



BSI Standards Publication

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

Part 2: Technical and statistical background

National foreword

This Published Document is the UK implementation of CEN/TR 16797-2:2015.

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.

© The British Standards Institution 2015. Published by BSI Standards Limited 2015

ISBN 978 0 580 85718 8

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 16797-2

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 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.

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and United Kingdom.



EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

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

Contents

Page

European foreword.....	4
0 Introduction.....	5
0.1 General	5
0.2 Background.....	5
0.3 Assessment of construction products.....	6
0.4 Reading guide to CEN/TR 16797-2.....	9
0.4.1 General introduction	9
0.4.2 Rules of application	9
0.4.3 Statistical background	9
0.4.4 Annexes.....	9
1 Scope	10
2 Terms, definitions, abbreviations and symbols	10
2.1 Terms and definitions	10
2.2 Abbreviations and symbols	14
3 Context	16
4 Quality level of performance with respect to the release, emission or content of RDS	17
5 Methods for statistical assessment of declared values for RDS	17
5.1 Goal of the assessment	17
5.2 Assessment of the production.....	17
5.3 Assessment of clusters	19
5.4 Assessment of no-further-testing.....	20
5.5 Methods of assessment.....	23
5.5.1 Introduction.....	23
5.5.2 Assessment by variables	23
5.5.3 Assessment by attributes.....	24
5.6 Description of the assessment procedure	24
5.6.1 Type testing	24
5.6.2 Further-testing	25
5.6.3 Clusters	26
5.6.4 No-further-testing	29
5.7 Banned substances.....	29
6 Assessment by variables	30
6.1 Single production units	30
6.1.1 Type testing	30
6.1.2 Further-testing	31
6.1.3 Rule of application for products where the test values are significantly below the declared value (Gamma rule)	33
6.1.4 Rule of application for products where a small number of test results may be expected	33
6.2 Cluster of production units	34
6.2.1 Type testing	34
6.2.2 Further-testing	36
6.2.3 Rule of application for cluster products where the test values are significantly below the declared value (Gamma rule).....	37
6.3 No-further-testing	37
6.4 Handling values lower than the detection limit.....	38
6.5 Identifying outliers	38

6.6	Choosing a declared value	39
7	Assessment by attributes	40
7.1	Single production units	40
7.1.1	Type testing	40
7.1.2	Further-testing	41
7.2	Cluster of production units	42
7.2.1	Type testing	42
7.2.2	Further-testing	43
7.3	No-further-testing	44
7.4	Handling values lower than the detection limit	44
7.5	Identifying outliers	44
7.6	Choosing a declared value	45
8	Statistical principles of the rules of application	45
8.1	Introduction	45
8.2	Assessment of a production part	45
8.3	Test error	50
8.4	Assessment by variables	51
8.4.1	Type testing and further-testing	51
8.4.2	Test frequency for further-testing	52
8.4.3	Gamma rule	56
8.4.4	No-further-testing	56
8.5	Assessment by attributes	57
8.5.1	Type testing and further-testing	57
8.5.2	No-further-testing	59
8.6	Consumer's and producer's risk	60
8.6.1	Acceptance and non-acceptance of batches that exceed the declared value	60
8.6.2	Estimation of the consumer's risk	63
8.6.3	Practical approach	64
9	Additional sampling requirements	65
9.1	General	65
9.2	Probabilistic sampling	66
9.3	Judgemental sampling	68
10	Indirect tests	68
10.1	General	68
10.2	Correlation	69
10.3	No correlation	70
	Annex A Examples of the rules of application	71
	Annex B Distribution of test values	87
	Annex C Checklist for Technical Committees	90
	Annex D Model clauses for product standards	92
	Annex E Critical values for assessment by variables	113
	Annex F Gamma factor	117
	Bibliography	120

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.

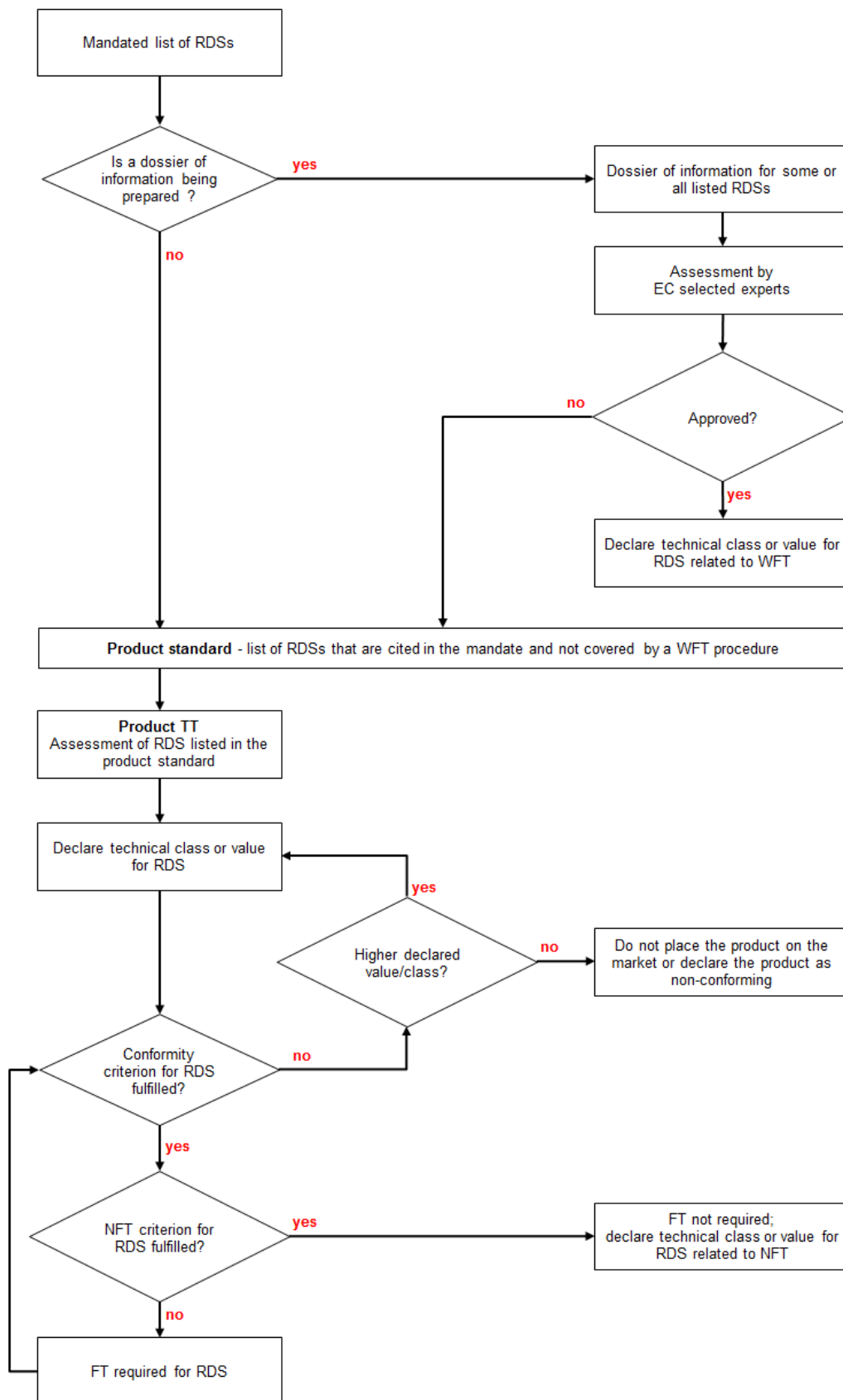


Figure 1 — Possibilities of WFT, FT and NFT for construction products

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)]

Note 1 to entry: With respect to the assessment of the release, emission or content of RDS 'magnitude of the characteristic' means the test result.

2.1.3

batch

amount of *construction product* at which *conformity* is established

Note 1 to entry: Within this document the size of a batch is undefined. The batch size should be defined in the product standard.

2.1.4

batch testing

procedure where every *batch* is tested prior to it being placed on the market

2.1.5

cluster

group of *production units* that are considered as one with respect to type testing and routine control of RDS

2.1.6

coefficient of variation

standard deviation divided by the *mean*

[SOURCE: [10]]

2.1.7

conformity

fulfilment of a requirement

2.1.8

construction product

product which is produced for incorporation in a permanent manner in construction works and placed as such on the market

[SOURCE [6]]

2.1.9

consumer's risk

probability of accepting a *batch* that has a release greater than the *declared value*

[SOURCE [11] (adapted)]

2.1.10

continuous random variable

random variable having a continuous distribution

[SOURCE [10]]

2.1.11

declared value

level, expressed as a numerical value, declared by the producer, having a very low probability of being exceeded in the production

Note 1 to entry: Where the term 'declared value' is used in this document, it may be interchanged with the terms 'regulatory class limit' or 'technical class limit'.

2.1.12

discrete random variable

random variable having a discrete distribution

[SOURCE [10]]

Note 1 to entry: The value of a discrete random variable is not expressed as a number but as a non-arithmetical expression, e.g. yes/no, pass/fail.

