PD CEN/TR 16797-1:2015

BSI Standards Publication

Construction products: Assessment of release of dangerous substances — Guidance on the statistical assessment of declared values

Part 1: Principles and rules of application

National foreword

This Published Document is the UK implementation of CEN/TR 16797-1:2015.

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.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

ISBN 978 0 580 85717 1

ICS 03.120.20; 91.100.01

Compliance with a British Standard cannot confer immunity from legal obligations.

This Published Document was published under the authority of the Standards Policy and Strategy Committee on 30 September 2015.

Amendments issued since publication

Date	Text affected

TECHNICAL REPORT

RAPPORT TECHNIQUE

TECHNISCHER BERICHT

CEN/TR 16797-1

August 2015

ICS 03.120.20; 91.100.01

English Version

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

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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CEN-CENELEC Management Centre: Avenue Marnix 17, B-1000 Brussels

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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.

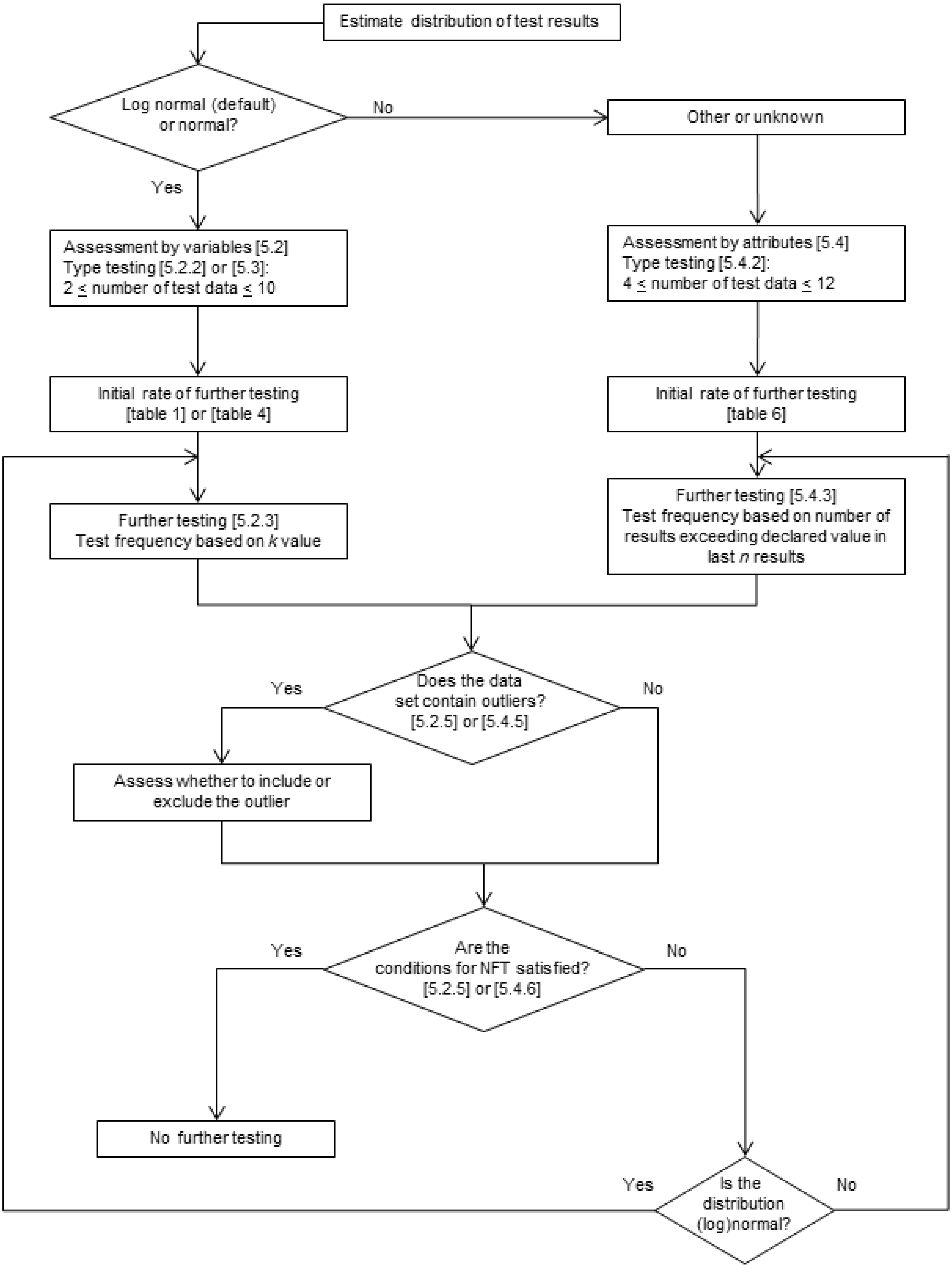


Figure 1 —Flowchart on the selection of the rule of application

The term 'assessment' is used as the procedure described herein is more than an analysis of data. The purpose of the assessment is to verify that the declared value is technically justified.

