allow the users to select products that will lead to the construction works satisfying the regulations with respect to release/emission of RDSs in the place of use. In the case of RDS classes, product committees should start with the horizontal set of classes developed by CEN/TC 351 and adopt either all or some of these classes or have a justifiable technical reason for using a different set.

The CEN product committee is also free to explore the possibility of combining relevant RDSs into sets of RDS classes, see Figure 4. If the CEN product committee opts to group RDSs into sets, the product standard will have to clearly explain what RDSs are covered by the sets of RDS classes. It would be very convenient to users if these sets could be labelled with the national abbreviation, e.g. Set NL, Set D. CEN/TC 351 recommends that the Commission Services permit this form of labelling for sets of RDSs. Product committees should also consider the practicality of having a single set for a particular release scenario that satisfies **all** the European Union and Member State regulations and this should be labelled 'Set EU'. This is a practical solution where the most onerous RDS classes for all relevant RDSs for a given release scenario are easily satisfied.

NOTE 1 CEN/TC 351 is not proposing to use this system for individual RDS classes as it is expected that there will be far fewer classes for an RDS than Member States.

NOTE 2 If the Commission do not permit CEN/TC 351 to use national identifiers for sets of RDSs classes, it may be better to remove 'Sets of RDS classes' from the CE marking and leave the manufacturer to provide the most useful information outside of CE marking.

Figure 4 also shows the sort of information that could be included in product standards, footnotes excluded. As it is expected that any WT procedure will contain limits on applicability, these limits will have to be included in the product standard, perhaps as footnotes to the table.

Mandated RDS	Test method [b] when required	RDS class [c]	Class limit incl. units	Assessment procedure	RDS class [c]	Class limit incl. units	Assessment procedure	RDS class [c]	Class limit incl. units
Cr [a]	EN xxxxx	Cr class 0.xx	0.xx µg/l	WT	Cr class 0.yy	0.xx µg/l	WT	Cr class NPD	None
Cu	EN xxxxx	Cu class 0.aa	0.aa µg/l	WFT/FT [d]	Cu class 0.aa	0.aa µg/l	WFT/FT [d]	Cu class NPD	None
Vd	EN yyyyy	Vd class 0.dd	0.dd µg/l	WT	Vd class 0.dd	0.xx µg/l	WT	Vd class NPD	None
Zn	EN yyyyy	Zn class 0.ss	0.ss µg/l	WT	No require-ment (NPD)	0.xx µg/l	Not relevant	Zn class NPD	None
Pb	EN zzzzz	Pb class 0.mm	0.mm µg/l	WFT/FT [d] [e]	Pb class 0.nn	0.nn µg/l	WT [e]	Pb class NPD	None
Hg	EN zzzzz	Hg class 0.zz	0.zz µg/l	WT	Hg class 0.zz	0.zz µg/l	WT	Hg class NPD	None
PAH	EN zzzzz	No require-ment (NPD)	None	Not relevant	PAH class 0.gg	0.gg µg/l	WFT/FT [d] [e]	PAH class NPD	None
…..	EN …..	…..		…..	……		……	…..	None
…..	EN …..	…..		…..	…..		…..	…..	None
RDS 'n'	EN aaaaa	RDS class 0.xx	0.xx µg/l	WT	RDS class 0.yy	0.yy µg/l	WT	RDS class NPD	None
Set of RDS classes [f] [g] [h]		**Set D**			**Set NL**			**Set NPD**	

a) This column contains a list of all the mandated RDSs for the product with respect to a release scenario.

b) Harmonised European test method plus product specific procedures.

c) In practice the RDS limit values will be aligned with a particular regulatory level.

d) Until the ITA has been completed, it is not possible to determine if 'Further testing' is required.

e) To achieve the lowest RDS class, a WFT-procedure, possibly followed by FT, may be needed, while a higher RDS class may be determined on the basis of a WT procedure.

f) In general a 'set of RDS class' will satisfy for the stated release scenario all the regulatory requirements for the product in one or more MS.

g) Sets of RDS classes are based on regulatory requirements in a Member State and one Set may not contain all the lowest RDS classes.

h) The set of RDS classes would form part of the information accompanying CE-marking.

