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Revised Position Paper

Use of Historical Assessment Data

1 INTRODUCTION

When a new harmonised standard is introduced, the manufacturer will normally need to subject his construction product to a new assessment of performance. However, the manufacturer may already have useful test results obtained in accordance with the previously applicable rules for the construction product in question. Such previously applicable rules would either be previous national rules or a previous version of the harmonised standard.

Similarly, when a new version of a harmonised standard is superseding the previous version, *significant changes* compared to the previous version may necessitate a new assessment of performance. However, also in such cases test results obtained to the previous version may be useful as basis for the assessment of performance to the new version.

In many cases, the change from one version of a harmonised standard to a new version would not mean any *significant change*, i.e. the result of the assessment of performance would be the same, independently of which of the two versions is applied. In such cases, there would be no need to make a new assessment of performance.

In line with general principles of Union law, to avoid unnecessary burdens on the manufacturer, it should be considered if Historical Test Results would be useful as basis for the assessment of performance to the new harmonised standard.

As notified bodies are not responsible for the assessment of performance of products for which ETAs have been issued, this position paper covers only construction products covered by harmonised standards.

In AVCP system 2+, the notified FPC certification body is not responsible for the assessment of performance. Accordingly, the notified FPC certification body will not need to make any decisions whether or not to use Historical Assessment Data. However, the notified FPC certification body will need to satisfy itself that the assessment of performance carried out by the manufacturer can serve as basis for the verification of constancy of performance. If the assessment of performance is fully or partially based on Historical Assessment Data the notified FPC certification body will need to take that into consideration.

It must be emphasised that Historical Assessment Data should not be used by manufacturers as a means of circumventing the current rules. Only when technically justified the notified body may at its own discretion accept to use Historical Assessment Data as basis for the assessment of performance.

This position paper is intended to clarify the general conditions for the use of Historical Assessment Data by notified bodies.

Sector Groups may develop guidance specifically for harmonised standards within their scopes of work.

2 DEFINITIONS

This position paper applies the terminology defined by the document NB-CPR 18/775, including the below:

Historical Assessment Data: Data obtained to a previously applicable set of rules used as basis for the assessment of performance. Historical Assessment Data may comprise:

- Historical Test Results,
- Historical Test Procedure, and
- Historical Sample Information

Historical Test Result: Result of testing previously conducted in accordance with previous requirements using a historical test procedure and historical test sample(s).

Historical Test Procedure: Test procedure previously used.

Historical Sample Information:

Information about the test specimens used for historical testing, their origin and sampling

Current production The actual manufacturing in its entirety, as carried out in practice, including but not limited to the use of raw materials, constituents, machinery, processes, and Factory Production Control, in relation to construction products to be placed on the market.

Significant change A change which is likely to adversely affect the conformity of the construction product with the declaration of performance.

The change may concern (non-exhaustive list):

- The harmonised technical specification
- A supporting standard, e.g. a test method
- The manufacturing processes
- Constituents or components of the construction product
- The Factory Production Control

NOTE: Regarding “significant changes”, this position paper relates only to changes to harmonised technical specifications and supporting standards (first and second pins). Significant changes to manufacturing processes, constituents, or components, and to the factory production control (3 last pins) are not covered by this position paper.

3 GENERAL PRINCIPLES

3.1 CASES WHERE HISTORICAL ASSESSMENT DATA MAY BE USED

In the below cases of significant changes, it may be considered if historical assessment data can be used.

- 1) When a new harmonised standard is introduced to make the harmonisation effective for products previously subject to Member State rules.

- 2) When a revised harmonised standard introduces significantly changed methods and/or criteria for the assessment of performance.
- 3) When a supporting standard (test/classification standard) called up by an undated reference is significantly changed.

Whether or not a change is a *significant change*, will be subject to a case-by-case assessment.

