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Construction products: Assessment of release of dangerous substances - Guidance on the statistical assessment of declared values - Part 1: Principles and rules of application

Produits de construction - Evaluation de l'émission de substances dangereuses Guide pour l'évaluation de la performance et la vérification de sa constance - Partie 1 : Principes et règles d'application

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EUROPEAN COMMITTEE FOR STANDARDIZATION
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European foreword

This document (CEN/TR 16797-1:2015) 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* [the present document];

— *Part 2: Technical and statistical background*.

Introduction

The present document provides a brief introduction as to how to declare performance for the potential release, emission and/or content of dangerous substances from or in construction products and gives the principles which underpin the acceptance criteria of test results in relation to a declared value. The main rules of application are introduced, all of which satisfy the given principles.

CEN/TR 16797-2 [1] provides more detailed background and technical explanation together with examples and the statistical justification for the rules of application. The definitions and abbreviations listed in CEN/TR 16797-2:2015, Clause 2 also apply to CEN/TR 16797-1:2015. CEN/TR 16797-2:2015, Annex D contains a model clause and the rules of application introduced in this Part are drafted 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 Technical Report 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.

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 Technical 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 the present document 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. The present document introduces these assessment procedures and CEN/TR 16797-2 provides more detail and the statistical proof that they satisfy the principles defined in this document. 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 CEN/TR 16797-2.

CEN/TR 16797-2 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 CEN/TR 16797-2 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 Declared values

Any declared value with respect to the potential release, emission and/or content of dangerous substances needs to be justified. This justification is based on either:

— the product conforming to the conditions given in the relevant product standard for a declared value/class based on the without-further-testing concept; or,

— type-testing followed by further-testing at the determined frequency.

Where there is no requirement to carry out a determination, the producer may declare performance for this characteristic as 'NPD' using the ‘no-performance determined’ option.

The Construction Products Regulation [2] defines the ways in which a declaration of performance may be made by the producer. The declared value, or declared class, provides a level of release, emission and/or content that has a low probability of being exceeded in the production. A producer is free to select the value to be declared. The validity of the declared value is assessed using statistical techniques described in this CEN Technical Report using a sufficient number of tests according to a standardized test procedure (the reference test or a combination of tests with the reference test and adequate indirect tests). The declared value applies on the scale of a batch as defined in the product standard. As it is a numerical value it can, where required, be compared directly with a limit value in a regulation or specification. If, in those cases, the declared value is equal to or less than the limit value, the product satisfies the requirement. A product technical committee is also free to introduce classes (as technical classes), but the upper numerical value defining these classes has the same technical meaning as a declared value. The lower numerical limit of the class will be zero.

Where a product is to be placed on a regulated market, and where the mean value based on the reference test method is low in relation to the regulatory limit, a producer may benefit from setting the declared value at the regulatory limit. Doing so will tend to minimize the test frequency and may lead to satisfying the conditions for no-further-testing (NFT) given in 5.2.6 and 5.4.6. Whereas, a declared value that is significantly lower than the regulatory limit, and hence much nearer to the mean value, will probably result in a higher test frequency or even batch testing under these rules of application. On the other hand, setting a high declared value in order to minimize the test frequency might affect a product's competitiveness in relation to products with a lower declared value. So the freedom for the producer to select the declared value introduces more flexibility. It is, however, for the product technical committee to decide whether performance should be declared using declared values or classes or whether both options are permitted in its product standards.

If the confidence at which the declared value is to be achieved were only to be defined (qualitatively) as ‘a low probability of being exceeded in the production’, its meaning would be interpreted differently by different product technical committees and different regulators. In existing legislation and formal enforcement procedures in different Member States requirements are specified on the reliability of the declared values and while these specifications are not harmonized, the intentions are usually similar. Therefore, a common, agreed quantitative, i.e. statistical, definition is necessary and based on existing regulations and experience, the following is proposed:

Principle 1: The rules of application verify with a confidence of 90 % that the 50th percentile of the production is less than or equal to the declared value when the scale of declaration is a batch as defined in the product standard.

Put another way, it should be expected that the average quality of a batch would be equal to or better than the declared value after taking into account uncertainty (see Clause 4). The criterion of 50th percentile may seem too relaxed, but in practice it means that products placed on the market will rarely exceed the declared values. This is explained in detail in CEN/TR 16797-2.

The rules of application described in this document all satisfy this principle and the technical explanation as to why is given in CEN/TR 16797-2:2015, Clause 8. In the following sections where the term ‘declared value’ is used, it may be interchanged with the terms ‘regulatory class limit’ or ‘technical class limit’.

3 Other principles

It is assumed that the reader is familiar with the principles of the Construction Products Regulation and therefore these principles are not repeated in this Technical Report. There are also a number of principles associated with issues such as confidence in the test laboratory and rules for enforcement testing, but these are outside the scope of this Technical Report.

The following principles all relate to the declared values with respect to the potential release, emission or content of dangerous substances.

Principle 2: The declared value relates to the performance of the product in a reference test procedure.

The appropriate test method will be defined in the product standard.

Principle 3: The test frequency is permitted to vary. The test frequency reduces as the risk of exceeding the declared value diminishes, e.g.:

— the distance between the mean value and the declared value increases;

— the standard deviation reduces.

Producers should benefit from lower rates of testing where test results show low variability and where:

— declared values are particularly conservative i.e. where the mean value is well below the declared value;

— and/or the mean value is well below a market's regulatory limit.

This variable test frequency therefore acts as an incentive to producers to control their products and reduce the environmental impact.

Principle 4: The production is split into batches in order to facilitate the variable test frequency. For continually produced products, the batch size associated with Principle 1 is not more than one tenth (10 %) of the production over one year and the maximum batch size needs to be defined by the product technical committee.