Figure 4 — Example: Sets of RDS classes for product YY with respect to release/emission into soil, groundwater and surface water

9 Initial Type Assessment

The initial type assessment, including a shared assessment, for a construction product with respect to RDSs should:

a) identify the intended use and the appropriate release/emission scenario;

b) identify the Member State markets into which it will be placed and the sets of RDS classes that have to be satisfied;

c) characterise the construction product being assessed, e.g. type of product, specific constituents;

d) determine the information available about release/emission from this type of construction product, if necessary including chemical and physical mechanisms that control the release/emission;

e) determine the variability (ranges) of performance of the relevant parameters;

f) from this information and the information given in the product standard determine the method for assessing each relevant mandated RDS;

g) for RDSs not assessed by the WT procedure, undertake the initial type testing defined in the product standard to determine the RDS class;

h) classify each relevant mandated RDS and, optionally, the sets of RDSs to which it will conform;

i) check if the construction product is suitable for the intended Member State markets.

The WT procedure is likely to have some conditions placed on its scope, e.g. the constituents used to make the material and construction product, and the initial type assessment needs to establish that the construction product satisfies these conditions and is likely to continue to satisfy these conditions during routine production. See clause 10 for the details of the WT procedure.

The product standard should contain the reference test methods for determining the RDS classes. The performance established using these reference test methods has precedence over any other way of assessment. However, the manufacturer is free to include alternative test methods or screening test methods in the WT and WFT testing programmes. The results of an alternative test are correlated to the reference method, taking into account uncertainty, so that the alternative test may be used in the further testing or factory production control to determine the release/emission. The screening test is used in a different way. It is used to establish a limit such that when the construction product satisfies this limit, it will conform to defined RDS classes. For example if the content of lead was not more than x% m/m, the construction product conforms to Pb class 0.nn.

As the initial type assessment will identify what parameters need to be dealt with in order that the release/emission of RDSs is controlled, this process will also lead to the identification of suitable tests for routine control.

Where the WFT/FT procedure is to be applied for one or more RDSs, it is not possible to classify a construction product on the basis of a single test, as the location of that test result in the general population will be unknown. A full characterisation is needed to determine the source(s) of the RDS and likely variability and, if possible, the reasons for the variability. It is acceptable for the manufacturer to use historical information or information gained by or with other manufacturers of similar construction products (shared ITT). Care is needed when using such pooled data as a single manufacturer may use a source of a constituent that gives release/emission close to the class limit value while the use of other defined sources gives values that lead to a low frequency of further testing or no further testing. A comprehensive characterization helps the manufacturer control the product using often-simple tests and the user having greater confidence in the declared performance.

If a construction product is being classified on the basis of using alternative tests, the relationship between the alternative test and the reference method should be established and documented.

If the initial type testing shows that the average value is at least 's' standard deviations from the class limit and the characterization shows that these release/emission characteristics are unlikely to change, the construction product may be placed in the RDS class without the need for further testing. This is called the WFT procedure. As there will not be further testing by the manufacturer for the evaluation of conformity to this RDS class, it is reasonable to require the average value to be further away from the RDS class limit than with a RDS that is subject to further testing.

NOTE 1 It may not be possible to assess a RDS for a construction product on the basis of the WT procedure because some sources of materials give release/emission values that are too close to the class limit. An objective of the initial type assessment procedure is to characterize the construction product sufficiently well to enable the manufacturers with the safe sources of materials to be able to use the WFT procedure.

EXAMPLE 1 If a RDS class limit is based on a 95% probability of not exceeding the class limit this means that the average value will be at least 1.64σ below the class limit. If an outlier is defined as being 3σ or more above the average value, some intermediate value seems appropriate for the application of the WFT procedure. A margin of 1.96σ gives a 97.5 % probability that the class limit will not be exceeded.

NOTE 2 Statistical approaches, as described above, are only possible if tests results are sufficiently precise. CEN/TC 351 has agreed that all test methods should include a precision statement and that a test will not be published as a full European standard (EN) until it is sufficiently precise. In addition, the tests should be undertaken in a laboratory that is sufficiently qualified and experienced to guarantee execution of the tests in an adequate and reproducible way. In order to develop confidence in the system, the use of proficiency testing should be considered by the Task Groups and Working Groups dealing with the developments and use of these tests.