3.2 ASSESSMENT OF PERFORMANCE

3.2.1 REFERENCE FOR THE ASSESSMENT OF PERFORMANCE

The assessment of performance shall always be made with reference to the **current harmonised standard**. If the harmonised standard is significantly changed, the assessment of performance must be repeated or updated to the new/current version of the harmonised standard.

In no circumstances, the assessment of performance can be made to a previous version of the harmonised standard; even if the test results have been obtained to a previous edition or if the same product type has been marketed and CE marked to a previous version of the same harmonised standard.

It should be clear that a “historical assessment of performance” cannot be used as such. However, in some cases it may be permissible to use *historical assessment data* as basis for the new assessment of performance to the current harmonised standard.

In such cases, it would not be necessary to repeat the testing; only a new assessment of performance may be carried out on the basis of the ‘old’ test results, provided that these old test results are validated and found applicable.

3.2.2 BASIS FOR THE ASSESSMENT OF PERFORMANCE

For all systems of AVCP, CPR Annex V requires the assessment of performance to be carried out *on the basis of testing, calculation, tabulated values or descriptive documentation of the product*.

It is necessary to distinguish between the *assessment of performance* and the *testing, calculation, tabulated values or descriptive documentation of the product* forming basis for it.

Hence, it is a prerequisite for the use of historical assessment data that they can be ‘translated’ into the terms of the current harmonised standard.

3.2.3 SHARED AND CASCADED HISTORICAL TEST RESULTS

CPR Article 36 defines the conditions for manufacturers using test results obtained by another manufacturer or by a system provider.

Similarly, Historical Test Results may be shared and cascaded.

However, the notified body will need to satisfy itself that the combination of sharing/cascading and historical test results will not compromise the integrity of the assessment of performance.

If historical test results are shared or cascaded the use of them would need to be justified by “Appropriate Technical Documentation” (ATD). In such cases, the ATD would have to take into account that the Historical Test Results have been obtained to a previous standard.

3.3 PROPORTIONALITY

CPR Article 52(2) states:

Assessments and verifications of constancy of performance shall be carried out with transparency as regards the manufacturer, and in a proportionate manner, avoiding an unnecessary burden for economic operators. The notified bodies shall perform their activities taking due account of the size of the undertaking, the sector in which the undertaking operates, its structure, the degree of complexity of the product technology in question and the mass or serial nature of the production process.

In so doing, the notified bodies shall nevertheless respect the degree of rigour required for the product by this Regulation and the part played by the product for the fulfilment of all basic requirements for construction works.

When a notified body is responsible for the assessment of performance, i.e. in AVCP systems 1+, 1 and 3, the notified body may be requested by a manufacturer to use historical assessment data as (part of) the basis for the assessment of performance.

In line with the principle of proportionality, the notified body will need to consider if it would be justifiable to use these Historical Assessment Data in the concrete circumstances.

Then the notified body would need to consider if the burdens (costs) on the manufacturer caused by requiring a new basis to be established for the assessment of performance would be proportionate taking into account the public interest as expressed by the 2nd indent of Article 52(2).

In that respect, it is emphasised that Historical Assessment Data may only be used if the level of protection of public interest is safeguarded. In particular, the safety level shall not be compromised.

If the basis for the assessment of performance is *calculation, tabulated values, or descriptive documentation of the product*, it may be less burdensome to have the basis updated to the new current standard than if the basis is *testing*.

To have a calculation, a statement on the use of tabulated, or descriptive documentation updated to the current version of the harmonised standard would normally not place any disproportionate burdens on the manufacturer.

It is different with tests as it may not be possible to update a test without redoing the entire procedure including sampling, which in some cases may cause substantial burdens on the manufacturer.

Therefore, this position paper does not cover use of historical results of calculations, tabulated values or descriptive documentation. Only *historical test results* are covered.