2.1.13

further-testing (FT)

assessment procedure where the AVCP requires routine testing by the manufacturer to verify that the *declared value* is being achieved

[SOURCE: [2] (adapted)]

Note 1 to entry: Further-testing is applied when the type assessment shows there is a risk that the declared value may be exceeded.

2.1.14

mean

sum of the test values divided by the number of test values

[SOURCE: [10] (adapted)]

Note 1 to entry: For a series of n random test results, i.e. $\{x_1, x_2, \dots, x_n\}$, the **sample mean** $\bar{x}$ is:

$$\bar{x} = \frac{1}{n} \sum_{i=1}^n x_i \quad (1)$$

2.1.15

no-further-testing (NFT)

deemed-to-conform assessment procedure for determining the *declared value* based on type assessment, type testing and routine testing where at some point it is shown that there is a very low risk that the *declared value* may be exceeded

2.1.16

non-conformity

non-fulfilment of a requirement

[SOURCE: [11]]

2.1.17

operation characteristic curve (OC-curve)

curve showing the relationship between the probability of acceptance of a *batch* and the percentage of the *production* that has a release greater than the *declared value* and the incoming quality level for a given assessment scheme

[SOURCE: [11] (adapted)]

2.1.18

outlier

member of a set of values which is inconsistent with the other members of that set

[SOURCE: [10]]

2.1.19

process

set of interrelated or interacting activities which transform inputs into outputs

[SOURCE: [11]]

2.1.20

producer's risk

probability of rejecting a *batch* that has a release equal to or lower than the *declared value*

[SOURCE: [11] (adapted)]

2.1.21

product

result of a *process*

[SOURCE: [11]]

2.1.22

production

entire (statistically assumed to be infinite) amount of *construction product* that has been and will be produced, that is divided into batches of equal size for testing purposes and that may be defined as the amount represented by:

- one type of construction product as defined in the product standard from one *production unit*; or
- a group of construction products with similar properties from one *production unit*; or
- one type of construction product as defined in the product standard that is grouped into a *cluster* for AVCP; or
- a group of construction products with similar properties from a *cluster*

Note 1 to entry: In the case of RDS, the declaration of performance (covered by CE-marking) is based on the properties of the production and not on the properties of single *batches* except when testing every batch.

2.1.23

production unit

location where a construction product is manufactured

2.1.24

random testing

procedure where a limited number of randomly selected *batches* is tested

2.1.25

sample

representative portion of material selected from a *batch* and which reflects the average properties of that *batch* as much as possible

[SOURCE: [6] (adapted)]

2.1.26

standard deviation

non-negative square root of the *variance*

[SOURCE: [10] (adapted)]

Note 1 to entry: This is a measure of the spread of results around their *mean*.

2.1.27

variance

sum of squared deviations of the test values from their *mean* divided by the number of test values minus one

[SOURCE: [10] (adapted)]

Note 1 to entry: For a series of n random test results, i.e. $\{x_1, x_2, \dots, x_n\}$, with sample mean $\bar{x}$ the **sample variance** s^2 is:

$$s^2 = \frac{1}{n-1} \sum_{i=1}^n (x_i - \bar{x})^2 \quad (2)$$

2.1.28

without-further-testing (WFT)

deemed-to-conform assessment procedure for determining the declared value based on assessment of the generic product alone and specified in the relevant product standard

[SOURCE: [2] (adapted)]

Note 1 to entry: Assessment by the WFT procedure means that the release, emission or content of the relevant RDS in the construction product is determined on a generic level; an individual producer does not need to determine the release, emission or content of the relevant RDS in the construction product by type testing followed by further-testing. Type assessment is required to show that the product conforms to the requirements for using a declaration of performance based on WFT.

2.2 Abbreviations and symbols

For the purposes of this document, the following abbreviations and symbols apply:

AVCP	Assessment and verification of constancy of performance
CB	certification body
CEN	Comité Européen de Normalisation (European Committee for Standardization)
EEA	European Economic Area
FPC	factory production control
FT	further-testing
NB	notified body
NFT	no-further-testing
NPD	no performance determined
$P\{\text{event}\}$	probability of the event
RDS	regulated dangerous substance(s)
TC	technical committee
TG	task group
TR	technical report (CEN deliverable)
TT	type testing (determination of the prototype)
WFT	without-further-testing

For the purposes of this document, the following symbols apply:

a	slope
b	intercept
c_s	coefficient of variation of due to the sampling error
c_t	coefficient of variation due to the testing error
c_v	coefficient of variation of the test value
c_w	coefficient of variation due to the spatial and/or temporal variation
G_p	critical value according to Grubbs' test
H_0	null hypothesis
i	index number
k_0	critical value for k_n multiplication factor of the non-central t-distribution
L_D	declared value
m	number of increments per sample
n	number of test values
n_a	acceptable number of test values that exceed the declared value
n_e	number of test values that exceed the declared value
p	percentage of the production exceeding the declared value
PF	precision factor
s	sample standard deviation
x	test value
x'	equivalent value for the reference test
$\bar{x}$	sample mean
x_1	the last (most recent) test value
x_i	test value
x_{max}	largest test value
x_{min}	smallest test value
z_i	upper 100i percentage point of the standard normal distribution
α	uncertainty
β	fraction of production that exceeds the declared value
Γ	gamma factor
μ	true value of the mean of a property
μ_0	true production mean
σ	true value of the standard deviation

σ_s	standard deviation due the sampling error
σ_t	standard deviation due to the testing error (see test standard)
σ_v	standard deviation of the test value
σ_w	standard deviation of the spatial and/or temporal variation

3 Context

In order to put this CEN/TR into its context, the following is a brief review of the overall procedure for declaring performance from the viewpoint of a producer. Much more detail is provided in CEN/TR 15858 [2] and CEN/TR 16496 [5]. For the producer, the starting point is the product standard and/or the contract to supply. The actions before this point are for the product technical committee preparing the product standard and those preparing a generic dossier of information (see Figure 1).

The European product standard that has a revised or amended mandate for the product being produced should give a list of dangerous substances. Except where the dangerous substance is limited at the European level, these lists will not contain limit values as these values, if any, are set at the national level. Producers identify their market (national members of the EEA) to determine if it includes one or more regulated markets, i.e. ones with defined limits on the release, emission or content of dangerous substances, and identify from the list in the product standard those dangerous substances that are applicable in their regulated markets. In addition to the dangerous substances listed in the product standards, there may be the need to conform to other regulations valid in the place of use that set limits or ban certain additional dangerous substances. The applicable RDS may be some, all or more than those listed in the product standard. Producers are expected to know what regulations (legal requirements) are placed on the products they are putting on the market.

Producers may use the database CP-DS (<http://ec.europa.eu/growth/tools-databases/cp-ds/>) for information on national and European legislation on dangerous substances and construction products, and they may make use of the contact points for the CPR in each Member State.

NOTE The rules of application described in this CEN/TR are applicable to all RDS, including those not listed in product standards.

For those substances listed in the product standard, the producer is required to provide information to the market in the form of a technical class or declared value (where permitted in the product standard) under CE-marking. Essential characteristics (in particular for the release, emission or content of dangerous substances) shall be declared according to the cited harmonized standard or as NPD to legally place products in the market (EFTA). The regulations of some Member States may require the declaration of some essential characteristics for specific intended uses.

Some essential characteristics may be declared through the WFT procedure. In this case the declared value/class is fixed and does not require testing. For essential characteristics not covered by the WFT procedure, manufacturers shall follow the defined AVCP and declare the value/class or NPD.

Where a WFT procedure is applicable and used, the producer needs to document in the FPC system that the product conforms to the requirements for using the WFT procedure. After TT and periods of routine testing, the producer may have the opportunity to see if the test data satisfy the requirements for declaring performance with no-further-testing (the NFT-procedure). The criteria for such assessments are given in this CEN/TR, but they only have validity if these criteria are transposed into the relevant product standard or cited in a normative way as being applicable. The procedures that are relevant to the NFT-procedure are given in 5.4.

4 Quality level of performance with respect to the release, emission or content of RDS

With respect to the release, emission or content of RDS it is highly recommended to apply the same quality level of performance to all construction products. In this way users of construction products and regulators are able to compare performances of different (competitive) construction products without doubt about the risk of getting a non-conforming product, e.g. a product that has a higher release, emission or content of one or more RDS than declared by the producer.

For the release, emission and content of RDS the following two quality levels of performance are proposed:

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/class.

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/class.

The assessment system described in this CEN Technical Report and the according consumer's risk and producer's risk are based on this quality level of performance when the scale of declaration is a batch as defined in the product standard. The quality level of performance for the statistical assessment of declared values is based on the Dutch Soil Quality Decree which has proven to give sufficient protection for the environment with respect to the release of RDS from construction products.

5 Methods for statistical assessment of declared values for RDS

5.1 Goal of the assessment

The goal of assessing the potential release, emission or content of dangerous substances is to allow a producer to define a declared value or technical class for a product in such a way that testing is reduced to a minimum while users and regulators are still able to conclude with sufficient trust whether the product fulfils the (national) requirements for release, emission or content of dangerous substances.

To find a balance between testing effort and trust a risk based approach is proposed, meaning that the risk of exceeding the declared value is acceptable within the framework of (national) regulations.

