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GUIDANCE PAPER M

(concerning Council Directive - 89/106/EEC (CPD))

CONFORMITY ASSESSMENT*) UNDER THE CPD: Initial type-testing and Factory production control

(*final text April 2005*)

Preface

Article 20 of the Construction Products Directive (89/106/EEC) states that the Standing Committee may, "at the request of its Chairman or a Member State, examine any question posed by the implementation and the practical application of this Directive".

In order to ensure as far as possible a common understanding between the Commission and the Member States as well as among the Member States themselves as to how the Directive will operate, the competent services of the Commission, assuming the chair and secretariat of the Standing Committee, may issue a series of ***Guidance Papers*** *dealing with specific matters related to the implementation, practical implementation and application of the Directive.*

These papers are not legal interpretations of the Directive.

They are not judicially binding and they do not modify or amend the Directive in any way. Where procedures are dealt with, this does not in principle exclude other procedures that may equally satisfy the Directive.

They will be primarily of interest and use to those involved in giving effect to the Directive, from a legal, technical and administrative standpoint.

They may be further elaborated, amended or withdrawn by the same procedure leading to their issue.

*) This is the term introduced by the European Commission Guide to the implementation of directives based on the New Approach and the Global Approach (2000), the so-called "Blue Guide". Other Guidance Papers and many technical specifications (harmonised European standards and European Technical Approvals) use instead the term **"evaluation of conformity"**.

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GUIDANCE PAPER M

CONFORMITY ASSESSMENT*) UNDER THE CPD: Initial type-testing and Factory production control

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Acronyms used

AB: Approval Bodies (Bodies authorised by the Members States according to Article 10 of the CPD to issue European Technical Approvals)

AoC: Attestation of conformity according to Chapter V and Annex III of the CPD

CEN: European Committee of Standardisation (Comité Européen de Normalisation)

CEN/TC: Technical Committee of CEN

CENELEC: European Committee for Electrotechnical Standardization (Comité Européen de Normalisation de l'Electricité)

CPD: Council Directive 89/106/EEC (Construction Products Directive)

CUAP Common Understanding of Assessment Procedure for European Technical Approval without guideline (art. 9.2 of the CPD)

CWFT Classified Without the need for Further Testing

EC: European Commission Services

EEA: European Economic Area

EOTA: European Organisation for Technical Approvals

ETA: European Technical Approval (CPD Chapter III type of "technical specification")

ETAG: Guideline for European Technical Approval

FPC: Factory Production Control

GNB: Group of Notified Bodies

GNB-SG Sector Group of Notified Bodies

hEN: harmonised European Standard (CPD Chapter II type of "technical specification")

ITT: Initial Type Testing

NB: Notified Body (also called "Conformity Assessment Body" under other New Approach Directives), which have been designated by Members States for tasks to be carried out for the purpose of conformity assessment). According to the CPD, Notified Bodies include *certification bodies*, *inspection bodies* and *testing laboratories*,

NPD: No Performance Determined

OJEU	Official Journal of the European Union
TC	technical committee
WG	working group

1. Introduction

1.1. This Guidance paper addresses the issue of conformity assessment[1] within the context of the implementation of Council Directive 89/106/EEC[2] (hereafter referred to as the Construction Products Directive - CPD), as amended. Only aspects related to the immediate production of technical specifications are considered.

1.2. The Guidance Paper is intended for technical specification writers (CEN/CENELEC and EOTA), for consideration together with the respective mandates and provisions given therein. Furthermore, it may as well be of interest, for information purposes, to regulators and enforcement authorities within the European Economic Area (EEA), notified bodies and manufacturers, although the technical specifications, once available will contain all relevant detailed provisions applicable to a given product. In any case, unless it expressly states otherwise, the Guidance Paper must not be used for arrangements not covered by technical specifications. It takes account of the Communication of the Commission with regard to the interpretative documents of Directive 89/106/EEC[3].

1.3. Taking into account the experience collected during the elaboration and the implementation of the first harmonised technical specifications (hENs or ETAs), this document is intended to give the principles and layout which the specification writers starting to draft clauses on conformity assessment in new harmonised technical specifications should follow.

1.4. For the existing harmonised standards (hENs) and Guidelines for European Technical Approvals (ETAGs) whose reference has been published in the OJEU (part C) and which are already in force, specification writers should modify clauses to conform to the principles shown here when the technical specification comes up for 5-yearly review, or by earlier amendment. For those currently considered finalised but without the reference already published, they should do so without delay before the reference will be published in the OJEU. In both cases, in order not to delay the application of best feasible technical specifications, specification writers should decide what clauses have priority to be modified.