For continuous production, it may be simpler to split the year into 12 batches; each month of production representing one batch. The maximum test frequency is one test per batch but in most cases the test frequency is significantly less (down to one batch per three years). While the maximum batch size needs to be specified in the product standard, the producer may benefit from using this maximum size during random testing and using a smaller batch size during batch testing. During batch testing a smaller batch size helps speed the end of batch testing and reduces the quantity of product at risk if it is declared as non-conforming.

Products conform to the declared value until non-conformity is shown by the test results in combination with a statistical evaluation detailed in this report.

Principle 5: For one product and intended use there is a single reference test method. In the case of dispute the reference method has precedence.

This principle does not stop the use of alternative test methods ('indirect tests') for further-testing, but they need to be correlated to, or a safe relationship established with, the reference method, see CEN/TR 16797-2:2015, Clause 10. From the point at which the reference methods are introduced, type-testing of 'new' products will require their use; however, see 5.2.4 and 5.4.4 for the discretionary use of existing test data.

Principle 6: The assessment approach is allowed for products in a production that have a normal, more or less known, variation of release, emission or content. If the factory production control expects that a change in production or materials might lead to products outside the normal variations, a separate assessment procedure should be started.

The assessment approach for declared values needs to include factory production control systems on the input materials and processing. In some cases the dangerous substances are part of the raw materials used in production and the producer has little control over the content of dangerous substances. In other cases, selection and processing can significantly control the level of dangerous substances. The assumption on which the assessment of conformity is based is that the product is homogeneous, i.e. its variability is controlled within limits, and the factory production control system needs to ensure that this assumption is valid. If, for example, raw materials are used with much higher content of dangerous substances that might influence release from the final product, this should be assessed as a different product.

Principle 7: For products from specific sources where the mean value is well below the producers declared value, a point may be reached where no-further-testing (NFT) is needed to fulfil Principle 1. Assessment of NFT verifies with a confidence of 99 % that the 90th percentile of the production is less than or equal to the declared value when the scale of declaration is a batch as defined in the product standard.

Statistically it makes no sense to continue to test a product that has been shown to consistently meet the declared value by a very large margin; however, NFT is only valid if the product does not change and the factory production control needs to ensure that the product has not changed.

The NFT procedure is different to the 'without-further-testing' (WFT) procedure. The WFT procedure is a generic way for declaring release, emission or content. If a product conforms to certain rules defined in the product standard, a given declared value/class may be stated without testing by the producer for release,

emission or content. The use of the WFT procedure to declaring a value/class is based on a dossier of historical test data for a generic product that has been approved by the European Commission. On the other hand declaring a value based on the NFT procedure is specific to a manufacturer's particular product and it is a technical process based on the assessment of previous test results, either using the reference method or a correlated alternative method, and conditional on the product not changing.

4 Uncertainty

There is always some uncertainty in the relationship between a test result and the true mean value of the product it is representing. There are two main sources of uncertainty and neither can be eliminated entirely. The first is the uncertainty associated with the sample being the true average quality of the product being represented. With certain products, e.g. an aggregate, it is practical to take a series of spot samples over the period of production, combine the samples and take a representative sample from this combined sample. Such a procedure will minimize sampling uncertainty. With other products it is not always possible to combine samples sufficiently, e.g. windows or doors, and in these cases the uncertainty associated with sampling is likely to be greater. This sampling uncertainty can be reduced by testing more than one sample in separate tests, or include several items in one test procedure. (e.g. 5 or more bricks in one tank leaching test, or several wooden panels in an emission test chamber.) The product technical committee is expected to define the minimum sample size and number of increments. If the product is variable and the release close to the declared value, testing more than the minimum number of increments may reduce the variability of successive test results and the frequency of testing.

The other source of uncertainty is associated with the test procedure. When a test is repeated using identical material, a range of results is obtained. This range is greater when there is more than one operator using different sets of equipment of the same type. It is normal for a European test standard to include the uncertainty associated with the test procedure. This is usually given as the repeatability and reproducibility of the test procedure. There is a 95 % probability that the true mean of the sample will be between ± R of the test result where R is the reproducibility limit for the test. The lower the values of repeatability and reproducibility the more precise is the test.

When testing a specific batch for conformity:

— where the test result is just below the declared value, not taking account of uncertainty will lead to this batch being accepted whereas it might truly be non-conforming (this is called the consumer's risk); or,

— where the test result is just above the declared value, not taking account of uncertainty will lead to this batch being rejected whereas it might truly be conforming (this is called the producer's risk).

As these risks to the consumer and producer balance out, no allowance for the uncertainty of sampling and measurement is given when assessing a single batch for conformity.

NOTE The uncertainty of measurement is taken into account for enforcement purposes in the Netherlands and Finland. In these cases all the product under investigation is regarded as a single 'batch'.

Uncertainty will be reflected in successive test results and lead to the spread of the test results being larger with higher uncertainty. It is therefore taken into account when random testing, i.e. not testing every batch.

5 Rules of application

5.1 Introduction to the rules of application

The flowchart in Figure 1 provides a guide to the choice of the appropriate rule of application.

The relevant product technical committee needs to select the appropriate rule(s) of application. All the rules of application given in this Technical Report fulfil the principles given in Clauses 2 and 3.

All procedures for the analysis of test data use statistical techniques, but it is not necessary at the production level to understand the statistical detail or background; the basics that are needed is the conscientious application of the ‘rules’.

The model clause given in CEN/TR 16797-2:2015, Annex D requires the expected production to be split into batches. For continual production, a batch needs to be no more than 1/10 of a year’s production. It is simpler to split the year into 12 batches; each month of production representing one batch.