Based on the Dutch experiences, a risk of exceeding a limit value of not more than about 20 % seems acceptable.

The Dutch system of assessment of the release of dangerous substances is based on a statistical approach of testing randomly selected batches. From an evaluation of the Dutch Soil Quality Decree in 2011 [14], it was concluded by the Ministry of Infrastructure and the Environment that the requirements of the decree provide sufficient protection for the environment with respect to the use of construction products. The statistical rules used to assess the release of dangerous substances give a maximum risk of exceeding a limit value of about 21 %.

It should be noted that the statistical rules to assess the release of dangerous substances are just one aspect within the framework of the Dutch Soil Quality Decree. A whole set of additional rules is part of the Dutch system to control the environmental quality of a construction product and its uses.

5.2 Assessment of the production

In its most simple form, assessment of the properties of a production is done by testing each and every batch. The batch conforms when the measured values of all tested properties fulfil the criteria specified. Testing each batch may lead to a lot of unnecessary testing and high cost for the producers

and their customers, because the risk of exceeding a declared value is not taken into account. If this risk is dealt with in a proper way, it is possible to limit the amount of testing without significant risk. Moreover, when the risk of exceeding the declared value defines the test frequency, the system of testing will be cost effective.

The method of assessment of the release, emission or content of dangerous substances in this CEN/TR incorporates a risk based testing system for use within the quality control system of the producer for routine testing.

If the risk is (very) low, assessment is based on testing randomly selected batches (**random testing**). The test frequency decreases gradually when the risk of exceeding the declared value becomes smaller. In the case of random testing the declared value is not a hard limit, because the risk of exceeding this value is low and it is only used to estimate the risk of exceeding this value. Testing randomly selected batches implies that not all batches are tested and no batches are rejected; however, the assessment of conformity applies to all batches, including the batches which are produced in between those tested. As not all batches are tested, there is always a (very) low risk that a batch which exceeds the declared value is part of the accepted production and placed on the market (this is true for all product characteristics, not just RDS). But as long as the product's conformity is established by testing randomly selected batches, the product may be put on the market before conformity is established, because there is no necessity to wait for the result as the risk of exceeding the declared value is (very) low (the reference leaching tests take 1 month to 2½ months, depending on the type of test).

On the other hand every batch is tested when the risk of exceeding the declared value is relatively high (**batch testing**). Under this condition this value is a hard limit. Exceeding the declared value means that the batch is rejected, consequently only conforming batches are placed on the market. This requires that the product is tested and conformity is established before it is placed on the market. Nevertheless, there are a few products that need to be placed on the market before the assessment of conformity is completed, e.g. screeds. Experience has shown that these products are unlikely to require batch testing.

The advantage of batch testing is that there is no uncertainty about conformity of the batch (except for the uncertainty due to the test error), although testing will be more expensive and time consuming. Batch testing allows a producer to prevent batches that do not exceed the declared value being rejected and batches that exceed this value being placed on the market. On the other hand it also highly motivates a producer to improve the quality of his product in order to reduce the testing effort and to be able to switch to random testing.

The described method for the assessment of conformity has the following characteristics:

- risk based approach: a maximum risk that a CE-marked product which has been placed on the market exceeds a declared value for the release, emission or content of a dangerous substance;
- where the risk of exceeding the declared value is high every batch is tested and the declared value is a hard limit;
- conformity is assessed on the scale of the batch size;
- the statistical assessment of declared values when based on assessment by variables is based on the running mean of at least five test results which include all valid test values that are collected during FT; for assessment by variables the safety margin to limit the risk of a batch which exceeds the declared value being placed on the market is obtained by taking into account the variation between batches due to the variation in product quality. In the case of assessment by attributes this is achieved by limiting the acceptable number of test values that exceed the declared value;

- conformity is assessed separately for each RDS. The combined risk for all RDS of a construction product is not considered and consequently any RDS can determine the test frequency and ultimately the non-acceptance of a batch;
- the distribution of test values is assumed to be either lognormal (assessment by variables) or unknown (assessment by attributes). Other distributions are not considered;
- variable test frequency based on the risk of exceeding the declared value;
- arbitrarily, the assessment method is based on a true maximum risk of about 10 % (in practice the true maximum risk will be lower than the theoretical maximum risk as producers will be motivated to aim at the lowest test frequency).

If a construction product is characterized by more than one relevant RDS, the theoretical maximum risk of exceeding one of the declared values is equal to $1 - 0,90^n$, where n is the number of relevant RDS and assuming a maximum risk of 10 % of exceeding the declared value for one relevant RDS (e.g. in the case of 3 relevant RDS the theoretical maximum risk that a declared value is exceeded equals 27 % instead of 10 % for one relevant RDS).

In practice the risk is lower than this theoretical maximum risk due to the facts that:

- the release of one of the RDS may be dependent on the release of another RDS, which means that only one of the two controls the risk of exceeding a declared value. For example, in some slags the leaching of Ba and SO_4 is controlled by the solubility of BaSO_4 : the presence of oxidized sulphur (sulphates) prevents leaching of Ba;
- the system of assessing the release, emission or content of RDS is controlled by the RDS that gives the highest risk. In practice with most construction products one relevant RDS controls conformity.

Therefore it is hardly possible to estimate the true risk, unless the true risk for each of the RDS of a construction product is known which requires a lot of testing. For this reason, the assessment system is focused on assessing individual RDS only instead of the entire set of RDS of a construction product.

Although two distributions are considered, the use of assessment by variables is preferred for practical reasons; however, the use of assessment by variables requires a normally distributed dataset. As explained in 5.5.1 for dangerous substances a logarithmic transformation is used to (more or less) normalize data sets. If the data set already has a normal distribution by itself, an $\ln$ -transformation is not needed. Also an $\ln$ -transformation is not always the optimal choice and more appropriate statistical techniques, like the use of the Box-Cox transformation, may give a better result.

Because it is considered too complex for users to allow different normalization options in a product standard, $\ln$ -transformation is the best available and relatively easy to use option. Also, one of the goals of standardization is limiting options. Therefore the method of assessment in this CEN/TR focuses on $\ln$ -transformation with respect to assessment by variables. If it is shown by a user that no transformation is needed or that another type of transformation gives a better approximation of normality for a certain product or substance, it is recommended to allow other statistical techniques to improve normality of data sets. In all cases the formulas for assessment by variables presented in this CEN/TR may be used.

5.3 Assessment of clusters

The concept of clusters, i.e. group/groups of manufacturers sharing logistics of testing, test results and information within a national or international construction products approval scheme, may be an efficient and cost effective way of testing construction products that have a relatively low risk of exceeding declared values. Although this CEN/TR gives technical rules for the assessment of construction products only, some legal and commercial aspects are mentioned as they are believed to

be crucial for the functioning of clusters. One of these aspects is that clusters need to be managed by an independent organization, the so-called cluster organization, if the cluster comprises more than one producer.

Clusters may be organized in different ways.

- 1) A producer who owns several plants might decide to create an in-company cluster for some or all of his plants. In this case a third party cluster organization is not needed.
- 2) A trade association might create a cluster that is available to its members; one of the privileges of membership may be a reduced cost for AVCP with respect to dangerous substances.
- 3) A commercial organization makes cluster facilities available for any producer who wishes to join and their product can meet the technical criteria for membership.

In Cases 2) and 3) the involvement of an independent cluster organization is required. In a normal situation, where a producer tests his product independently, test data remain the property of the producer and any third party, e.g. certification body, is not permitted to disclose these data to another party or use these data for their own commercial gain. The cluster system however, requires a different relationship between the parties where a third party, the cluster organization, is free to use all the data to show conformity of the cluster and to exclude members if their results are outside the normal variation and/or lead to an increase in the frequency of testing. Such sharing of commercially sensitive information between different commercial organizations should meet the rules for free competition and would need the explicit approval of the Competition Authorities. Therefore it is suggested that the cluster organization should be a totally independent legal entity that has no connections to any of its members if the cluster comprises more than one producer.

In theory Situations 2) and 3) could lead to an unlimited number of companies joining a cluster. In practice however, the number of companies will be limited, as the release properties of the products in one cluster need to be more or less the same in order to keep the risk of exceeding the declared value in control. Only low-risk construction products, where the release, emission or content is significantly below the declared value, may be grouped in one cluster.

NOTE An example is the cluster of Dutch bituminous mixtures (Asphalt Cluster). This cluster comprises most of the asphalt mixtures that are being placed on the market by the Dutch producers. Despite the cluster being quite large (about 45 production units), cluster control has been proven to be sufficiently reliable for checking the release of RDS.

According to the CEN Rules a standard should give requirements, methods for verification of these requirements and AVCP without assigning these tasks to a specific organization. Cluster management, however, should always include third party involvement (except for situation 1). Addressing this involvement collides with the CEN Rules. For this reason the technical rules for clusters in CEN standards are informative or could simply cite this CEN/TR (see D.4).

5.4 Assessment of no-further-testing

In this document no-further-testing (NFT) is considered an option for a specific product or cluster following TT or when sufficient test results have become available during FT for one or more RDS. This NFT is an assessment based on all available test values and based on the same principles as described in 5.2; however, the risk based approach of the method described in 5.2 is not appropriate for the assessment of NFT.