10 Conformity to a class limit on the basis of a WT procedure

10.1 General

The WT procedure is only applicable to RDSs that have been identified as relevant for the product in its use(s) and mandated.

The applicant, usually a CEN product committee or a European manufacturers association, will have to prepare a dossier of information that is submitted to the authorized body appointed by the European Commission. The authorized body will make an evaluation of the dossier and decide if the RDSs covered by the application are deemed-to-conform to selected RDS class limits for the defined release scenarios and stated conditions without the need for initial type testing or further testing. When agreed, the conditions that lead to a deemed-to-conform RDS classes will be reproduced in the relevant product standard. If the application is rejected, the reasons for the rejection must be given. The applicant should have the right to appeal and the right to re-submit with new data that covers the issues that led to its rejection. Even if a dossier of information is rejected, the information contained within the dossier may be helpful for the initial type assessment of the product.

An initial type assessment will be required to determine if the construction product(s) satisfy the requirements in the product standard for assessing some or all of the RDSs by the WT procedure. As part of factory production control, the manufacturer will have to ensure that the construction product(s) continues to conform to all the conditions that led to the deemed-to-conform assessment.

10.2 Dossier of information

The dossier of information is expected to cover any construction product that conforms to the cited European product standard, except where the applicant has limited the scope of the application. The applicant is free to select what mandated RDSs are included in the application, but these need to be listed. It may be helpful to the authorized body to list the mandated RDSs not included in the application.

It is also necessary to define for each selected RDS the RDS class for which the WT procedure is to apply. This may not always be the most stringent RDS class. For example, if a very stringent RDS class is needed to satisfy the regulations in a single Member State, it may be necessary to verify this RDS class by further testing. However, conformity to less stringent RDS classes could be on the basis of a WT procedure.

The dossier will need to define the release scenarios for which an assessment via a WT procedure is being sought.

The construction products should be characterized generally by release/emission or where this is not practicable, by content of RDSs. When the characterization is based on release/emission, data have to be provided to show that the regulatory requirements have not been exceeded and there is an adequate margin between the measured values and the limit. When the range of composition of the construction product(s) is defined, any limitations on the application should be clearly identified, e.g. excluding products made with material *u*, material *x* where the content of *aaa* exceeds *bbb*, constituent *Y*; of class *Z* or higher. For certain products, this may best be achieved by defining the constituent/raw materials that are covered by the application and the standards/specifications to which they conform. Information on the constituents and on the composition should distinguish between cases where RDSs are introduced in the construction product through traces in the constituents and/or process materials (including ashes from burning materials) or cases where the RDS is specifically used to manufacture the product. The documentation may include evidence on the influence of the statistical variation of the content of RDSs in the product or the release/emission of RDSs.

A brief description of the manufacturing process may be given indicating whether the process can create or destroy regulated dangerous substances. For example, a construction product that is derived from a high temperature process (around 1000°C or more) is unlikely to contain any significant level of organic substances provided such products are not processed afterwards (e.g. by adding plasticizers, fasteners, stabilizers, colouring agents).

The heart of the dossier will be the evidence needed to justify a deemed-to-conform assessment. The following list is a non-exhaustive list of forms of evidence that may be included in the dossier:

a) evidence that the construction product(s) has satisfied relevant regulations for the release/emission of RDSs;

b) laboratory test data showing levels of release/emission of RDSs below regulatory levels or where these do not exist, below accepted good practice;

NOTE The test procedures used to obtain the data have to be clearly defined. When test methods for release/emission of RDSs are published as European standards, further testing should be in accordance with these standards.

c) field data showing low levels of release/emission of RDSs;

d) information showing that certain RDSs are not normally present;

e) compliance with other relevant Directives/Regulations, e.g. Biocidal Directive [16], REACH regulation [6];

f) expert environmental risk assessment(s) already carried out; safety data sheets;

g) documented evidence of satisfactory performance in practice.

It is not necessary for a dossier to contain all these forms of evidence. However, it is necessary for sufficient evidence to be provided to justify any deemed-to-conform assessment. The evidence should include all conditions of intended use covered by the application.

