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English Version

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

Produits de construction - Evaluation de l'émission de substances dangereuses - Guide pour l'évaluation de la performance et la vérification de sa constance - Partie 2 : Données techniques et statistiques

This Technical Report was approved by CEN on 16 January 2015. It has been drawn up by the Technical Committee CEN/TC 351.

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EUROPEAN COMMITTEE FOR STANDARDIZATION  
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## European foreword

This document (CEN/TR 16797-2:2015) has been prepared by Technical Committee CEN/TC 351 “Construction products: Assessment of release of dangerous substances”, the secretariat of which is held by NEN.

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

CEN/TR 16797, *Construction products: Assessment of release of dangerous substances — Guidance on the statistical assessment of declared values*, comprises the following two parts:

- *Part 1: Principles and rules of application;*
- *Part 2: Technical and statistical background* [the present document].

## 0 Introduction

### 0.1 General

CEN/TR 16797-1 [1] provides a brief introduction to declaring performance for the potential release, emission and/or content of dangerous substances from or in construction products and gives the principles which underpin the assessment and verification of constancy of performance (AVCP) of the product in respect of such declarations. The main rules of application are introduced, all of which satisfy the given principles.

CEN/TR 16797-2 provides a more detailed background and technical explanation together with examples and the statistical justification for the rules of application. The definitions and abbreviations listed in Clause 2 also apply to CEN/TR 16797-1. Annex D contains a model clause and the rules of application as normative text that may be copied into or cited by product standards. A recommended solution is to copy the model clause into the product standard and specify the 'rule of application given in CEN/TR 16797-2:2015, Annex D' to be used.

This Technical Report was developed on the basis of experience with the control of release into soil and water. As it is an assessment of data against a declared value regardless of the source of the data, it is the technical view of CEN/TC 351 that these procedures are also valid for the assessment of emission from construction products into indoor air and assessment of gamma radiation from construction products.

It is suggested that all product technical committees follow the principles set out in this CEN/TR and it is hoped that all regulators will accept that these principles achieve their objectives with respect to an acceptable AVCP procedure. The rules of application are examples of the ways in which these principles may be applied. There is no obligation on a product technical committee to adopt these rules of application and they are free to determine their own rules of application. The given rules of application may also be used as a benchmark for assessing alternative rules of application.

If product technical committees and producers could streamline their approaches in a way that could be accepted by all regulators, it might support a common understanding on the European market and it might encourage regulators to harmonize their existing different approaches and requirements on reliability and meaning of performance declarations in legislation and enforcement.

### 0.2 Background

CEN/TC 351 in its Resolution 162 (Milan 2011) has allocated to its TG 7 the task of drafting a technical report with the following content:

*'This technical report provides guidance to Technical Committees on the evaluation of conformity of test results with regard to dangerous substances from or in construction products. Where further-testing is required, methods for assessing whether the product conforms to the information provided on the potential release of dangerous substances is described and justified. This technical report also describes the conditions and assumptions under which the proposals are given.'*

In undertaking this task, TG 7 reviewed existing systems that are accepted by regulators. In practice these were the Dutch Soil Quality Decree system, a statistically based system where the rate of testing is a function of the closeness of the measured values to the regulatory limit value, and the German technical approval system. Technical Approvals normally apply to products not covered by CEN standards, but in Germany they are also being applied to the characteristic of release of dangerous substances, as this characteristic is not yet covered by CEN procedures. The German Technical Approval defines a rate of routine testing for release (not a constant between different products) and the product needs to achieve a release not greater than the defined value. The simplicity of this pass/fail criterion has merit, but there is no possibility of reducing the rate of testing (or incentive to the producer to achieve the lowest possible values of potential release) and when used

in a CEN system, the declaration of non-conformity over a period of months would have disproportionate consequences.

After reviewing the options, CEN/TC 351 is proposing a single statistically based system that includes the concept of a producer being able to reach a point where no-further-testing is required and a system that is applicable to a wide range of construction products, allowing a uniform assessment of release or emission which is not dependent of the type of construction product.

The objective of this CEN/TR is to provide guidance to product technical committees and information to regulators on the statistical assessment of declared values/classes for release, emission or content of dangerous substances.

### **0.3 Assessment of construction products**

CEN/TR 15858 [2] describes three procedures for classifying the potential release of RDS: without-testing, without-further-testing and further-testing. Without-testing (WT) is a generic procedure where a comprehensive dossier of information containing information and previous test data on release from a product is prepared and submitted to the European Commission. The Commission appoints an expert group that includes regulators and product experts to review the dossier of information. If approved by the expert group and endorsed by the Commission, the product standard may include generic procedures for declaring classes of release based on composition, without the need for type testing and further-testing by the producer. Document DS 129 [4], however, describes this procedure as WFT on the basis that a dossier will not be approved without test data.

In this technical report, only the term WFT will be used, following the way it is used in DS 129.