The described method of assessment for NFT has the following characteristics:

- risk based approach where the assessment is based on all available test values;
- NFT is assessed for each RDS separately;

- the distribution of test values is assumed to be either (log)normal or unknown. Other distributions are not considered.

As the background of historic data will probably be unknown, the batch size represented by the test results will probably be unknown as well. In case of assessment of NFT this uncertainty is included in the criteria.

If it is decided that the NFT option should not be a producer's decision, a third party would need to be involved. This leaves two options:

- 1) A low level decision taken by a third party. For practical reasons, a notified body or certification body seems most appropriate to take this decision. For this reason the system of AVCP should be 1+, allowing the NB or CB to take and test samples independently (see Figure 2).

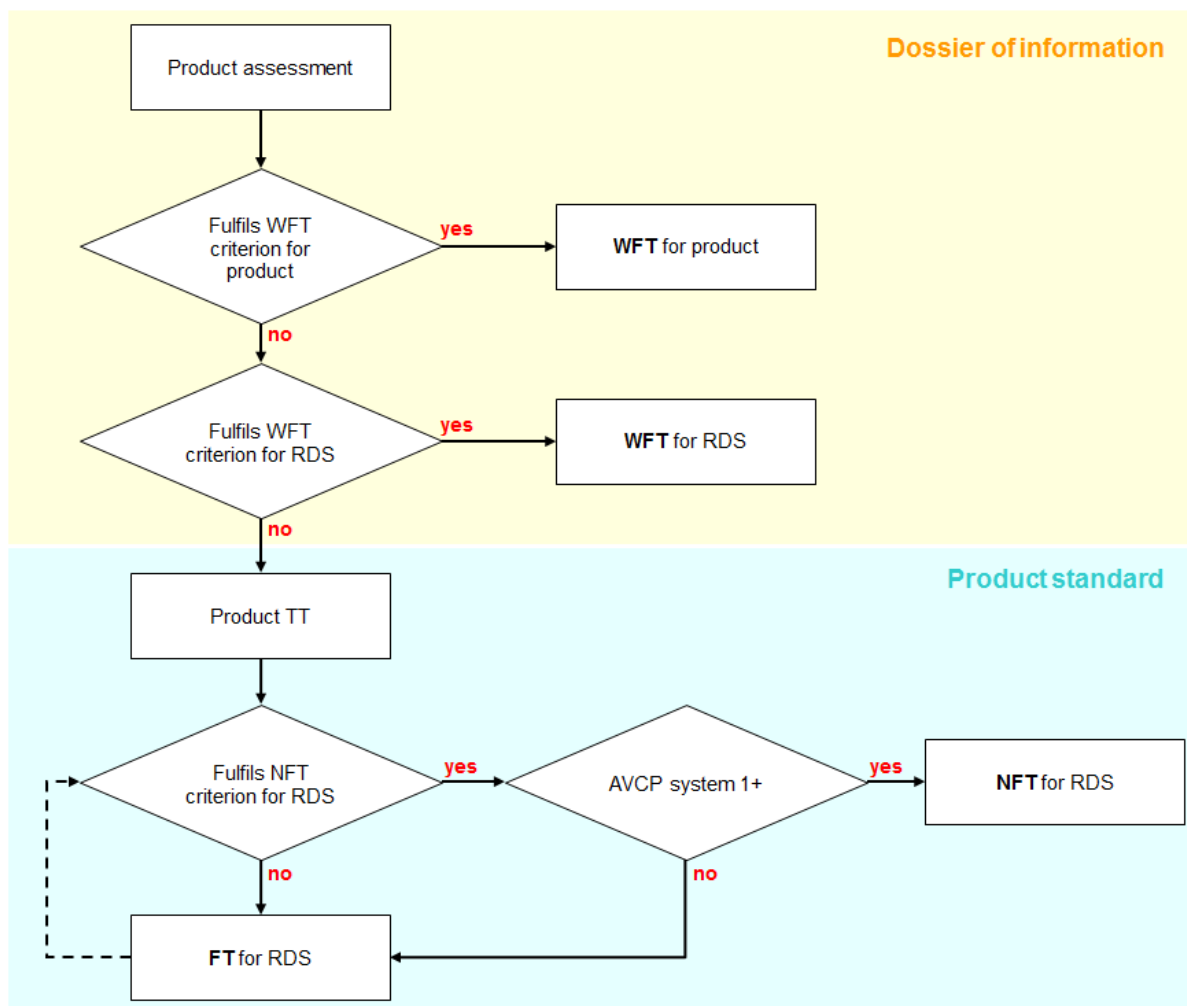


Figure 2 — WFT-FT-NFT procedures for construction products option 1: third party control

- 2) An update of the WFT dossier of information, in which case the decision is a high level generic one taken by the EC (see Figure 3). A disadvantage of this procedure is that it is not possible for a single producer to apply directly for a generic WFT procedure.

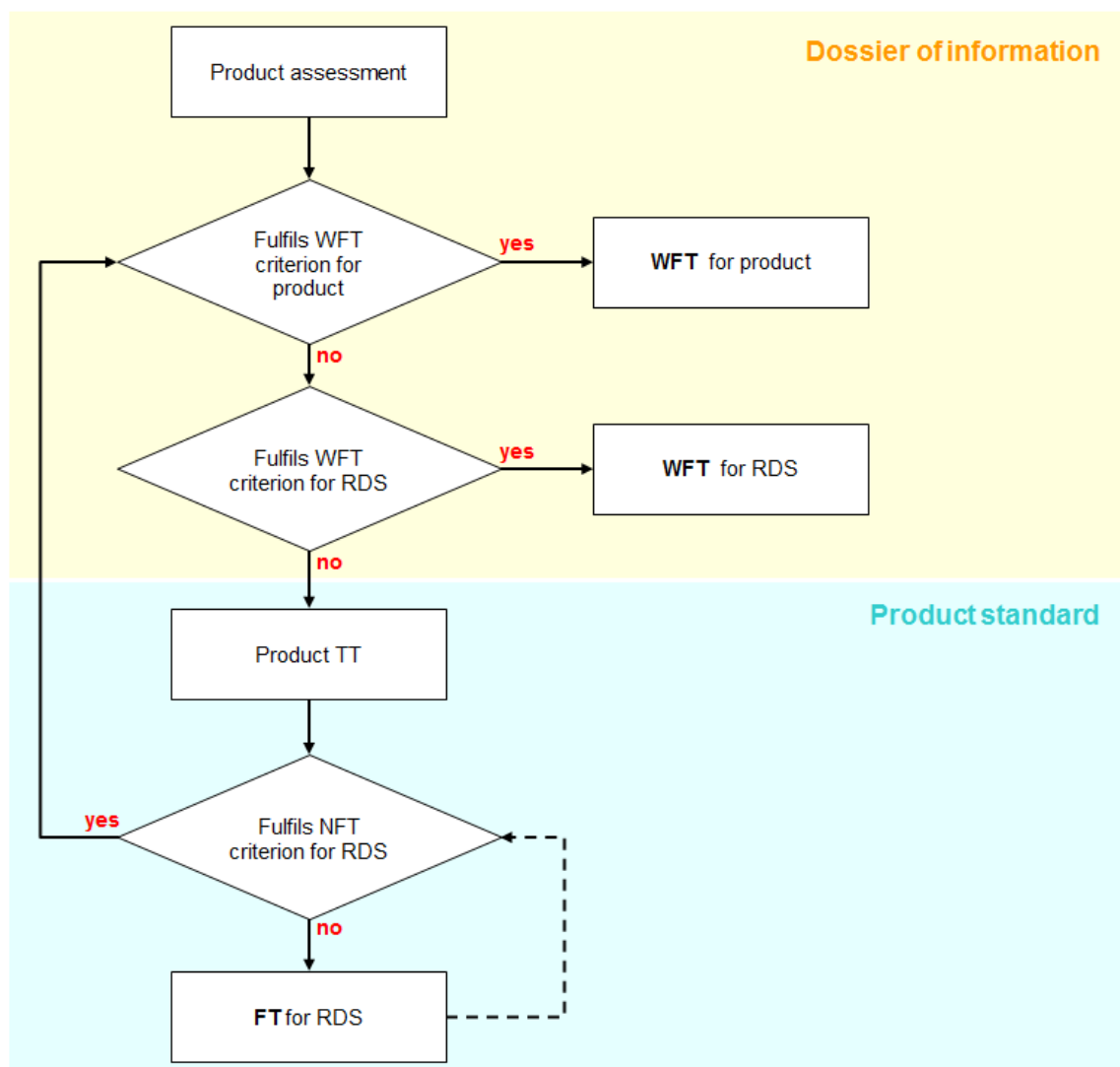


Figure 3 — WFT-FT-NFT procedures for construction products option 2: update dossier

Conditions for a NFT status of a dangerous substance are:

- a well-defined product with respect to composition, raw materials, (technical) properties relevant to the release, emission or content of dangerous substances, etc.,
- the product's composition, properties etc. remains within a defined range,
- a continual surveillance of the product's properties that are linked to the NFT decision.