5.2 describes the main rule of application and it is based on assessment by variables. Assessment by variables is a technique that uses the mean value of the last *n* consecutive results and the spread of these results around the mean value. This is the main and recommended option, as it will require the minimum amount of testing to fulfil Principle 1. This rule of application applies when the distribution of test results is known and is normally or log-normally distributed.

Where a product technical committee knows that the release or emission is low in relation to what will be the declared value and the variability in test results is dominated by the test procedure, they may specify type-testing using the rule of application given in 5.3 (only low values – 'Gamma rule') in place of the procedure given in 5.2. Once there are five test results, it is necessary to revert back to the rule of application given in 5.2. At present the rule of application given in 5.3 only applies to data from leaching tests. Potentially the technique could also be used for emission into indoor air and ionizing radiations, but at the time of drafting this Technical Report the essential statistical parameter, the coefficient of variation of the test data, is unknown. This needs to be known before the correct criteria can be determined.

5.4 describes a rule of application based on the assessment by attributes. Assessment by attributes permits a low proportion of test results to exceed the declared value within a defined number of consecutive test results. The disadvantage of assessment by attributes is that a higher number of test results are needed to fulfil Principle 1.

The rule of application given in 5.4 should be adopted where one of the following applies:

— the production process may substantially affect the test result; or,

— the distribution of tests results is unknown.

These two conditions may lead to the situation where the data are not normally or log-normally distributed and so it is not technically sound to apply the rules of application given in 5.2 and 5.3.

The approach and calculations need to be executed separately for each of the substances for which the performance will be declared. This may lead to different required test frequencies for different substances for the same product.

To fulfil the conditions for testing a product under the rules of application given in 5.2 to 5.4 (or any other rule of application), the product needs to be well defined and it needs to be clear that the product to be tested has a limited variability. The definition of the product to be assessed should not, for example, include aggregates from different quarries from which it is known or expected that certain parameters or substances may differ a lot, or include material from parts of the quarry that are known or expected to be polluted/burdened with significant higher levels than other parts. In such cases a material needs to be split into different products.

The assessment may lead to batches being declared as non-conforming. It is permissible to re-classify such batches at a higher declared value and place them on the market. Such batches may not meet the regulatory limit in some countries.

5.2 Rule of application based on assessment by variables

5.2.1 Principles of assessment by variables

The normal rule of application is assessment by variables using a running-mean of five or 10 results assuming a log-normal distribution. In plain language:

— Assessment by variables is a technique that uses the mean value of the last five or 10 consecutive results and the spread of these results around the mean value.

— The mean value is determined by adding the individual values and dividing by the number of individual values (5 or 10 in this case).

— The spread of results is measured using a parameter called the ‘standard deviation’. In practice the calculation of this parameter (and the mean value) can be done using computer software such as spread sheets. A low standard deviation means little variability about the mean value and a high standard deviation means a wide spread of results.

Where a random variable is normally distributed, a normal distribution curve can be computed, Figure 2, using just the mean value and the standard deviation. A normally distributed set of results is a bell-shaped set of results that is symmetrically spread around the mean value. Most measured values are normally distributed, e.g. the strength of a product, but this is not always the case. Experience with measuring the release or emission of dangerous substances from construction products, shows that the distribution of results is often skewed, Figure 3; however, if the log of the skewed values are taken the distribution of results becomes approximately normal. This is called a log-normal distribution. The main reasons for getting a skewed distribution for dangerous substances are the facts that test results:

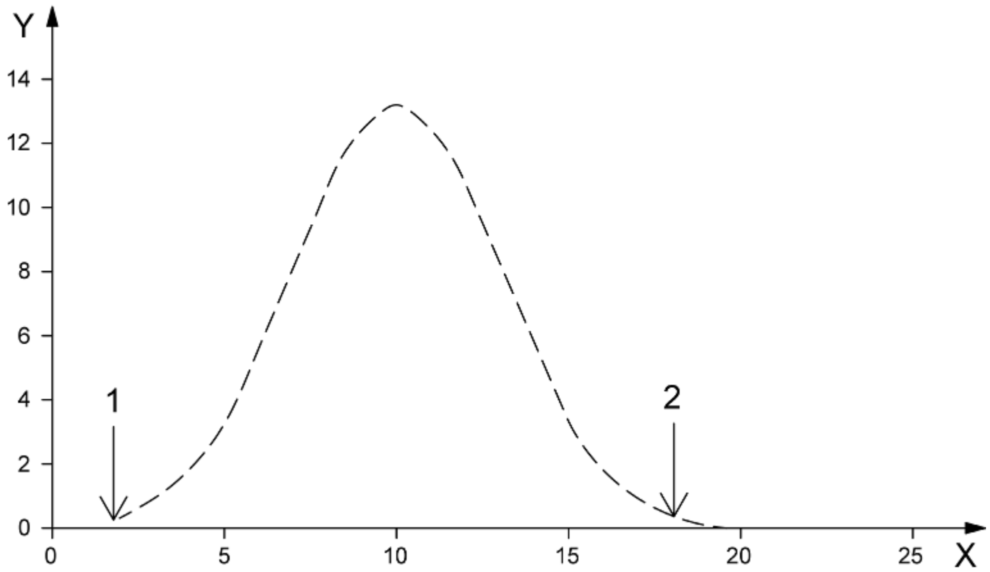
— are usually very low, but they cannot have negative values (values less than nothing); and,