It must be emphasised that the acceptance to use historical assessment data should not be used by manufacturers as a means of circumventing the current rules. Hence, only manufacturers whose product types have in fact been subject to previous rules should be permitted to use Historical Assessment Data as basis for the assessment of performance. New manufacturers or manufacturers of new product types introduced in the current regime should not be permitted to use Historical Assessment Data obtained to previous rules to which their product types have not been subjected.

3.4 RESPONSIBILITIES

The AVCP systems are determined by the Commission in accordance with CPR Article 28(2). For each system of AVCP, the responsibility for the assessment of performance is defined by CPR Annex V.

Any use of Historical Assessment Data would not change the responsibility for the assessment of performance.

- In AVCP systems 2+ and 4, the manufacturer is solely responsible for the assessment of performance.
- In AVCP systems 1+, 1, and 3, the notified body is responsible for the assessment of performance.

This means that in systems 1+, 1, and 3, the notified body must take full responsibility for any use of Historical Assessment Data as basis for any assessment of performance it carries out.

3.5 PROVISIONS OF HARMONISED STANDARDS REGARDING HISTORICAL DATA

Some harmonised standards include particular provisions regarding historical data.

Notified bodies should be aware that such provisions may not have sufficient basis in the CPR.

CPR Article 17(3) requires harmonised standards to provide the methods and the criteria for assessing the performance, CPR Article 17(4) requires the standardisation bodies to determine in harmonised standards the applicable factory production control and technical details necessary for the implementation of the system of AVCP.

Any provision going beyond the above may not be considered to have sufficient legal basis. That may for instance be the case if harmonised standards include a time limit to the use of Historical Assessment Data.

4 VALIDATION OF HISTORICAL TEST RESULTS

4.1 CASE BY CASE ASSESSMENT

The notified body will need to assess case by case if Historical Test Results can be validated as basis for the assessment of performance of a particular construction product. Notified bodies being requested to use Historical Test Results are supposed to raise the matter in the relevant sector group to ensure that they operate in line with the consensus view of that Sector Group.

The decision of a notified body will not be binding for market surveillance authorities, which will retain the freedom to assess if the assessment of performance is conducted correctly.

Similarly, the decision of one notified body to reject Historical Test Results will not preclude other notified bodies from accepting the same Historical Test Results.

NOTE:

The decision of one notified body to accept or reject Historical Test Results will not be binding for other notified bodies.

4.2 CRITERIA FOR ASSESSING HISTORICAL TEST RESULTS

To use Historical Assessment Data, the notified body shall satisfy itself that the Historical Assessment Data meet reasonable criteria regarding:

- Technical correctness and compliance
- Competence, impartiality and independency
- Integrity
- Suitability

These criteria are described further below.

4.2.1 TECHNICAL CORRECTNESS AND COMPLIANCE

Historical Test Results shall provide evidence based on the Historical Test Procedure applied.

As part of the validation, the notified body shall assess if test results obtained to the historical test procedure can be translated into the terms of the current harmonised standard.

Sector Groups may develop guidance related to specific Historical Test Procedures.

4.2.2 COMPETENCE, IMPARTIALITY AND INDEPENDENCE

The requirements regarding competence, impartiality and independence found in CPR Article 43 shall be met by all notified bodies and their subcontractors.

When work is subcontracted by a notified body, e.g. when a testing laboratory is requested to conduct testing in systems 1+, 1, or 3, it is the responsibility of the notified body to ensure that the subcontractor meets the requirements of CPR Article 43 (See document NB-CPR 17/744)

Similarly, when using Historical Assessment Data, the notified body shall satisfy itself that the body/organisation that provided the Historical Assessment Data at the time when the Historical Assessment Data were provided did meet the requirements of CPR Article 43.

Generally, if the Historical Assessment Data were provided under accreditation the body may be considered to meet the requirements regarding competence and impartiality. However, with regard to independency the requirements of CPR Article 43 are more demanding than the requirements of the accreditation standards.