In principle, the level of the system of AVCP will remain the same as in the original product mandate. Member States, however, may ask the European Commission to introduce another level of AVCP via a Commission Decision (legal act). As a system 1+ is most desirable with respect to dangerous substances, for some standards such a request is likely to be made.

In practice it will not be useful to apply NFT to all RDS for all construction products. In the case of some products the release, emission or content of certain RDS depends on the quality of the production process or the use of a specific raw material.

NOTE An example is the leaching of sulfate from recycling aggregate. Sulfate is related to the presence of gypsum and aerated concrete. The quality of the process to remove gypsum and aerated concrete from the construction waste at the construction site and the quality of the production process of the recycling aggregate (how does the producer deal with gypsum or aerated concrete contaminated construction waste) determine the quality of the final product.

In these special cases where the quality of the process determines the quality of the product, NFT is not an appropriate option. On the other hand, NFT is a useful option for intrinsic micro contaminations that cannot be controlled, but from which it is known that the release, emission or content of these RDS is significantly below the declared value.

5.5 Methods of assessment

5.5.1 Introduction

The statistical assessment of declared values is based on two statistical methods which depend on the distribution of the test values: assessment by variables or assessment by attributes. Assessment by variables assumes a lognormal distribution; assessment by attributes assumes an unknown distribution. Annex B gives background information on the statistical distribution of RDS. Where (log)normality cannot be established assessment by variables will probably lead to false conclusions and unjust rejection of products. In this case assessment by attributes may be more appropriate, although more test results will be needed.

As a starting point it is assumed that for all situations a lognormal distribution may be applied. If a normal distribution or other normalized distribution is more appropriate, the producer may choose to apply the normal or normalized distribution instead. This does not affect the quality level of performance or rules of application.

In the case of **outdoor soil and groundwater** (leaching) there are many test results available based on the experiences with the Dutch Soil Quality Decree where for many RDS the declared value is substantially higher than the detection limit of the leaching tests (depending on the type of construction product). For this reason assessment by variables is the most appropriate method even if the test values are close to or lower than the detection limit.

In the case of **indoor air** (emission) the results of the robustness testing seem to give a similar picture.

In the case of **content**, the declared value may be substantially higher than the detection limit of the test method or close to or even lower than the detection limit (according to the experiences with the Dutch Soil Quality Decree). Depending on the type of dangerous substance assessment by variables (e.g. heavy metals) or assessment by attributes (e.g. asbestos) may be used.

Nevertheless, for all situations it is possible to use assessment by attributes.

5.5.2 Assessment by variables

Because most test values for the release, emission or content of dangerous substances are relatively close to zero, it is assumed that test values have a skewed distribution and taking the log of the test values gives an approximately normal distribution (for brevity this is described as a lognormal distribution). For most dangerous substances this appears to be a correct assumption, although the distribution tends to change to normal when the lowest test values for a specific product and dangerous substance are considerably greater than zero.

As the level of release, emission or content is not known in advance and the effect on the risk of exceeding a declared value by assuming a lognormal distribution instead of taking into account the true distribution is minor or on the safe side, it was decided to ignore this in order not to complicate the method of assessment.

In case of a lognormal distribution the statistical principle is based on the so-called **assessment by variables**. In this case the statistics for normal distributions apply to ln-transformed test values. This implies that the assessment is based on the sample mean and sample standard deviation of ln-transformed test values. Because the true mean and true standard deviation of a set of test values may change in time (e.g. due to minor changes in the production process, switching between different constituents, seasonal influences or oxidation of certain compounds), it is not possible to assume that the samples are taken from a constant production. Also, it will not be likely that the true percentage of the production exceeding the declared value is known. Therefore, criteria for assessment of conformity need to be based on statistics that include these unknown variations of the production process and unknown percentage of production exceeding the declared value.

For these reasons statistics based on the non-central t-distribution are used for assessment by variables. When defining conformity criteria based on assessment by variables, the number of samples and the probability of accepting a non-conforming product for a given percentage of production exceeding the declared value are chosen. The multiplication factor to fulfil these conditions is calculated or taken from a table.

5.5.3 Assessment by attributes

In the case where the assumption of a lognormal (normal or other normalized) distribution (see NOTE 2 in 5.2) is not appropriate, e.g. when the test values are close to or lower than the detection limit or when test values can be substantially affected by the production process, the statistics that apply to an unknown distribution may be used. For this **assessment by attributes** the statistical assessment of declared values is based on the number of test values that exceed the declared value within a defined number of test values. The number of test values that exceed the declared value cannot be greater than the number of test results that are permitted to exceed the declared value.

The advantage of using attributes is that it is not necessary to know the distribution of the test values and that it may be used for continuous random variables as well as discrete random variables. On the other hand, a larger number of test values than for assessment by variables are needed to obtain the same level of confidence in the declaration.

Statistics for assessment by attributes are based on the binomial distribution. When defining conformity criteria based on assessment by attributes, the number of samples and the probability of accepting a non-conforming product for a given percentage of production exceeding the declared value are chosen. The number of test values that are permitted to exceed the declared value to fulfil these conditions is calculated or taken from a table.

5.6 Description of the assessment procedure

5.6.1 Type testing

An early end to type testing is only possible if the mean value is low in relation to the declared value.

Type testing is the start of the assessment procedure and comprises testing every batch. Where using the method of variables, type testing comprises at least two, but not more than ten, test results. Where using the method of attributes, type testing comprises at least four, but not more than twelve, test results. On the basis of the TT results and a declared value it is decided whether the production is conforming and the product should be placed on the market, see Figure 4. Also the frequency of FT testing is established: if the production conforms to the declared value in accordance with the random testing criteria given in 6.2.2 and 7.1.2, FT is based on random testing. If not, FT is based on batch testing.

If the criterion for random testing is not fulfilled the producer may change the declared value to some higher value (but such product may not satisfy the criteria for certain markets), or the producer may

decide that FT is based on **batch testing**, in which case each batch is tested and every batch that exceeds the declared value is rejected.

In the case of **random testing** not all batches are tested, but a smaller number of randomly selected batches and no batches are rejected (thus, batches which exceed the declared value are accepted). Additionally the results may be checked for NFT if at least 5 test results are available.

As the introduction of testing RDS in product standards will affect ongoing production, it is suggested to carry on production in the case of an existing production and take decisions after finishing TT. If TT concerns a new product, TT should preferably be finished before the product is placed on the market. If that is not feasible, during TT conformity of each batch tested should be established before placing the batch on the market.

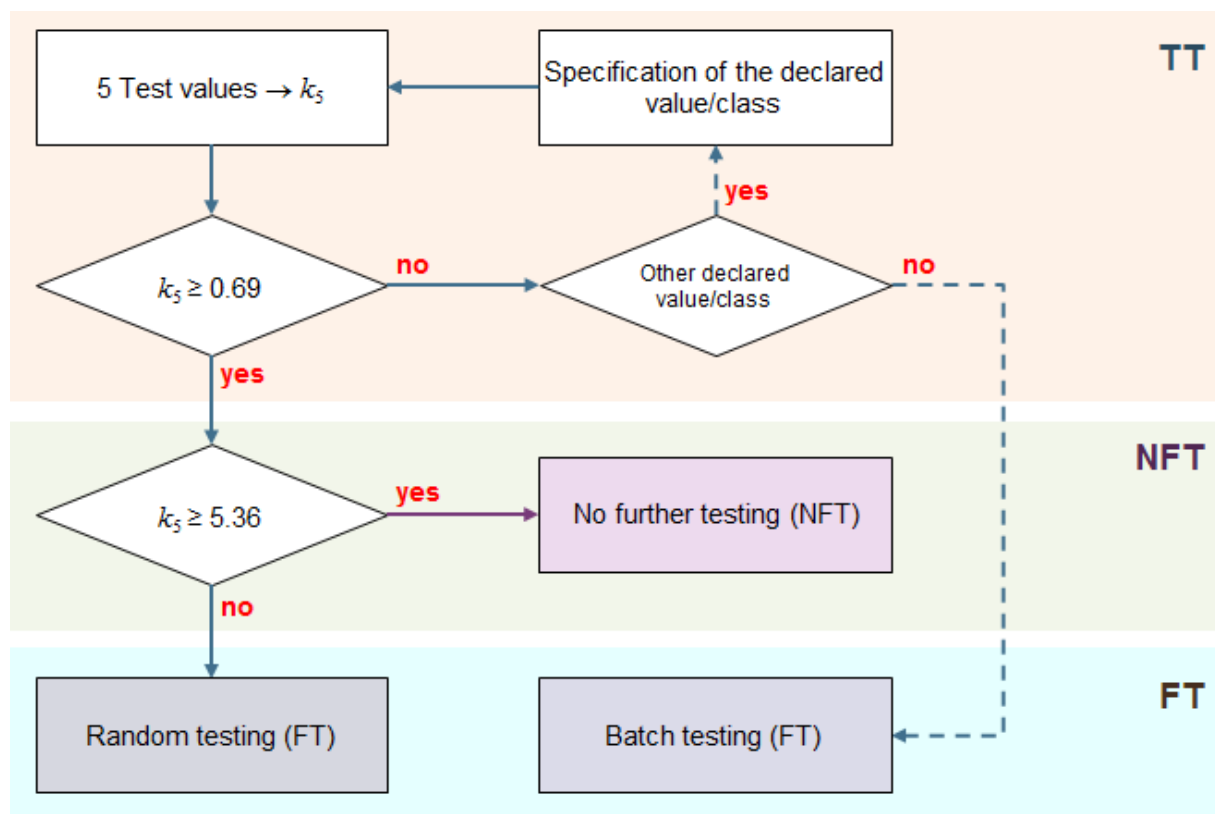


Figure 4 — TT procedure, example of assessment by variables based on 5 test values. In the case of NFT more requirements need to be satisfied, see 5.4

5.6.2 Further-testing

Type testing is followed by further-testing at a rate that is a function of the closeness of the measured values to the declared value. When the risk of exceeding the declared value becomes higher (the closer the measured values are to the declared value or the more variable the results) the more frequent is the testing. When the risk becomes too high every batch is tested.

