CPD	Co-ordination of Notified Bodies for the Construction Products (NB-CPD) on Council Directive 89/106/EEC	NB-CPD/04/093 rev1 Issued: 12 August 2005 **Working Document**

Historic data (Previously existing data)

This document combines information from the adopted EC Guidance paper M (May 2005), the already AG approved document NB-CPD/AG/03/003 and draft document NB-CPD/04/93, accepted during the AG meeting in September 2004. Elements not yet covered by those documents have been indicated.

Summary & conclusions

If historic values are a significant issue for a given product family, then the appropriate forum for producing guidance is the relevant CEN/TC and/or the appropriate Sector Group.

Historic data should only be used if:
- the NB is certain that its MS is satisfied of the NB's competency regarding historic data and under what conditions,

and when one or more of the following are met:
- adequate provisions are made in the harmonised standard, or
- where the prhEN is not materially different from the hEN regarding its impact on testing, or
- where the test EN used is not materially different from that called up in the hEN regarding its impact on testing or
- the SG has agreed a position paper that has been approved.

For a manufacturer to CE mark his product with test results of a NB prior to the body being fully notified then the NB needs to reissue historic test reports, or issue a written declaration, with all the information required by GP 'K' part 'Sample marking and Reporting' - to complete the manufacturer's technical file.

It may be entirely appropriate to ignore historic test data eg because matters relating to sampling or test methods are not in accordance with the hEN.

1. Introduction

Historic data (or previously existing data) has been defined by EC Guidance paper M as test results following the provisions of the product technical specification, obtained before it was in force (i.e. the start of the coexistence period of a harmonised product standard or ETAG) and/or before the third party involved in attestation tasks was formally notified to the EC for the relevant attestation tasks included in the harmonised technical specification[1].

[1] Any other result obtained according to any other technical specification (e.g. national standards or national approvals) previously in use in specific countries is not necessarily accepted as previously existing data. To be accepted as previously existing data the test results need to comply with the requirements of the harmonised technical specification for which the reference has been published in Official Journal and which allow to CE mark the product.

It is generally assumed that CE marking takes place by bodies fully notified to the Commission, against published harmonised standards after the date of availability, and using the test methods strictly according to Annex ZA and EC Guidance Paper K, §4.8[2].
Historic data in this paper is considered as any data that does not equate to this i.e. historic data covers:

- work carried out by any certification or test body that was **not** fully notified at the time of testing and/or certification.
- the harmonised product standard was **not** available at the time the work was undertaken i.e. before the date of availability (DAV), and
- the product is not tested strictly according to the test standards/test methods referred to in Annex ZA of the standard.

The use of historic data, whilst avoiding unnecessary cost to the manufacturer and reducing the pressure on scarce test facilities, has drawbacks and it may be entirely appropriate to ignore historic test data. This paper provides guidance on the use of historic data to NBs and SGs should the NB wish to exploit historic data.

In some harmonised standards the issue of historic data is partially addressed[3], whilst in others it is not. If this is omitted in the hEN then the SG should assure themselves that the CEN/TC wish the SG to consider historic data. The following guidance is to inform NBs and SGs about the matter. Where there are valid reasons to use historic data then this guidance sets out safeguards to ensure that it is done responsibly by a NB i.e.:

- in the knowledge that the relevant MS regards the NB as competent when it did the work,
- using criteria that are open and transparent, and
- with the knowledge and approval of the SG, AG and CEN/TCs where the matter is not self-evident.

Under all systems of attestation, any declared performances in the CE marking and set values in the harmonised standard must be met with as much confidence as if the full range of tests and assessments had been carried out according to the harmonised standard after the date of availability (DAV).

The use of historic data for CE marking has to involve a considered judgement by the manufacturer and by the test body or certification body according to their division of responsibilities for CE marking. The further the test conditions are from the 'normal' situation then the greater the degree of care is necessary and it may be appropriate to ignore historic test data.

[2] Guidance Paper 'K' states '…4.8) Notification of bodies to the Commission does not automatically mean that tasks performed by them can lead to the affixing of the CE marking. Such CE marking can only take place once all the necessary conditions have been fulfilled, i.e. the availability of harmonised technical specification together with all the necessary test and/or assessment methods. …'

[3] Many hENs permit the use of historic data by means of the sentence 'Tests previously performed in accordance with the provisions of this standard (same product, same characteristic(s), same or more onerous test method, sampling method and attestation of conformity) may be taken into account.'

2. Manufacturer's technical file and CE Marking

If historic test data is used then the manufacturer's technical file must satisfy market surveillance authorities on two key points, i.e.:

- there must be full records of the actual historic tests or assessments[4] carried out, including:
  - sample marking and reporting information in accordance with GP 'K'[5], and
  - how they relate to those cited in the harmonised standard and the attestation provisions
- evidence in the FPC that the product tested is representative of the product now being CE marked,

Hence, the technical file should indicate the following:

- those tests/assessments carried out entirely according to the requirements of the hEN.
- those tests/assessments where historic data has been used with a full description of the tests/assessments on which the historic data is based, including
  - evaluation of the equivalence between the historic test/assessment methods and those referenced in the hEN.
  - correlations between minimum or maximum values, levels, or classes determined according to the test/assessment methods in the hEN and the equivalent performance obtained by the historic method; alternatively, proof of a more onerous test.
  - supporting evidence that current production relates adequately to the samples historically tested ie the product produced now is the same regarding the declared performance as the product and samples used in the historic testing.

Where historic data has been used, the declared performance of the product should be expressed in the same terms as those set out in the hEN and the CE marking is not modified to indicate that historic values have been used

3. The status and responsibility of a NB regarding historic data

At the time that the attestation work was carried out, the status of the Notified Body may have been one of the following in relation to the product concerned:

- fully notified
- provisionally notified
- neither fully or provisionally notified but meeting its MS's criteria for notification e.g. accreditation for the historic tests
- not notified, and not meeting its MS's criteria.