— are frequently at the limit of detection of the test equipment. In cases of values below the detection limit, a value of 0,7 × limit of detection is assumed in the calculations for the mean and the standard deviation.

Where there are results at the limit of detection of the test equipment, it is highly unlikely that all these results will have a true level of release or emission that is exactly at the limit of detection. It is more likely that there will be a spread of results between zero and the limit of detection.

For the application of the Dutch Soil Quality Decree, there is agreement that these values should all be taken as being 0,7 × limit of detection and this value has been adopted for these rules of application.

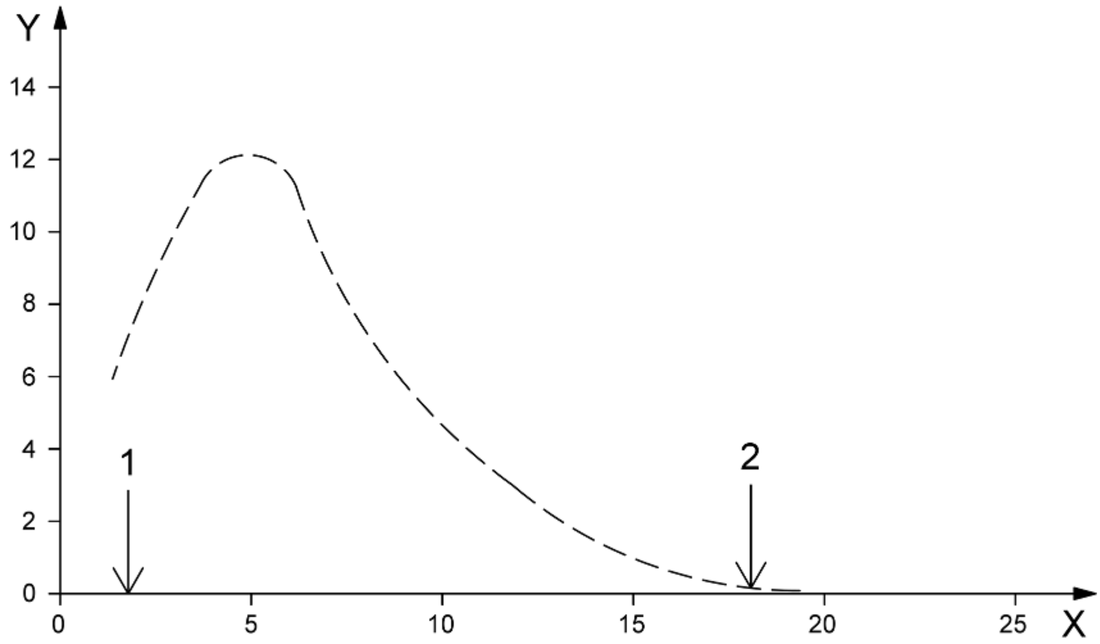
The minimum test frequency is based on a coefficient k_n, which is the number of standard deviations between the declared value and mean value; as the number gets larger the risk of the product exceeding the declared value gets lower and the minimum test frequency is lower to achieve the criterion in Principle 1.



Key

X = Test result, mg/kg
Y = Frequency of test result
1 = Limit of detection by test; all results at limit of detection taken as 0,7 × limit of detection
2 = Declared performance

Figure 2 — Normally distributed data



Key

X = Test result, mg/kg

Y = Frequency of test result

1 = Limit of detection by test; all results at limit of detection taken as 0,7 × limit of detection

2 = Declared performance

Figure 3 — Skewed distributed data

For determining the minimum test frequency, a coefficient k_n needs to be calculated, where, in general, n equals five or 10. Because a log-normal distribution is being assumed, it is the natural logs of these numbers that are used in the calculation of k_n. Until five test results are available, k_n is based on all the available test results.

The formula is:

$$k_n = \frac{\ln(L_D) - \bar{x}}{s} \quad (1)$$

where:

ln = natural logarithm of the value

$\bar{x}$ = running-mean of the last consecutive n ln-transformed test values,

s = running-standard deviation of the last consecutive n ln-transformed test values,

L_D = declared value.

An example of this calculation is given in CEN/TR 16797-2:2015, Annex A.

This rule of application by variables comprises a period of type-testing (TT) followed by further-testing (FT) at a rate depending upon the value of the coefficient k_n. If over time the specific production is consistently shown to be very 'conservative' in relation to the declared value and/or is safe in relation to a regulatory limit, no-further-testing may be applied.