Any outliers in a data set (see 3.27) should be examined to determine if there are grounds for excluding them from the assessment. Justification as to why a result should not be included in the assessment may be provided. However, in cases where there is no justification for exclusion, the result shall be included in the assessment e.g. an outlier may be from a different source to the other samples and should, therefore, be included in the assessment.

In summary, the dossier of information should contain:

a) name and contact details of the applicant;

b) construction products to which the application applies;

c) relevant European standard to which the product conforms;

d) intended use(s);

e) any limitations on the scope of the application, e.g. excluding products made with material '*yy*';

f) release/emission scenario (soil, groundwater and surface water or indoor air);

g) list of mandated RDSs and the RDS classes for which the WT procedure is being sought (there could be more than one list if the range of construction products covers products made with different materials);

h) mandated RDSs not included in the application (optional);

i) description of the construction product for which the application of the WT procedure is being sought;

j) description of the evidence of conformity to the relevant RDS classes.

10.3 Assessment of the dossier

The authorized body and invited experts from the CEN product committee should review the dossier of information. The application of rigid rules is not applicable.

Factors that should be taken into account include the number of data, the period over which data have been gathered, whether the data are from typical products or products at the extreme of performance and the closeness of the data to the RDS class limit. In addition the confidence in the data should be assessed, e.g. was it obtained by an independent third party or has it already been accepted by the European Commission or by a national regulator?

Where the applicant has concluded that certain RDSs on the mandated list are not practically relevant to a particular type of product, provide evidence to support this claim.

For the identified RDSs defined in the dossier and the data provided, the authorized body must be satisfied that there is a low risk of emission or release into soil, groundwater or surface water, or into indoor air in quantities above each RDS class limit.

The basis for decisions, which will be carried forward into product standards and will therefore be binding on all EU Member States, must be documented. Where authorization is refused, the reason given for the refusal shall be given to the applicant. Where refusal is based on the lack of specific data, the missing data shall be defined by the authorized body and the applicant be permitted to re-submit when new data have been generated.

An appeal procedure should be put in place, which implies the establishment of an appropriate independent body.

10.4 Application of the WT procedure

RDSs that are deemed-to-conform to a RDS class for the defined release scenarios and stated conditions through the WT procedure do not need to undergo any initial type testing or routine testing to verify conformity. If all the mandated RDSs are covered by the WT procedure, the construction product may be assigned a set of RDS classes without testing the specific construction product. However, the use of the WT procedure does not absolve the manufacturer from full responsibility for any claimed performance based on FPC.

11 Evaluation of conformity

CEN Guidance Paper M [5] focuses on the concept that any involved party, manufacturer, specifier, user may take a sample and evaluate whether the product they received satisfied their specification. This concept applies equally to the release/emission of RDSs. As such, it is clear that the reference test procedure has to be used for such an assessment.

This report proposes that consideration is given to defining the RDS class limits by a statistical probability that the class limit will not be exceeded. This would provide a sound technical basis for developing rules for the evaluation of conformity. CEN/TC 351 has agreed that a Task Group of experts and stakeholders is created to provide a set of recommendations, including conformity criteria and rates of testing, where required. These recommendations, when agreed by CEN/TC 351 would be adopted by all Working Groups and Task Groups and in particular lead to the revision of this report.

The European Union and Member States have lists of substances that are fully banned. It is clear that a manufacturer may not deliberately make a product with a banned substance, but trace amounts of banned substances are frequently found in many products, not just construction products. At such low levels, they pose no significant risk to human health or the environment. Simply defining ‘not containing a banned substances’ as being a value below the limit of detection is not a solution as, for example, a single particle of asbestos cement sheeting in a large sample of recycled aggregate is detectable. It would be helpful if the Workshop on the 27 October 2008 agrees a recommendation on the meaning of ‘not containing a banned substance’. Options should be discussed with the Commission Services, including departments that are responsible for the relevant regulations.

NOTE See 5.3 for reasons as to why the meaning of ‘not containing’ has to be transparent.

12 Factory production control of RDSs

12.1 General

FPC comprises:

a) an initial type assessment that may include initial type testing to classify the construction product for each relevant mandated RDS and, optionally, to classify the construction product into a set of RDS classes;

b) routine control of production to detect when the construction product changes from that determined under the initial type assessment and either to amend production to bring the construction product back in line with the original classification or to reclassify the construction product;

c) evaluation of conformity.