When in FT the conformity criterion is combined with risk based criteria for the determination of the test frequency for testing randomly selected batches. This means that the test effort for a RDS increases and more batches are tested when the risk of exceeding the declared value becomes higher. When the risk becomes too high and conformity cannot be ensured, every batch is tested. For both methods (assessment by variables and assessment by attributes) two alternative criteria are given. One criterion is for a relatively small number of test values and one for a larger number of test values.

When FT is established, new test values are assessed in conjunction with previous test values (random testing) or as single values (batch testing). After every new test value the frequency of testing is determined and it is decided whether random testing or batch testing is to be applied or whether it is allowed to switch from batch testing to random testing, see Figure 5.

NOTE The criteria in Figure 4 and Figure 5 are based on assessment by variables (see 6.1.1 and 6.1.2). For assessment by attributes (see 7.1.1 and 7.1.2) equivalent criteria are applied.

As long as random testing continues all batches, including the tested batch, may be placed on the market before the test results are available. The batch that causes a change from random testing to batch testing is not subjected to the batch testing criterion. If the test value of this batch exceeds the declared value, a practical dilemma occurs, because random testing allows the product to be placed on the market before the test result is available so that rejection is not possible unless this batch has not been placed on the market. Where batch testing is required batches cannot be placed on the market before the test result is available.

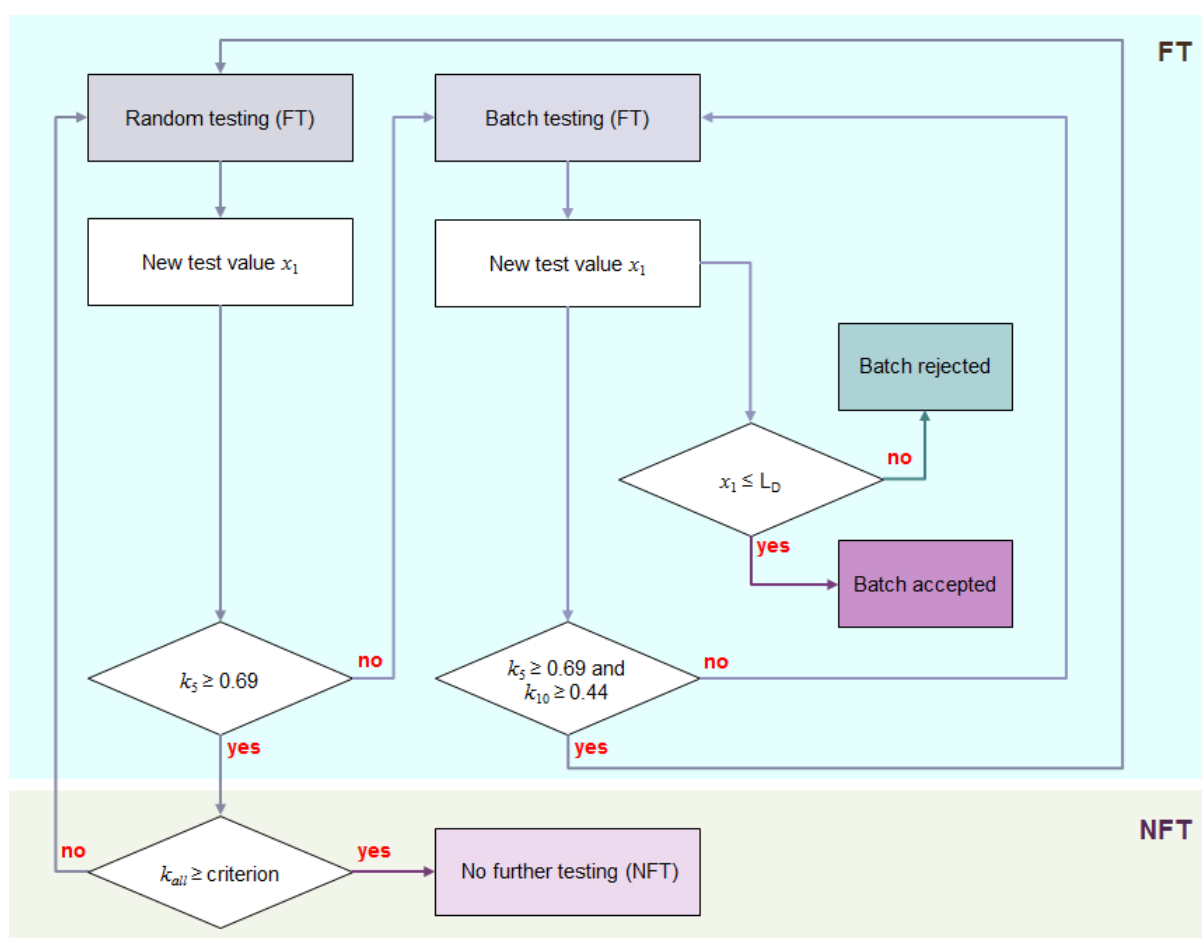


Figure 5 — FT procedure based on 5 test values and assessment by variables. In the case of NFT more requirements need to be satisfied, see 5.4. In the case of batch testing a return to random testing is delayed, see 6.2.2

5.6.3 Clusters

The assessment criteria described in this CEN/TR are applicable to both the production of a single production unit and to the production of clusters. In the case of a cluster additional requirements may be defined by the organization running the cluster with respect to the properties of the product(s) or quality system.

Cluster TT requires a thorough and complete description of the products in the cluster:

- definition of the product, including percentage or content ranges of constituents, composition, specific properties and other relevant aspects of the product;
- full description of all (potential) constituents, constituent parts, etc., including origin and relevant properties.

TT could then be focused on the 'extreme' combinations, so that TT covers the entire range of different combinations and all constituents.

The cluster should be run by an organization that is independent from any of the participating production units to avoid a conflict of interest.

The cluster organization may for instance be a notified body in the case of a group of producers or an independent quality control unit in the case of a group of production locations of one producer.

The cluster organization and production units should have a contract. This contract should include rights and obligations of the cluster organization and production unit, including on site quality control by the cluster organization. The technical requirements in the contract should be equal for all participating production units.

The cluster organization should establish and maintain a quality control manual setting out the procedures by which the requirements for quality control are satisfied. This manual should include:

- a description of the tasks, responsibilities and competences of the cluster organization and participating production units, including on site quality control by the cluster organization;
- a procedure for quality control by the participants, including sampling;
- a procedure for the coordination of all control activities by the cluster organization;
- a procedure for sample selection and testing by the cluster organization;
- a procedure for sample selection and testing by the cluster organization;
- a procedure and requirements for admittance to the cluster;
- a procedure for expelling from the cluster;
- a procedure for internal communication and protection of the anonymity of the participants;
- registration of the participating production units;
- maintenance of the product's definition.

If the test data of a RDS do not fulfil the requirements for applying the cluster system, all participating production units undertake separate testing of this RDS (or all RDS if this is considered more practical). In order to be sure that proper measures have been taken after the cluster system has been rejected and FT changed from random testing of the cluster to random (or batch) testing of all individual production units, each production unit is required to test at least one batch before it is allowed to return to random testing of the cluster. If the cluster consists of less than 5 production units, at least 5 batches need to be tested in total.

The sequence of testing all individual production units is repeated as long as the cluster system is rejected (see Figure 6).

When the risk of exceeding the declared value is too high for a specific RDS the cluster system cannot be applied for this RDS and all members need to test it based on the rules for single production units. As the risk level of switching from cluster testing to individual testing is lower than for switching from random testing to batch testing for a single production unit, cluster FT is based on a three step approach:

- 1) random testing for a cluster;
- 2) random testing for a single production unit;
- 3) batch testing for a single production unit.

If a new production unit is to be admitted to an existing cluster the following should be taken into account:

- the composition and other properties of the product should lie within the defined range of the cluster product(s);
- at least one sample should be tested to allow an assessment by variables or by attributes by adding the test value(s) to the cluster's data base.

Besides the technical criteria defined in 6.2 and 7.2, additional criteria might be considered, e.g. the requirement that the test frequency for the cluster product is not changed due to admitting a new production unit and/or that the test value lies within the range of the data base.