Where a WFT procedure is not provided in the product standard or not selected by the producer, the producer undertakes type testing (TT) to determine the initial rate of further testing. Further-testing usually follows type testing and this is where every batch (called 'batch testing') or more usually a random batch selected from a defined period of production is tested (called 'random testing') and this test result is used with previous test data to show the consistency of production and to determine the frequency of testing. Further-testing by the producer (FT) and the assessment as to whether the declared value is validated using these test data is fully described in this CEN/TR.

If the FT (and rarely the TT) shows the product is consistently safe and the distance between the measured values and declared values is large, FT may end provided certain other requirements are met (essentially to ensure the composition of the product or the process is not changed significantly) and with the involvement of an independent third party. The criteria for no-further-testing (NFT) are defined in this technical report. This technical report recommends that any NFT decision is approved and audited by an independent third party.

NOTE CEN/TR 15858 [2] described this end to FT as 'without-further-testing', but this term is used in DS 129 [4] and in this technical report to mean something else; see text above.

All methods of verifying the declared value/class have equal status and validity. Figure 1 shows the outline procedure for these options.

The conditions under which the statistical assessment of declared values/classes described in this CEN/TR applies are:

- the product is covered by a harmonized European product standard requiring information on the potential release, emission or content of RDS or the contract of supply requires the provision of information on the potential release of RDS;
- there is one or more RDS that require FT to confirm the technical class or value declared by the producer;

- the FPC system has specifically addressed the control of RDS.

This CEN/TR provides guidance on the statistical assessment of declared values where type testing followed by further testing is required with respect to RDS for:

- potential release into soil, groundwater and surface water;
- potential emission into indoor air;
- content;
- potential gamma radiation or emission (exhalation) of radon gas into indoor air

to support:

- declarations of performance made under CE-marking;
- for showing conformity of RDS restricted at the Community level;
- for showing conformity of RDS restricted by provisions valid in the place of use;
- for showing conformity to limits for RDS specified in the contract of supply.

In all four cases the procedure for the statistical assessment of the declared value is the same.