More technical detail is provided in CEN/TR 16797-2:2015, Clause 6, the statistical justification is given in CEN/TR 16797-2:2015, 8.4, an example of the procedure in CEN/TR 16797-2:2015, Annex A and a model rule of application is given in CEN/TR 16797-2:2015, Annex D.

5.2.2 Type-testing

Type-testing comprises testing every batch until at least two test results are available. When there are at least two test results, the value of k_n is calculated where n is the actual total number of test results obtained in TT. If the criterion for k_n in Table 1 is satisfied, random testing of batches at the minimum test frequency given in Table 2 is permitted; if it is not satisfied, testing every batch is required. To end TT after 2 or 3 test results requires a high k_n value, which means that there is a large difference between the mean value and the declared value and thus the risk of a non-tested batch exceeding the declared value is low.

The criteria given in Table 1 are used to determine the conformity of the batch and the criterion for continuing with batch testing.

If not already ended, TT ends when there are 10 test results. Testing every batch needs to continue if it is required by the criterion given in Table 2.

Alternatively a product technical committee may select for type-testing the rule of application given in 5.3. Both options should not be permitted within one product standard as the two different approaches may lead to different test frequencies, confusion and lack of clarity as to what test frequency is required.

During type-testing (and where batch testing is required) every batch should be tested. The criterion for accepting the batch and permitting it to be placed on the market is a test value using the reference test procedure not exceeding the declared value. Any batch that is not equal to or less than the declared value is not placed on the market. As the production has been split into a series of batches and every batch is tested to prove conformity, there are no gaps that allow non-conforming product to be placed on the market.

5.2.3 Further-testing

TT leads to the establishment of the initial rate of random testing or the need to continue with batch testing during further-testing. ‘Random testing’ is where not every batch is tested; one batch is tested within a defined number of successive batches. The minimum test frequency for random testing is given in Column VI of Table 2. Where random testing is permitted, all the product may be placed on the market and accepted as being in conformity. In general, the last five or 10 test results are used to determine the minimum test frequency, see Table 2, which for most construction products will be at a rate that is a lot less frequent than testing every batch.

Each time a new test result is available, the value of k_n is re-calculated and it is used to determine the minimum test frequency according to Table 2. When there are less than five test results (after switching from TT to FT) the minimum test frequency is based on columns I to III in Table 2. When there are five to nine test results, the coefficient k_n is based on the running-mean value and running-standard deviation of the last consecutive five test results (Column IV of Table 2). When there are 10 test results, the running-mean and running-standard deviation may be based on the last consecutive 5 (Column IV of Table 2) or 10 test results (Column V of Table 2). The producer is free to select whether the assessment is based on the running-mean of the last 5 or last 10 consecutive test results and this choice should be documented. If k_{10} is selected the number of standard deviations between the declared value and the mean value is reduced, but it may take decades to get 10 consecutive test data.

It is good practice to check every test result for conformity to the declared value even when such a check is not required by the ‘rules’. In every case where the batch is found to be above the declared value, measures are needed to prevent a re-occurrence of product exceeding the declared value.

The rule of application by variables and also that of the gamma rule (5.3) and attributes (5.4) can be evaluated with a simple spread sheet. As each new test result becomes available, it is recorded and checked that it does not exceed the declared value. The natural log of this value is also calculated using a standard function. If a running-mean of five is being used, the natural log of this new test result is added to the natural logs of the previous four test results and divided by 5 to give the running-mean of five. If a running-mean of 10 is being used, the new test result is added to the previous nine test results and divided by 10 to give the running mean of 10. The standard deviation of the last consecutive five or 10 natural log values is calculated using the spread sheet software to determine the sample standard deviation.

Inspection of the data might show the data are normally distributed. In this case, k_n may be calculated using the mean of the last 5 or last 10 measured test values directly, the sample standard deviation based on the measured test values and the declared value. In this case none of these values are transformed into their natural log values. Table 1 and Table 2 also apply to the values of k_n calculated by this procedure.

During continuous production, failure to achieve a $k_5 \geq 0{,}69$ or a $k_{10} \geq 0{,}44$ (or in the case of two to four results the appropriate minimum values of k_n according to Table 1) results in a requirement to test every batch for conformity: batches that do not conform to the declared value are declared as non-conforming and batches that are below the declared value are regarded as conforming. Where testing every batch is required during continuous production, at least five new batches need to be tested and the results need to give a $k_5 \geq 0{,}69$ and a $k_{10} \geq 0{,}44$ before it is permitted to change from testing every batch to random testing.

NOTE When and only when the conditions for testing every batch apply, the conformity criterion for individual batches is applied. The technical explanation for this approach is given in CEN/TR 16797-2:2015, Clause 8.

When random testing, the penalty for producing a deviating result for a batch is a lower k_n value and this reduction in k_n may result in an increase in the minimum test frequency.