In AVCP systems 1+, and 1, Assessment Data shall originate either from the notified product certification body itself or from an independent 3rd-party laboratory, operating as a subcontractor to the notified product certification body, and at the responsibility of that notified product certification body.

Accordingly, in AVCP systems 1+ 1, when Historical Assessment Data were obtained to a previous version of a harmonised standard, the historical assessment data should originate from a laboratory operating as a subcontractor to the notified product certification body, and at the responsibility of that notified product certification body.

It is emphasised that the possibility for a notified product certification body to use Historical Assessment Data in systems 1+ and 1 shall not make it an option for a manufacturer to have testing for the assessment of performance carried out by a laboratory, which is not subcontracted by the notified product certification body, and subsequently have the test results considered as Historical Assessment Data.

However, Historical Assessment Data obtained to previous national rules, valid before the citation of the applicable harmonised standard, should not be excluded, even though such rules may have had different provisions for the relationship between the laboratory and the product certification body.

If Historical Assessment Data, in accordance with such previous national rules, originate from a 3rd-party laboratory *not* operating at the responsibility of product certification body, the notified product certification body shall pay particular attention to the verification of *suitability* (see section 4.2.4), i.e. that the sample(s) tested by that 3rd-party laboratory remain(s) suitable to represent the current production of construction products to be placed on the market), to which the new assessment of performance shall apply.

In AVCP systems 1+ and 1, Historical Assessment Data cannot originate from the manufacturer as that would be contrary to the division of responsibilities defined by CPR Annex V for systems 1+ and 1. This would also be the case if the Historical Assessment Data were provided by an accredited laboratory of the manufacturer.

In AVCP system 3, Historical Test Results shall originate from a laboratory, which is independent of the manufacturer. Historical Sample Information may be provided by the manufacturer.

4.2.3 INTEGRITY

To validate Historical Assessment Data, notified bodies shall satisfy themselves that documents, notably test reports, provided to them are the entire valid editions of the documents. Origin and validity may be confirmed by the organisation that issued the documents.

Notified bodies should be aware that

- documents may have been revised and/or withdrawn and that obsolete documents may not have been contained. (Note: Usually, excerpts of reports shall not be accepted),
- a manufacturer who had his construction product tested two or more times in one or more laboratories may only supply the notified product certification body with the test reports showing favourable results and leave out disadvantageous results.

4.2.4 SUITABILITY

In AVCP systems 1+ and 1, the notified product certification body shall satisfy itself that Historical Assessment Data are suitable to represent the current production to which the new assessment of performance shall apply.

Normally, in AVCP systems 1+ and 1 the sampling conducted by the notified product certification body is supposed to ensure the link between the samples tested and the on-going production.

For Historical Assessment Data, the link between the Historical Test Results and the on-going production shall be established by the Historical Sample Information.

If the Historical Sample Information does not provide full information about the sampling procedure applied, it may be possible to establish by other means a reliable link between the test results and the on-going production. If for instance a test report contains detailed descriptions and drawings of the specimens tested it may be possible to verify, e.g. in connection with the initial inspection, that the current production is in conformity with the specimens tested.

In AVCP system 3, the notified laboratory shall satisfy itself that Historical Assessment Data are suitable to represent the sample provided by the manufacturer.

As the manufacturer is responsible for the sampling, the notified laboratory will not need to consider the suitability of the Historical Assessment Data to represent the on-going production.

To satisfy oneself that Historical Assessment Data are suitable, in some cases, it may be relevant to carry out 'identification test(s)' of a sample of the current production for comparison with the Historical Sample Information.

5 VERIFICATION OF CONSTANCY OF PERFORMANCE

In AVCP systems 1+, 1, the notified certification body will need to satisfy itself that the test results forming basis for the assessment of performance remains suitable to represent the current production (see section 2).

This will include assessing if the Historical Sample Information is sufficient to allow for the verification of constancy of performance by means of the methods provided by the current harmonised standard.