12.2 Routine control of production

CEN requires all product standards to contain a clause requiring the manufacturer to adopt and apply an effective production control system that keep the product in a state of statistical control and conforming to the claims made by the manufacturer. How this is done is left to the manufacturer. The effectiveness of the production control is subject to assessment by a notified or certification body where this is required as a consequence of the level of attestation of conformity or specified. This procedure applies equally to any declared performance on the potential release/emission of RDSs.

For RDSs covered by the FT procedure, periodic testing is required. The frequency of further testing and whether this frequency of testing should depend upon the closeness to the RDS class limit are important details that have still to be elaborated.

There are some special circumstances related to banned substances where the European or a national environmental regulator may wish to convey to the notified and certification bodies what they regard as an acceptable factory production control procedure.

EXAMPLE Asbestos is a banned substance that may be found in certain sources of recycled aggregates. Dealing with this substance requires a comprehensive management approach starting with its identification in a structure prior to demolition, its careful removed and disposal before the rest of the building is demolished. Even with this care, there may be trace amounts left in the resulting recycled aggregate and it is necessary for the aggregate standard to have a low but measurable limit that accepts this as being in effect zero content. What would be regarded as unacceptable to environmental regulators is for the initial steps of identification and removed to be missed on the basis that the asbestos when calculated over the total of the recycled aggregate would satisfy the permitted limit value.

Production control with respect to RDSs may involve testing either of the constituents or the material. Release/emission tests are unlikely to be practical for controlling production and so the manufacturer might opt to use alternative tests including screening tests that were identified as being appropriate during the initial type assessment.

13 Recommended delivery of the proposed system

13.1 List of mandated RDSs

The Commission will be providing the lists of mandated RDSs for each construction product.

13.2 Statistical basis for the system

The CEN/TC 351 Workshop on the 27 October 2008 should try to agree the meaning of a class limit and make a recommendation to the European Commission on the following:

a) location of any hard limit above the class limit;

b) probability of not exceeding a class limit;

c) probability of not exceeding a class limit when the WFT procedure is applied;

d) rate of testing as a function of the closeness to the class limit;

e) meaning of ‘not containing a banned substance’.

NOTE The determination of the precision of the test methods is a separate matter.

The implications of applying such statistical criteria need to be carefully assessed against real data to avoid the situation where a construction product that has never failed a class limit or been close to a class limit becomes ineligible for the WFT procedure because of proposed statistical criteria.

Action: CEN/TC 351

CEN/TC 351/TG 3 should revise this CEN Technical Report to reflect these decisions.

Action: CEN/TC 351/TG 3

13.3 RDS classes and sets of RDS classes

The European Commission should consider the recommendation of CEN/TC 351 to permit the sets of RDS classes to include the national abbreviations, e.g. NL and respond formally to CEN.

Action: European Commission

When the procedures for the European test methods are known, the national regulators are requested to determine their regulatory limits and pass these to CEN/TC 351 who will turn these into recommended RDS classes and sets of RDS classes together with guidance for product committees.

Action: Regulators with notified regulations

CEN product technical committees should create RDS classes and sets of RDS classes for the construction products under their responsibility for each relevant release/emission scenario using some or all of the recommended classes from CEN/TC 351 or having justifiable technical reasons for having a deviating set of classes.

Action: CEN Product TCs

13.4 WT procedure

The European Commission has already confirmed that the WT procedure is substance based.

The European Commission is requested to consider the proposals in clause 10 for the WT procedure and to either accept or reject these proposals. If they accept these proposals, they should put in place the necessary administrative procedures, e.g. the constitution of the authorized body, the appeals procedure, whether the results of an approved application should be published in the Official Journal of the EU.

Action: European Commission

When the European Commission has agreed a WT procedure, applicants should prepare a dossier of information and submit it to the authorized body.

Action: Applicant

The authorized body should assess all applications and either accept or reject with reasons the each application.

Action: Authorized body

CEN product committees should identify in their product standards the RDSs that may be assessed on the basis of the WT procedure.

Action: CEN Product TCs

13.5 WFT procedure

When the statistical basis for the WFT procedure has been agreed, CEN/TC 351 should provide guidance to CEN product committees on how to include this procedure into their product standards, e.g. a draft text for inclusion.