Table 1 — Assessment by variables: Conformity criteria for TT

Number of test results	Conformity criterion for the batch	Criterion for ending TT
1	$x_1 \leq$ Declared value	None, as the second batch needs to be tested
2	$x_2 \leq$ Declared value	If $k_2 \geq 2{,}18$ transfer to Table 2 column I
3	$x_3 \leq$ Declared value	If $k_3 \geq 1{,}09$ transfer to Table 2 column II
4	$x_4 \leq$ Declared value	If $k_4 \geq 0{,}82$ transfer to Table 2 column III
5	$x_5 \leq$ Declared value	If $k_5 \geq 0{,}69$ transfer to Table 2 column IV
6 to 9	$x_i \leq$ Declared value	If $k_5 \geq 0{,}69$ transfer to Table 2 column IV
10 [a]	$x_{10} \leq$ Declared value	If $k_5 \geq 0{,}69$ transfer to Table 2 column IV or [b] If $k_{10} \geq 0{,}44$ transfer to Table 2 column V

[a] If not already ended, TT ends when there are 10 test results. Testing every batch needs to continue if it is required by the criterion given in Table 2.
[b] The producer may opt to use the running-mean of the last five or the last 10 consecutive tests results for FT.

Table 2 — Assessment by variables: Minimum test frequency for FT

Number of test results					Minimum test frequency [b]
2	3	4	Last consecutive 5 [a]	Last consecutive 10 [a]	
I	II	III	IV	V	VI
$k_2 \geq 24,58$	$k_3 \geq 9,65$	$k_4 \geq 7,13$	$k_5 \geq 6,11$	$k_{10} \geq 4,63$	1 batch per 3 year [c, d, e]
$18,50 \leq k_2 < 24,58$	$7,34 \leq k_3 < 9,65$	$5,44 \leq k_4 < 7,13$	$4,67 \leq k_5 < 6,11$	$3,53 \leq k_{10} < 4,63$	1 batch per year [d, e]
$10,25 \leq k_2 < 18,50$	$4,26 \leq k_3 < 7,34$	$3,19 \leq k_4 < 5,44$	$2,74 \leq k_5 < 4,67$	$2,07 \leq k_{10} < 3,53$	1:10 batches (≥ 5 batches per 3 years)
$4,88 \leq k_2 < 10,25$	$2,23 \leq k_3 < 4,26$	$1,69 \leq k_4 < 3,19$	$1,46 \leq k_5 < 2,74$	$1,07 \leq k_{10} < 2,07$	1:4 batches (≥ 10 batches per 3 years)
$2,18 \leq k_2 < 4,88$	$1,09 \leq k_3 < 2,23$	$0,82 \leq k_4 < 1,69$	$0,69 \leq k_5 < 1,46$	$0,44 \leq k_{10} < 1,07$	1:2 batches (≥ 5 batches per year)
$k_2 < 2,18$	$k_3 < 1,09$	$k_4 < 0,82$	$k_5 < 0,69$	$k_{10} < 0,44$	Test every batch [f, g]

[a] It is the producer's choice to base the assessment on the running-mean of the last 5 or 10 consecutive test results.

[b] Where not every batch is being tested, the batch for testing is selected at random from within the period of production given in the last column.

[c] If the last five consecutive test values are lower than the limit of detection of the test method, the minimum test frequency is 1 batch per 3 years.

[d] If the last five consecutive test values are lower than 0,27 × declared value, the minimum test frequency is 1 batch per year; if they are lower than 0,17 × declared value, the minimum test frequency is 1 batch per 3 years.

[e] If the last 10 consecutive test values are lower than 0,37 × declared value, the minimum test frequency is 1 batch per year; if they are lower than 0,23 × declared value, the minimum test frequency is 1 batch per 3 years.

[f] Any batch above the declared value is classified as non-conforming.

[g] Where batch testing is required during continuous production, at least five new batches need to be tested and the results give a $k_5 \geq 0,69$ and a $k_{10} \geq 0,44$ before it is permitted to change from testing every batch.

5.2.4 Use of existing data and sharing data

Where existing test data are based on test methods that are similar to the reference methods, it is acceptable to use these data for the type-testing.

NOTE 1 For example the leaching test methods that have been developed by CEN/TC 351 are similar to the existing leaching test methods used in Germany and the Netherlands.

Consequently in many cases this will mean that repeat type-testing is not required and the assessment starts with the rules for further-testing. If the number of previous data are greater than 5 or 10, the last five or 10 results are used to determine the initial test frequency; the choice of five or 10 depends upon the choice as to the basis of the running-mean.

Based on documented experience, a CEN Technical Committee may introduce in the product standard a mechanism which permits the producer of a generic product to start with the criteria for continuous production at a defined test rate. When new test data are generated, the test frequency will be self-correcting.

NOTE 2 Most documented experience is in Germany and the Netherlands.