The organization that runs the cluster may define criteria for discarding a product from the cluster in order to protect the cluster from being disrupted, e.g. by defining when a production unit produces outlying results, or when a production unit changes its raw materials. If a product is discarded from the cluster all test data from this specific product should be deleted from the cluster data base.

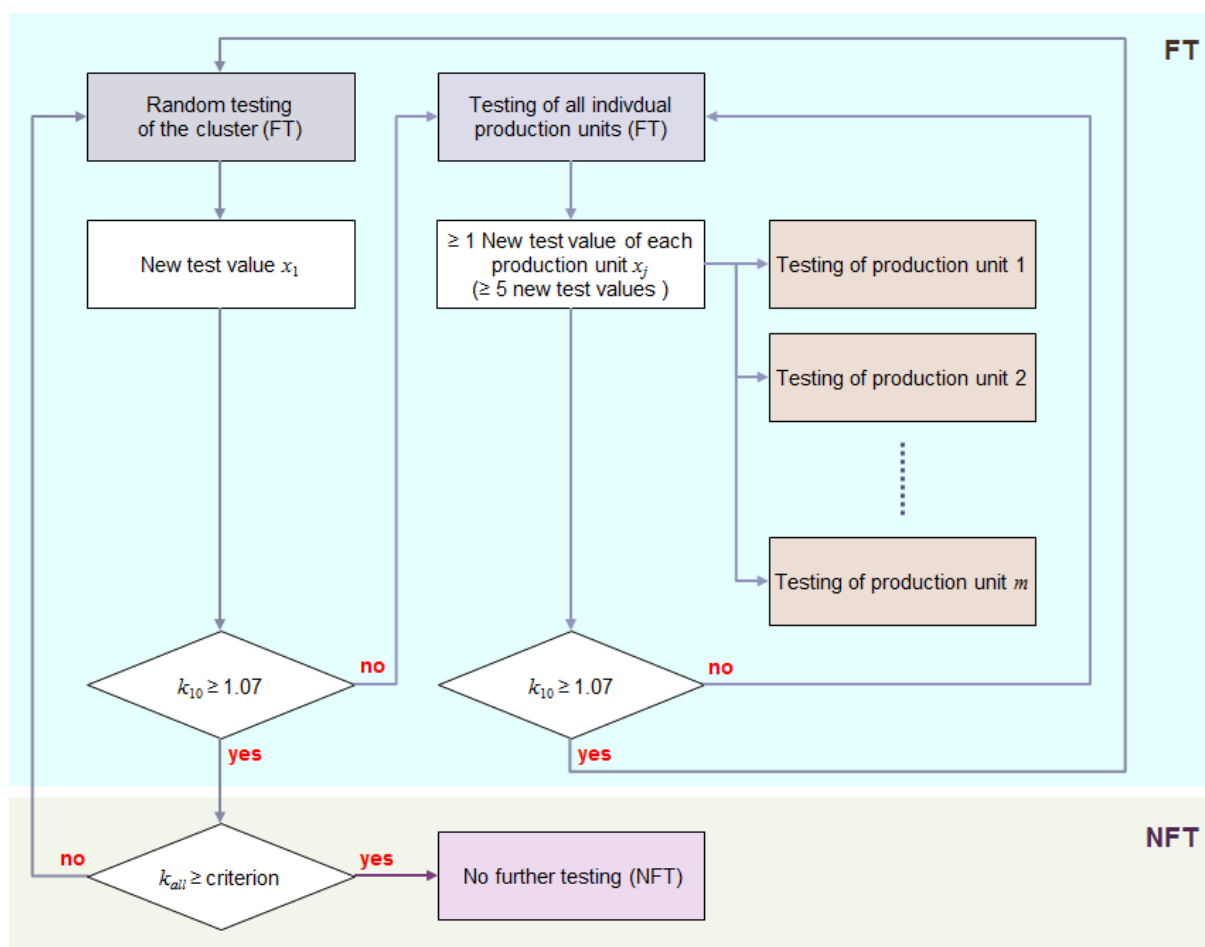


Figure 6 — FT cluster system based on 10 test values and assessment by variables

5.6.4 No-further-testing

In this document NFT is considered as an option within TT and FT when sufficient data are collected and there is sufficient proof that release values will stay within a certain range.

Because NFT is an irreversible decision, the criteria for NFT cannot be based on the same starting points as TT and FT. NFT assessment requires a more stringent approach, because in principle no new test data will be generated. Therefore the NFT criterion is based on a more stringent statistical basis and it is based on all available valid test results. Also additional organizational rules may be needed to apply NFT (see 5.4).

As with FT, the choice between assessment by variables and assessment by attributes depends on the assumption made about the distribution of the test values and the level of the declared value with respect to level of the detection limit of the test method. For NFT the considerations for the different situations are the same as for FT.

NOTE WFT in relation to product dossiers is not dealt with in this document.

5.7 Banned substances

In most products produced from primary materials banned substances should not be a problem with respect to the assessment of their presence. They are simply not allowed. In some products, however, e.g. recycled products, it is not always possible to entirely prevent or remove a banned substance from the input materials. For instance demolition waste may contain some asbestos, even when

asbestos is removed prior to demolition as much as possible. For these situations it is not realistic to set a declared value or regulatory limit value of zero or a value equal to the detection limit, but the declared value should be based on what is left after applying the best available techniques to remove a banned substance from waste.

NOTE E.g. in the Netherlands the regulatory limit value for the weighted content of asbestos in recycled aggregates equals 100 mg/kg, which is a calculated value equal to the serpentine asbestos content plus 10 times the amphibole asbestos content, while the detection limit equals 1 mg/kg.

For these specific cases it is possible to use the assessment criteria for dangerous substances as described in this report.

6 Assessment by variables

6.1 Single production units

6.1.1 Type testing

For assessment by variables TT consists of testing at least two batches. It is however recommended to base TT on at least five batches. Each batch needs to conform if it is being placed on the market. TT may end if the value of k_n is greater than or equal to the critical value k_0 according to Table 1. For 6 to 9 test values, k_5 is used to determine if TT may be ended.

Table 1 — Criteria for ending TT for a single production unit – assessment by variables

Number of test values n	Conformity criterion for the batch	Criterion for ending TT
1	$x_1 \leq L_D$	not allowed
2	$x_2 \leq L_D$	$k_2 \geq 2,18$
3	$x_3 \leq L_D$	$k_3 \geq 1,09$
4	$x_4 \leq L_D$	$k_4 \geq 0,82$
5	$x_5 \leq L_D$	$k_5 \geq 0,69$
6	$x_6 \leq L_D$	$k_5 \geq 0,69$
7	$x_7 \leq L_D$	$k_5 \geq 0,69$
8	$x_8 \leq L_D$	$k_5 \geq 0,69$
9	$x_9 \leq L_D$	$k_5 \geq 0,69$
10	$x_{10} \leq L_D$	$k_{10} \geq 0,44$

The coefficient k_n is calculated from:

$$k_n = \frac{\ln(L_D) - \bar{x}}{s} \quad (3)$$

where

n = number of test values;

- x_i = last test 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.

NOTE In the case that a normal or normalized distribution is more appropriate, the ln-transformation of test values and declared value is not applied.

TT ends when there are ten test values, but this does not necessarily mean the end of batch testing. This depends on the value of k_{10} .

6.1.2 Further-testing

Further-testing is based on the last five or ten consecutive test values. In general FT will be based on ten values, but for certain conditions (e.g. changes after taking a corrective measure) five may be more appropriate. The production conforms when there is random testing but for the continuation of random testing:

$$k_5 \geq 0,69 \text{ or } k_{10} \geq 0,44 \quad (4)$$

where

- k_5 = value of k_n of the last consecutive 5 ln-transformed test values;
 k_{10} = value of k_n of the last consecutive 10 ln-transformed test values.

The frequency of random testing should be in accordance with Table 2. If the last consecutive 5 or more test values are lower than the detection limit, the test frequency equals 1 batch per 3 years.

If the criterion for random testing is not satisfied ($k_5 < 0,69$ or $k_{10} < 0,44$) the production should be batch tested and the conformity criterion applied to each batch is:

$$x_1 \leq L_D \quad (5)$$

where

- x_1 = last (most recent) test value;
 L_D = declared value.

When batch testing no account is taken of the uncertainty of measurement; when random testing, the uncertainty of measurement is reflected in the standard deviation.