Action: CEN/TC 351

If expressed as a number of standard deviations, CEN product committees should transpose this margin into numerical values for conformity assessment purposes.

Action: CEN Product TCs

13.6 FT procedure

CEN/TC 351 should provide guidance to CEN product committees, e.g. a draft text for inclusion, on the FT procedure including test methods, the rate of testing and the criteria for increasing/decreasing this rate of testing.

NOTE See clause 11 for conformity criteria.

Action: CEN/TC 351

13.7 Evaluation of conformity

The European Commission is requested to consider the proposals for the evaluation of conformity given in this CEN Technical Report and to either accept or reject these proposals.

Action: European Commission

If these proposals are accepted by the European Commission, CEN/TC 351/TG7 should determine the rate at which the evaluation of conformity should be increased when the measured value is above the class limit and what action should be taken with respect to the factory production control and recommend these proposals to CEN/TC 351.

Action: CEN/TC 351/TG 7

When approved by CEN/TC 351, CEN product committees should include these requirements in their product standards.

Action: CEN Product TCs

Annex A

(informative)

Implementation of the proposed system by a manufacturer of a product

Figure A.1 is a flowchart that sets out the procedure for providing information on release/emission of RDSs.

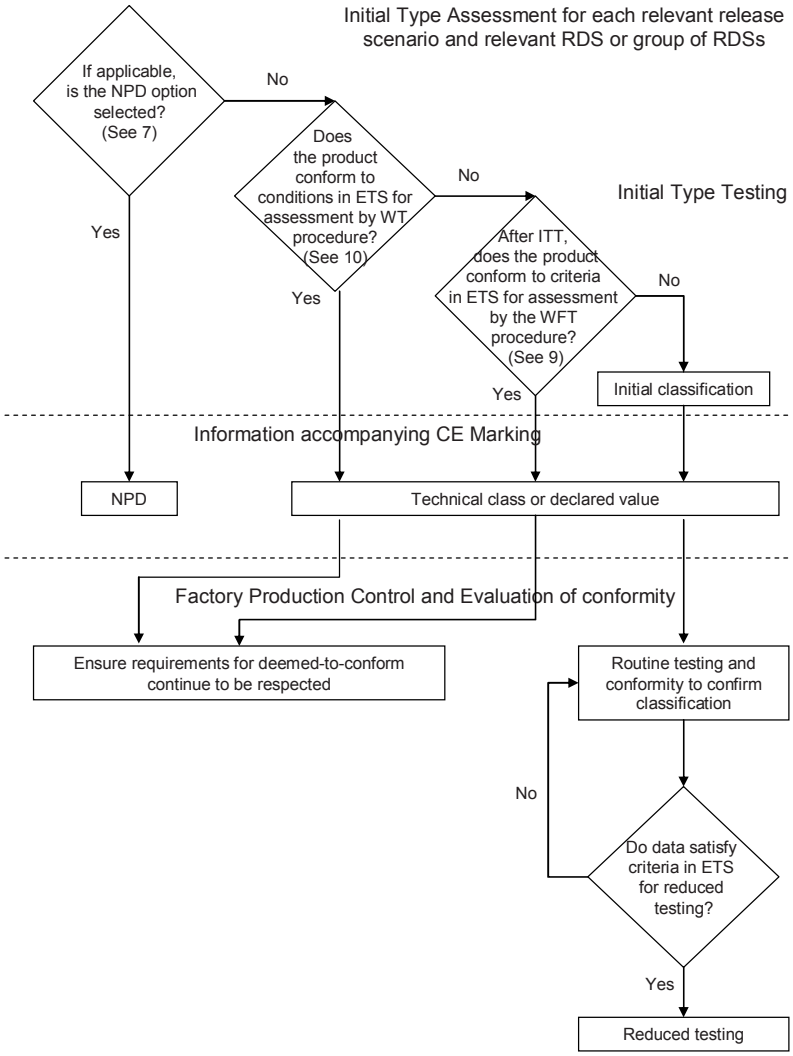


Figure A.1 — Flowchart for the procedure to be used by the manufacturer to provide information about release/emission of regulated dangerous substances listed in the product standard

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