There might be an opportunity for the producer to join a cluster or share data in another way. A cluster is a group of manufacturers/ production units where the test data are pooled for conformity purposes. Joining a cluster usually reduces the frequency of testing for an individual producer/production unit and consequently their cost of testing. The technical rules for a cluster are given in CEN/TR 16797-2:2015, 6.2 and on joining a cluster a producer will be instructed by the cluster organizer on the procedures to follow.

NOTE 3 CEN/TR 16797-2:2015, 5.6.3 provides general information about clusters and CEN/TR 16797-2:2015, Annex C provides guidance on cluster organization.

5.2.5 Outliers

Where there are sufficient data, it is possible to determine if a particular test result is an outlier. An outlier is a test result so far away from the mean value that its value should be treated with suspicion. The criteria for determining outliers are given in CEN/TR 16797-2:2015, 6.5.

If the result is an outlier, the cause should be identified. If it is proven to be due to sampling or testing error, the result should be rejected. If a valid outlier identifies a batch that is significantly above the declared value, the producer should consider not placing this batch on the market (if practical) and take urgent action to identify the cause of the outlier and take corrective action.

5.2.6 No-further-testing (NFT)

If over time the specific production is consistently shown to be very 'conservative' in relation to the declared value, a point may be reached where no-further-testing (NFT) is possible. As NFT is an irreversible decision for the declared value, the criteria are more severe than those used for type-testing and further-testing i.e. as set by Principle 1. NFT requires a confidence of 99 % that the 90th percentile of the production is less than or equal to the declared value (see Principle 7). This possibility would only be permitted where there are checks on the constancy of the product composition, manufacture and constituents used to manufacture the product. For added confidence in a NFT decision, such a decision and the subsequent product controls should be audited by the appropriate certification body. If the system of AVCP is 4, there will be no involvement of a certification body and therefore in these cases the product technical committee should consider not permitting the option of NFT.

Consideration for NFT needs to be based on all available test results and the number of test results needs to be not less than five. The criteria on k_n for NFT are given in Table 3.

Table 3 — Assessment by variables: Criterion for no-further-testing

Number of test results	Criterion for NFT as critical values where $k_n \geq$ the relevant values below
5	$k_5 \geq 5{,}36$
6	$k_6 \geq 4{,}41$
7	$k_7 \geq 3{,}86$

Number of test results	**Criterion for NFT as critical values where k_n ≥ the relevant values below**
8	$k_8 \geq 3,50$
9	$k_9 \geq 3,24$
10	$k_{10} \geq 3,05$
11	$k_{11} \geq 2,90$
12	$k_{12} \geq 2,78$
13	$k_{13} \geq 2,68$
14	$k_{14} \geq 2,59$
> 14	See CEN/TR 16797-2:2015, Annex F.
∞	$k_\infty \geq 1,28$

Lowering the declared value, e.g. due to developments on the market or changes in regulatory limit values, requires a new assessment to determine if NFT is still a valid procedure for a different declared value.

For further guidance on NFT, see CEN/TR 16797-2:2015, 5.6.4, 6.4 and 8.5.2.

5.3 Rule of application for products where the test values are significantly below the declared value (gamma rule)

Where a product technical committee knows that the release or emission is low and the variability in test results is dominated by the test procedure, this rule of application may be specified for type-testing in place of the procedure given in 5.2.

This rule of application only applies to type-testing with two to four test data and where the data are normally or log-normally distributed and the coefficient of variation is known from previous testing of similar products. When there are five test values, assessment by variables should be used. Tables 4 and 5 apply to data that have a coefficient of variation (i.e. standard deviation/mean value) of 0,65 or less. Data from leaching tests often give a coefficient of variation of 0,65 or less and so Tables 4 and 5 may be applied to leaching test data. The coefficients of variation of the indoor air test and the gamma radiation test have still to be established and consequently it is premature to apply this rule of application to indoor air and gamma radiation. Once the coefficients of variation are established for these tests, tables equivalent to Tables 4 and 5 can be developed.

Table 4 — Conformity criteria for TT for assessment by the gamma rule for data that has a coefficient of variation not greater than 0,65, e.g. leaching test data

Number of test results	Conformity criterion for the batch	Criterion for ending TT
1	x_1 ≤ Declared value	None, as the second batch needs to be tested
2	x_2 ≤ Declared value	If all x_i ≤ 0,64 × declared value (i = 1 to 2), minimum test frequency is given in Table 5
3	x_3 ≤ Declared value	If all x_i ≤ 0,82 × declared value (i = 1 to 3), minimum test frequency is given in Table 5
4	x_4 ≤ Declared value	If all x_i ≤ 0,96 × declared value (i = 1 to 4), minimum test frequency is given in Table 5

This rule of application uses the 'gamma factor' which is explained in CEN/TR 16797-2:2015, 6.1.3. Statistically this rule could be applied for a single result, but concerns about reducing the test frequency based on a single result led to a minimum of two results being required to apply this rule of application. This rule of application applies when there are two to four test results; once there are more than four test results the assessment should be by the production control rules in 5.2.