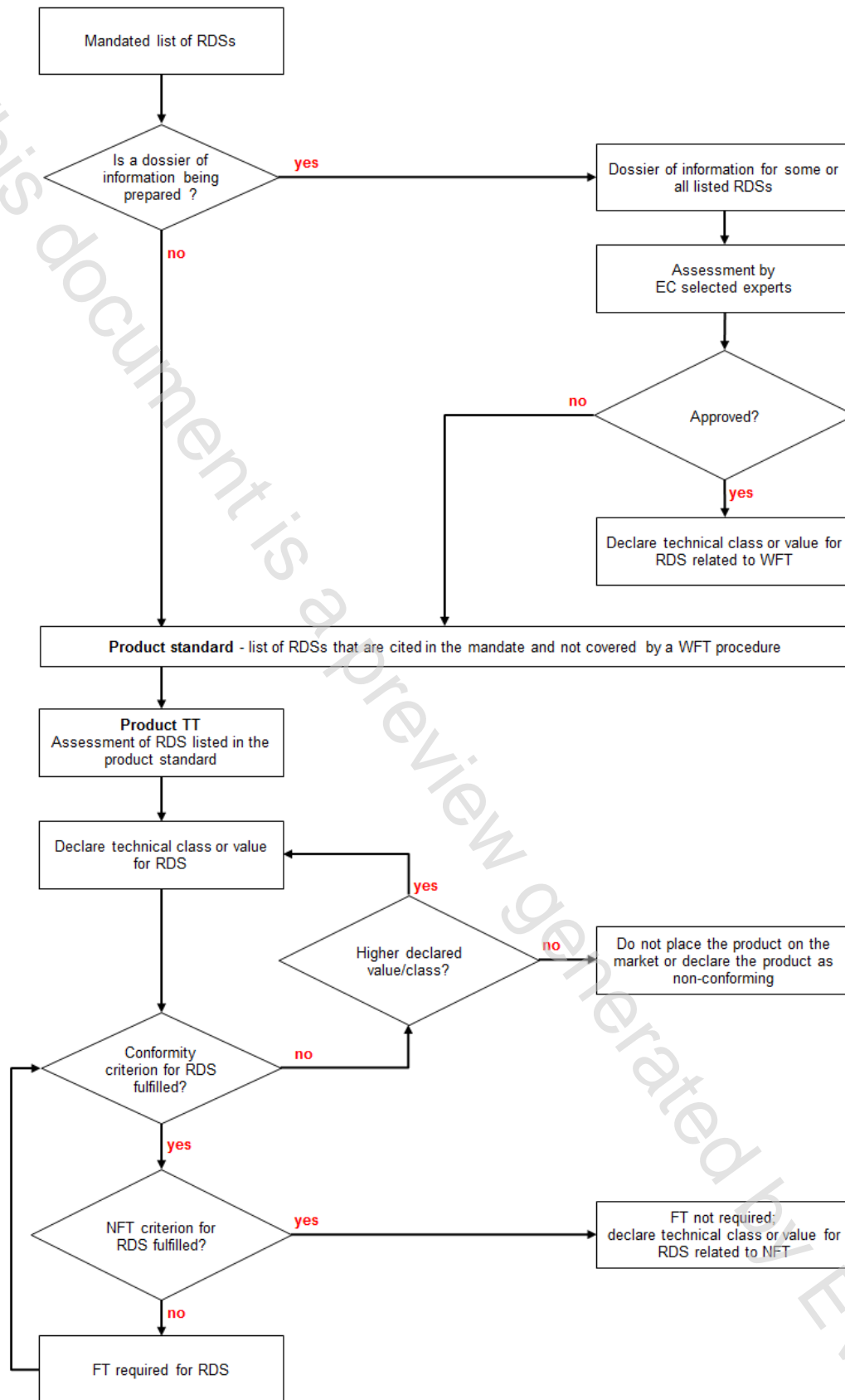


Figure 1 — Possibilities of WFT, FT and NFT for construction products



## **0.4 Reading guide to CEN/TR 16797-2**

### **0.4.1 General introduction**

A general introduction to the statistical assessment of declared values for the release, emission or content of RDS from or in construction products is given in Clauses 0, 1, 2 and 3. Terms and definitions are given in Clause 2 and Clause 3 puts CEN/TR 16797-2 into its context and identifies the tasks that need to be undertaken by CEN Technical Committees.

### **0.4.2 Rules of application**

The rules of application are explained in Clauses 4 to 7. In Clause 4 the quality level of performance of the rules of application are defined. The methods and basic rules for the statistical assessment of declared values are described in Clause 5 followed by a technical description of the rules of application for assessment by variables (Clause 6) and assessment by attributes (Clause 7), all of which satisfy the given principles.

### **0.4.3 Statistical background**

The statistical background of the rules of application is described in Clause 8. Clause 9 contains additional sampling requirements not addressed in CEN/TR 16220 [3], while Clause 10 gives guidance on the use of alternative, indirect test methods.

### **0.4.4 Annexes**

Annex A contains examples of the rules of application described in this CEN/TR. Background information on the statistical distribution of RDS are given in Annex B. Annex C contains a checklist for technical aspects related to RDS that need to be addressed in product standards. In Annex D examples of model text are given on how to include normative requirements for statistical assessment of declared values. Annex E gives an extensive table with values for some of the statistical parameters used in this CEN/TR. Annex F gives values for the factor of a specific tool called the gamma rule.

## 1 Scope

This Technical Report provides guidance on the statistical assessment of declared values with respect to the release, emission and/or content of dangerous substances. This report provides statistically-based criteria for type-testing (TT), further-testing (FT) and where a product has been shown to be consistent with measured values for the release, emission or content that are significantly below the declared values, the point where no-further-testing (NFT) is permitted.

A series of fundamental principles are defined in CEN/TR 16797-1 and two statistical approaches are defined. The first approach is to use assessment by variables and this approach requires the data to be normally or log-normally distributed. This approach is recommended as the default option. The alternative approach based on assessment by attributes is appropriate for data sets that are not normally or log-normally distributed. The downside to this form of assessment is that more test data are needed for the same level of reliability. CEN/TR 16797-1 introduces these assessment procedures and CEN/TR 16797-2 provides more detail and the statistical proof that they satisfy the principles defined in CEN/TR 16797-1. With both of these approaches the minimum frequency of testing is a function of the distance between the mean value and declared value and the variability of the data set, i.e. the sample standard deviation.

To reduce the costs of testing, production plants producing a similar product may share data, e.g. be grouping the product into clusters for statistical assessment of declared values. Rules for the use of clusters are given in this document.

This document also contains rules for identifying outliers within a data set and guidance on using tests other than the reference method for FT.

A list of tasks for product technical committees is given in this document as is a model clause for including in product standards and rules of applications that may be cited in the product standard or copied into product standards.

## 2 Terms, definitions, abbreviations and symbols

### 2.1 Terms and definitions

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

**NOTE** The following definitions are used in this document for the purposes of using and explaining the system of assessment. These definitions align with those given in EN 16687 [6], ISO 3534-1 [10] and ISO 3534-2 [11].

#### 2.1.1

##### **assessment by attributes**

assessment by noting the presence (or absence) of one or more particular characteristic(s) in each of the items in the group under consideration, and counting how many items do, or do not, possess the characteristic(s)

[SOURCE: [11] (adapted)]

Note 1 to entry: With respect to the assessment of the release, emission and/or content of RDS 'presence' or 'possessing the characteristic' means that the test result is greater than the declared value and 'absence' or 'not possessing the characteristic' means that the test results is equal to or lower than the declared value.

#### 2.1.2

##### **assessment by variables**

assessment by measuring the magnitude(s) of the characteristic(s) of an item

[SOURCE: [11] (adapted)]