Table 2 — Test frequency for a single production unit – assessment by variables

$k_n = \frac{\ln(UL) - \bar{x}}{s}$	Number of test values ^a	Test frequency ^b	Period of production
$k_2 \geq 24,58$ $k_3 \geq 9,65$ $k_4 \geq 7,13$ $k_5 \geq 6,11$ $k_{10} \geq 4,63$	2 3 4 5 10	1 batch per 3 years	3 years of production
$18,50 \leq k_2 < 24,58$ $7,34 \leq k_3 < 9,65$ $5,44 \leq k_4 < 7,13$ $4,67 \leq k_5 < 6,11$ $3,53 \leq k_{10} < 4,63$	2 3 4 5 10	1 batch per year	1 year of production
$10,25 \leq k_2 < 18,50$ $4,26 \leq k_3 < 7,34$ $3,19 \leq k_4 < 5,44$ $2,74 \leq k_5 < 4,67$ $2,07 \leq k_{10} < 3,53$	2 3 4 5 10	1:10 batches (≥ 5 batches per 3 years)	10 consecutive batches
$4,88 \leq k_2 < 10,25$ $2,23 \leq k_3 < 4,26$ $1,69 \leq k_4 < 3,19$ $1,46 \leq k_5 < 2,74$ $1,07 \leq k_{10} < 2,07$	2 3 4 5 10	1:4 batches (≥ 10 batches per 3 years)	4 consecutive batches
$2,18 \leq k_2 < 4,88$ $1,09 \leq k_3 < 2,23$ $0,82 \leq k_4 < 1,69$ $0,69 \leq k_5 < 1,46$ $0,44 \leq k_{10} < 1,07$	2 3 4 5 10	1:2 batches (≥ 5 batches per year)	2 consecutive batches
^a The criteria for 2, 3 and 4 test values can only be used to bridge TT and FT as long as there are less than 5 test values available. ^b For random testing the batch size should be not more than 1/10 of a year's production for continually produced products. For batch testing a smaller batch size could be used to reduce the impact of rejection.			

Where random testing has led back into batch testing, it is necessary to be sure that the product quality has stabilized before returning to random testing, so additional requirements are applied. Once batch testing is required at least 5 new consecutive batches are tested and the criteria $k_5 \geq 0,69$ and $k_{10} \geq 0,44$ satisfied before it is permitted to return to random testing (see Figure 5). Satisfying the criterion for k_5 shows that the latest production is stable enough, while satisfying the criterion for k_{10} shows consistency with the previous production.

An example of TT and FT assessment by variables of a single production unit is shown in Annex A (EXAMPLE 1).

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

In the case of continual very low test values and a very low risk of exceeding the declared value the following criteria may be applied in addition to the previously described rules of application based on variables.

If the last consecutive 5 or last consecutive 10 test values are smaller than $\Gamma \times L_D$ a test frequency according to Table 3 to may be applied, where:

Γ = gamma factor;

L_D = declared value.

Because the use of the gamma rule assumes a lognormal distribution of the test values, it can only be used as an alternative for assessment by variables.

Table 3 — Test frequency – gamma factor

Number of test values	Gamma factor Γ	Test frequency
5 10	0,31 0,41	1 batch per year
5 10	0,19 0,26	
		1 batch per 3 years

6.1.4 Rule of application for products where a small number of test results may be expected

If it is expected that only few test data will be available for TT and FT (due to large variation in products and little production volumes), the use of the gamma rule as describes in 6.1.3 may provide an alternative to assessment by variables as long there are less than 5 test values.

The use of the gamma rule assumes that the coefficient of variation of the test values is known. Annex F shows gamma factors for different coefficients of variation. When there are 5 or more test values available for FT, assessment by variables is considered more appropriate and more reliable because knowledge of the coefficient of variation is not required.

When applying the gamma rule the declared value is multiplied by the so-called gamma factor and TT may be ended if:

$$\sum_{i=1}^n \{x_i > \Gamma \cdot L_D\} = 0 \quad (6)$$

where

x_i = i^{th} test value;

n = number of test results;

Γ = gamma factor according to Table 4 or Annex F;

L_D = declared value.

Table 4 — Criteria for ending TT – Gamma rule for a coefficient of variation of 0,65

Number of test values n	Conformity criterion for the batch	Criterion for ending TT
1	$x_1 \leq L_D$	not allowed
2	$x_2 \leq L_D$	$\sum_{i=1}^2 (x_i > 0,38 \times L_D) = 0$
3	$x_3 \leq L_D$	$\sum_{i=1}^3 (x_i > 0,64 \times L_D) = 0$
4	$x_4 \leq L_D$	$\sum_{i=1}^4 (x_i > 0,82 \times L_D) = 0$

For leaching data a coefficient of variation of 0,65 may be applied to leaching data according to Dutch experiences.

The FT test frequency for random testing should be in accordance with Table 5. For batch testing the rules of 6.1.2 of apply.

6.2 Cluster of production units

6.2.1 Type testing

The total number of tests required for cluster TT depends on the product's description, with a minimum of 5 test results in total, but each production unit should contribute at least one test result. The critical value for k_n depends on the number of test results and should be selected from Table 6. Cluster TT is ended if the critical value for ending cluster TT is met ($k_n \geq k_0$). At this point cluster TT switches to cluster FT.

If the critical value for ending cluster TT cannot be met ($k_n < k_0$) it is not permitted to apply the cluster system to the set of production units and product as tested for the RDS under consideration. In this case it may be decided to change the cluster product by leaving out extreme products, leave out specific production units, select a higher declared value or even decide not to apply the cluster system and assess each production unit separately according to 6.1.1.

Table 5 — Test frequency for random testing – Gamma rule for a coefficient of variation of 0,65

Number of test values n	Gamma factor Γ	Test frequency ^a
2 3 4	0,12 0,15 0,18	$\sum_{i=1}^n (x_i > \Gamma \cdot L_D) = 0$ 1 batch per 3 years
2 3 4	0,19 0,24 0,28	$\sum_{i=1}^n (x_i > \Gamma \cdot L_D) = 0$ 1 batch per year

Number of test values n	Gamma factor Γ	Test frequency ^a
2 3 4	0,35 0,44 0,51	$\sum_{i=1}^n (x_i > \Gamma \cdot L_D) = 0$ 1:10 batches (≥ 5 batches per 3 years)
2 3 4	0,51 0,65 0,76	$\sum_{i=1}^n (x_i > \Gamma \cdot L_D) = 0$ 1:4 batches (≥ 10 batches per 3 years)
2 3 4	0,64 0,82 0,96	$\sum_{i=1}^n (x_i > \Gamma \cdot L_D) = 0$ 1:2 batches (≥ 5 batches per year)
^a For random testing the batch size should be not more than 1/10 of a year's production for continually produced products. For batch testing a smaller batch size could be used to reduce the impact of rejection.		

Table 6 — Criteria for ending TT for a cluster – assessment by variables

Number of test values	Criterion for ending cluster TT
1 to 4	not allowed
5	$k_5 \geq 1,46$
6	$k_6 \geq 1,32$
7	$k_7 \geq 1,23$
8	$k_8 \geq 1,16$
9	$k_9 \geq 1,11$
10	$k_{10} \geq 1,07$
11	$k_{11} \geq 1,03$
12	$k_{12} \geq 1,00$
13	$k_{13} \geq 0,98$
14	$k_{14} \geq 0,96$
15	$k_{15} \geq 0,94$
16	$k_{16} \geq 0,92$
17	$k_{17} \geq 0,91$
18	$k_{18} \geq 0,90$

Number of test values	Criterion for ending cluster TT
19	$k_{19} \geq 0,88$
20	$k_{20} \geq 0,87$
> 20	See Annex E.

6.2.2 Further-testing

The frequency of random testing for a cluster is based on the last 5, 10 or 20 consecutive test results and should be in accordance with Table 7. If the criterion for cluster testing is not satisfied ($k_5 < 1,46$, or $k_{10} < 1,07$, or $k_{20} < 0,87$) the cluster system cannot be applied and each production unit should be test individually according to 6.1.2.

Table 7 — Test frequency for a cluster – assessment by variables

$k_n = \frac{\ln(UL) - \bar{x}}{s}$	Number of test values	Test frequency ^a	Period of production
$k_5 \geq 6,11$ $k_{10} \geq 4,63$ $k_{20} \geq 4,01$	5 10 20	10 batches per 3 years, unless there are less than 20 production units, in which case the test frequency equals 1 batch per 3 years per 2 production units	at least 6 years of production per production unit
$4,67 \leq k_5 < 6,11$ $3,53 \leq k_{10} < 4,63$ $3,05 \leq k_{20} < 4,01$	5 10 20	10 batches per year, unless there are less than 20 production units, in which case the test frequency equals 1 batch per year per 2 production units	at least 2 years of production per production unit
$2,74 \leq k_5 < 4,67$ $2,07 \leq k_{10} < 3,53$ $1,77 \leq k_{20} < 3,05$	5 10 20	1:10 batches (≥ 5 batches per 3 years)	10 consecutive batches
$1,46 \leq k_5 < 2,74$ $1,07 \leq k_{10} < 2,07$ $0,87 \leq k_{20} < 1,77$	5 10 20	1:4 batches (≥ 10 batches per 3 years)	4 consecutive batches
^a The batch size should be not more than 1/10 of a year's production of a production unit for continually produced products.			

If the last consecutive 5 or more test values are lower than the detection limit, the test frequency equals 1 batch per 3 years.

Where random testing for a cluster has led back into testing single production units, it is necessary to be sure that the product quality has stabilized before returning to random testing for the cluster, so additional requirements are applied. Once testing single production units is required at least one new test value for each production unit should be produced and the criteria $k_5 \geq 1,46$ and $k_{10} \geq 1,07$ ($n = 5$ or 10) or $k_{10} \geq 1,46$ and $k_{20} \geq 0,87$ ($n = 20$) satisfied before it is allowed to return to random testing for the cluster (see Figure 6). Satisfying the criterion for k_5 (or k_{10} in case of a larger cluster) shows that