Criteria for reducing the test frequency for FT are shown in Table 5. As each new test result is generated, Table 5 is used to determine the minimum test frequency. The test result with the highest proportion of the declared value (i.e. the test result nearest the declared value) will determine the minimum test frequency. If this test value is higher than the limits given in the last three rows of Table 5, batch testing is required, as indicated in the table.

Table 5 — Minimum test frequency for FT for testing by the gamma rule for data that has a coefficient of variation not greater than 0,65, e.g. leaching test data

Number of test results	Every test result	Minimum test frequency
2	all x_i ≤ 0,12 × declared value (i = 1 to 2)	1 batch per 3 years
3	all x_i ≤ 0,15 × declared value (i = 1 to 3)	
4	all x_i ≤ 0,18 × declared value (i = 1 to 4)	
2	all x_i ≤ 0,19 × declared value (i = 1 to 2)	1 batch per year
3	all x_i ≤ 0,24 × declared value (i = 1 to 3)	
4	all x_i ≤ 0,28 × declared value (i = 1 to 4)	
2	all x_i ≤ 0,35 × declared value (i = 1 to 2)	1:10 batches (≥ 5 batches per 3 years)
3	all x_i ≤ 0,44 × declared value (i = 1 to 3)	
4	all x_i ≤ 0,51 × declared value (i = 1 to 4)	

Number of test results	Every test result	Minimum test frequency
2	all $x_i \le 0{,}51 \times$ declared value (i = 1 to 2)	1:4 batches (≥ 10 batches per 3 years)
3	all $x_i \le 0{,}56 \times$ declared value (i = 1 to 3)	
4	all $x_i \le 0{,}76 \times$ declared value (i = 1 to 4)	
2	all $x_i \le 0{,}64 \times$ declared value (i = 1 to 2)	1:2 batches (≥ 5 batches per year)
3	all $x_i \le 0{,}82 \times$ declared value (i = 1 to 3)	
4	all $x_i \le 0{,}96 \times$ declared value (i = 1 to 4)	
2	one $x_i > 0{,}64 \times$ declared value (i = 1 to 2)	Test every batch
3	one $x_i > 0{,}82 \times$ declared value (i = 1 to 3)	
4	one $x_i > 0{,}96 \times$ declared value (i = 1 to 4)	

As this rule of application is based on an assumed coefficient of variation, it is possible that the test frequency determined by this procedure and that determined from k_n using assessment by variables may differ. Consequently either this rule of application should be adopted for type-testing by a product technical committee or the rule of application given in 5.2; both approaches should never be permitted within a specific product standard.

5.4 Rule of application based on assessment by attributes

5.4.1 Where assessment by attributes should be selected

There are situations where assessment by variables (see 5.2) is inappropriate; for example, when the distribution of data is not known. An alternative approach is needed; this alternative approach is to use assessment by attributes as this does not rely upon the data being normally or log-normally distributed.

Assessment by attributes is a system where a low proportion of test results may exceed the declared value within a defined number of consecutive test results. Conformity and the test frequency are based simply on not more than a given number of test results (n_e) in a set of n consecutive results exceeding the declared value. The disadvantage of this approach is that a higher number of test results are needed to satisfy Principle 1, which means more test results are needed before the test frequency may be reduced.

When the test values:

— are below or at the limit of detection; or,

— where the production process may substantially affect the test result;

an unknown distribution of data ought to be assumed and assessment by attributes undertaken. An example of where the production process may substantially affect the test result is where a product may either be supplied immediately after processing or spend a variable period of time in a stockpile exposed to the weather. Immediately after production the distribution of a dangerous substance may be log-normally distributed. Exposure to weather may change the release of the dangerous substance such that the stockpile distribution is normal, but combining the test results from fresh and stockpiled material (the material placed on the market) gives neither a normal or log-normal distribution. In this situation assessment by attributes is appropriate.

5.4.2 Type-testing

Type-testing comprises testing every batch until at least four test results are available. When there are at least four test results, the number of test values that exceed the declared value is counted (n_e). Table 6 is used to determine the minimum frequency of testing, which may be a continuation of batch testing or random testing.

TT leads to the establishment of the initial rate of random testing or the need to continue with batch testing during further-testing.

An example of this rule of application is given in CEN/TR 16797-2:2015, Annex A.