It is a NB's own responsibility to satisfy itself that it is regarded by its MS as competent to use historic data and under what conditions (e.g. as part of the notification process, a candidate notified body should inform its notifying authority of any 'historic' work so that the notifying authority can confirm competence for the work already carried out in its appointment letter).

Work undertaken by a NB that is historic involves a degree of risk and the NB may have to repeat the work e.g. there are changes in the ENs or hENs that mean the tests cannot be accepted, and/or the sampling procedure is inadequate for CE marking.

The manufacturer can only legally presume that test reports issued after the body has been fully notified are valid for CE marking purposes. All certificates and test reports issued by NBs supporting CE marking in the manufacturer's technical file must satisfy the minimum requirements of Guidance

[4] An example would be a calculation.

[5] In the framework of historic data, sampling records may be substituted by documented traceability of samples subjected to testing towards the factory production control system, ensuring samples subjected to historic testing are representative for products placed on the market at the time of conformity assessment in the framework of CE Marking.

Paper 'K' regarding 'Sample marking and Reporting' to be valid. Hence for historic test reports of a NB to be valid for CE marking purposes, the NB as a **minimum** will have to formally write to the manufacturer with a declaration of the NB's registration number and link it to the relevant historic test report, or the NB may wish to reissue the test report in accordance with Guidance Paper 'K'.

4. Guidance on the use of historic data relating to earlier versions of the standards

In principle, many hENs permit the use of historic data by means of the sentence

> *"Tests previously performed in accordance with the provisions of this standard (same product, same characteristic(s), same or more onerous test method, sampling method and attestation of conformity system) may be taken into account."*

However, more detailed guidance on a product specific basis is required by NBs, SGs – see following.

4.1 Harmonised product standard (hEN) not yet available

If a NB anticipates the definitive content of a hEN (e.g. by testing according to the prhEN), then the NB may claim the historic test data is valid without the need for a SG position paper - provided there is no material difference between what the NB has done for the prhEN and what it would do for the final hEN and any SG position paper.

4.2 Historic test results according to a prEN or earlier EN test standard

A NB cannot assume that tests to any prEN or earlier EN are valid under all circumstances. The SG should consider the matter in their general scrutiny of hENs, and only where there is the possibility of earlier versions of the EN not being acceptable should the SG produce a position paper on the matter.

4.3 Historic test results according to other standards

Unless there is direct guidance in the National commentary of the transposed European standard then a NB cannot assume that tests to a national standard or other standard, e.g. ASTM test method, relate to an EN called up by a hEN. Where there is no guidance, an approved SG position paper covering such matters giving clear advices is required before a NB can validate such historic tests.

5. General guidance on use of historic results under the different attestation systems

5.1 System 1/1+

Product certification bodies should evaluate and satisfy themselves of the evidence to support the use of historic data. The manufacturer's production control records and test reports, whether by the manufacturer and/or a third party now notified for the tests, should support:

- the robustness of the historic data, including competence and independence of the test facilities and personnel used and the sampling regime adopted[6]
- the relationship established between the historic data and the European test methods cited, and
- that the samples taken for historic data are still representative of current production.

[6] Where another NB has validated historic test data then the product certification body still needs to be satisfied that sampling matters have been adequately addressed, and the test samples are representative of current production for the relevant essential characteristics.

5.2 System 2/2+

Under system 2/2+, the NB is **not** involved in initial type testing. According to Guidance Paper 'K' the certification of FPC includes

> *'... the evaluation of the internal control of production exercised by the producer to enable the achievement of the required product characteristics to be checked.'*

The SG should consider how this is addressed, particularly with historic data.

5.3 System 3

For manufacturers to use historic test reports for CE marking purposes the NB will need to either reissue the test report or make declarations about the validity of the historic test data for CE marking purposes and satisfy Guidance Paper 'K' on aspects regarding sample marking and test reports.

The NB shall look to available guidance before reissuing test reports or issuing declarations regarding historic work they have undertaken, from:

- the hEN including national forewords/annexes,
- Guidance Paper 'K', particularly the part on 'Sample marking and Reporting' – see Appendix 3', and
- relevant approved GNB guidance on CIRCA i.e. this AG paper and relevant approved SG position papers.

5.4 System 4

Under System 4, there is no compulsory involvement by a notified body.

6. Validation of historic data

It is possible that manufacturers contact Notified Bodies to have historical data "validated".
In the case of ITT under system 3, Notified laboratories will have no opportunity, nor do they have any responsibility, to verify whether the sample tested and described in those historical reports is representative for current production and when validating test reports, NBs should document this fact (e.g. "This validation should only be used in the framework of EC Directive 89/106/EEC if the manufacturer is able to demonstrate representativeness of the sample tested in this test report for the production covered by his EC Declaration of conformity. This representativeness has not been verified by the testing laboratory.").

Notified laboratories may be confronted with a number of situations, as far as the test laboratory is concerned:

- The test has been performed by the laboratory performing the validation, prior to its notification. In this case the laboratory is able to ascertain that all relevant requirements laid down for notification were fulfilled at the time of testing;
- The test has been performed by another laboratory, prior to its notification or pre-notification. In this case, the validating laboratory will need to contact the laboratory performing the test to see whether it met relevant notification requirements at the time of testing;
- The test has been performed by another laboratory, which is not notified or pre-notified at the time when validation is to take place. In this case it is recommended that such validation is not performed.

Overall, it is strongly recommended for manufacturers to have test reports validated by the laboratory that performed the test.