Table 6 — Minimum frequency of testing when using assessment by attributes

Number of the last *n* consecutive test results in the assessment and the number of results above the declared value n_e										**Minimum test frequency** [a, b, c]
n **4 to 6**		***n*** **7 to 11**		***n*** **12 to 21**		***n*** **22 to 37**		***n*** **≥ 38**		
n	n_e	***n***	n_e	***n***	n_e	***n***	n_e	***n***	n_e	
—	—	—	—	—	—	22	0	38	≤ 1	1:10 batches (≥ 5 batches per 3 years)
—	—	—	—	12	≤ 1	21 12	≤ 3 ≤ 1	21 12	≤ 3 ≤ 1	1:4 batches (≥ 10 batches per 3 years)
4	0	7	≤ 1	12 7	≤ 3 ≤ 1	12 7	≤ 3 ≤ 1	12 7	≤ 3 ≤ 1	1:2 batches (≥ 5 batches per year)
4	> 0	7	> 1	12	> 3	12	> 3	12	> 3	Test every batch [d, e]

[a] If the last five consecutive test values are lower than the limit of detection of the test method, the minimum test frequency is 1 batch per three years.

[b] If the last five consecutive test values are lower than (0,27 × declared value), the minimum test frequency is 1 batch per year; if they are lower than (0,17 × declared value), the minimum test frequency is 1 batch per three years.

[c] If the last 10 consecutive test values are lower than (0,37 × declared value), the minimum test frequency is 1 batch per year; if they are lower than (0,23 × declared value), the minimum test frequency is 1 batch per three years.

[d] Any batch above the declared value is classified as non-conforming.

[e] Before it is permitted to change from testing every batch at least five new batches need to be tested and the test results having not more than one result above the declared value in the last seven consecutive test results and not more than three results above the declared value in the last 12 consecutive test results.

5.4.3 Further-testing

TT leads to the establishment of the initial rate of random testing or the need to continue with batch testing during further-testing. 'Random testing' is where not every batch is tested; one batch is tested within a defined consecutive series of *n* test results. The minimum test frequency is given in the last column of Table 6. Where random testing is permitted, all the product may be placed on the market and accepted as being in conformity.

Each time a new test result is available the number of test data above the declared value in the last consecutive *n* results is recounted and used to determine the minimum test frequency according to Table 6. Although not required according to the rule for attributes where random testing is permitted, in every case where the batch is found to be above the declared value it is common practice to consider what measures are needed to prevent a re-occurrence of product exceeding the declared value.

Five of the cells in Table 6 have two criteria and one or the other of these criteria needs to be satisfied before the frequency of testing may be reduced or increased. For example, when there are more than 38 results and the frequency of testing is 1:4, due to n_e of 3 within the last 21 results. If the next result takes n_e to 4 within the last 21 results, the frequency of testing reduces to 1:2 unless the last 12 results give n_e not greater than 1. In this case the frequency of testing remains at 1:4. This is not manipulation, but a reflection that the product was borderline during the period when results 1 to 10 were taken but prior to this new result, none of the previous 11 test results were above the declared value. The exception to this generalization is when batch testing during continuous production is required. To ensure the product is under control and safe, there are two requirements before ending batch testing; these are not more than one result above the declared value in the last seven consecutive test results and not more than three results above the declared value in the last 12 consecutive test results.

During periods of batch testing, any batch above the declared value is non-conforming and it should not be placed on the market.

5.4.4 Use of existing data and sharing data

Previous data may be used to reduce the period of type-testing or even to jump straight to continuous assessment. Also joining a cluster might be an opportunity to reduce the frequency of testing for an individual producer/production unit and consequently their cost of testing, see CEN/TR 16797-2:2015, 7.2.

5.4.5 Outliers

One reason for selecting assessment by attributes is where the distribution of results is unknown. There is no appropriate statistical test for outliers when the distribution is unknown. In this situation the process data should be checked to determine if there is a valid reason for excluding this result. When sufficient data are available it may possible to determine the distribution of data and if it is normally or log-normally distributed the Grubb test described in CEN/TR 16797-2:2015, 6.5 may be applied to determine outliers. In this case the rules for handling outliers described in 5.2.5 apply. In such a case, it is also permissible to switch to the rule of application based on assessment by variables.

5.4.6 No-further-testing

As with assessment by variables, if the specific production is consistently shown to be very 'conservative' in relation to the declared value and/or is safe in relation to a regulatory limit, a point may be reached where no-further-testing (NFT) is required. At least 44 test results are required before such as assessment may be made. All available valid test results need to be used in the analysis. Where the rule of application is based on assessment by attributes, the criteria for no-further-testing are given in Table 7.

Table 7 — Criteria for no-further-testing

Number of test result	Criterion for NFT: Not more than the following number of test results above the declared value
44 — 63	0
64 — 80	1
81 — 96	2
97 — 112	3
113 — 126	4
127 — 141	5
142 — 155	6
156 — 169	7
170 — 182	8
183 — 196	9
197 — 209	10

Lowering the declared value, e.g. due to developments on the market or changes in regulatory limit values, requires a new assessment to determine if NFT is still a valid procedure.

Further guidance on assessment by attributes in given in CEN/TR 16797-2:2015, Clause 7, the statistical justification in CEN/TR 16797-2:2015, 8.5, an example of the calculation in CEN/TR 16797-2:2015, Annex A and a model rule of application in CEN/TR 16797-2:2015, Annex D.

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