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1 Other Guidance Papers and many technical specifications (harmonised European standards and European Technical Approvals) also use instead the term “evaluation of conformity”.

2 OJ L 40, 11.2.1989

3 OJ C 62, 28.2.1994

2. General principles

2.1. All harmonised technical specifications under the CPD shall address "Conformity assessment", i.e. how it will be shown that the product conforms to the technical specification. This may be in the product hENs or ETAs[4] itself, or in another standard referred to by the product technical specification.
The Conformity assessment clause is needed to demonstrate, by **initial type testing**, that the product complies with the requirements of the technical specification and that the performance declarations represent the true behaviour of the product and, by **factory production control**[5], that the performance declarations based on initial type testing results remain valid for subsequent products. In addition, it has to ensure that the performances declared by different manufacturers for a certain characteristic are reliable and truly comparable, determined with an equivalent confidence level, and that they can be used to satisfy the required classes or levels on works (e.g. in national regulations).
When the Commission decision determining the AoC system to be applied foresees that the latter depends on the uses(s) of the product, the harmonised technical specification shall clearly specify which characteristics are concerned and the particular procedure to be used.

2.2. *Standards*:
The Conformity assessment clause of harmonised standards should contain a sub-clause entitled “General” dealing with general aspects and introducing the basic methods of evaluation, followed by a sub-clause “Initial type testing [or assessment]” identifying how the characteristics of the products are tested or assessed[6] (which may contain a section entitled “sampling”, identifying how products are selected for testing or assessment, if not included elsewhere), and a sub-clause “Factory production control”.
The distribution of the tasks of manufacturer and notified bodies linked to AoC, i.e. conformity assessment for CE marking, has to be specified in Annex ZA of harmonised standards, and not in the body of the text (e.g. "initial type testing shall be carried out", not "the third party test lab shall perform type testing")[7].

2.3. *ETAs*:
The corner stones, i.e. minimum requirements, of the AoC tasks of the manufacturer and notified bodies, including FPC requirements, are defined in the ETAGs or CUAP. They should be sufficiently explained there and also in the public part of ETAs, while these tasks and requirements are detailed and further developed for the particular manufacturer in the Control Plan which is part of the confidential files which the individual ETA is referring to.

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[4] In the case of an ETA, the detailed tasks of conformity assessment are specified in the Control Plan which is part of the confidential files attached to the ETA. This means that, in this case, Initial type-testing takes into account approval testing without requiring the repetition of these tests.

[5] and, where required, by further testing.

[6] Although the term “initial type testing” is used, other methods of evaluation are possible, e.g. calculation or the use of tabulated data.

[7] although it is possible to require that "The manufacturer shall operate a factory production control system" as the CPD requires.

2.4. Any provisions on conformity assessment included in hEN or ETAG are equally binding for both manufacturers and any notified body. This means, for example, that where a hEN sets a minimum frequency of testing, no manufacturer can comply with the hEN by using a lower frequency and, equally, if his products fully conform to the hEN at the minimum frequency level, no notified body may oblige a manufacturer to use a higher frequency. For this reason, Conformity Assessment clauses need careful drafting, so as neither to disadvantage certain manufacturers who, for example, have sophisticated process control systems and may, therefore, be able to use low test or control frequencies, nor to reduce confidence levels to an extent which would cause genuine safety concerns. Moreover aspects related to Small and Medium Sized Entreprises (SMEs) should be taken into account when drafting provisions on conformity assessment (for ITT, see 4.4, 4.5 and 4.6 and for FPC see 5.11 and 5.12). For ETAs, a minimum frequency might be fixed in an ETAG or CUAP, while the real frequency is defined in the ETA.

3. Definitions

3.1. **Initial Type Testing (ITT):** the complete set of tests or other procedures (e.g. calculation) described in the technical specification, to determine the performance of samples of products representative of the product type, for the mandated characteristics (see Guidance Paper K).

3.2. **Product range:** group of products produced by one manufacturer for which the test results for one or more characteristics from any one product within the range are valid for all other products within this range.

3.3. **Previously existing data**: test results following the provisions of the product technical specification, obtained before it was in force (i.e.. the start of the co-existence 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[8].

3.4. **Classified without the need for further testing (CWFT)**: a procedure by which the specific performance[9] of a product is initially demonstrated by testing, in such a way that manufacturers may refer to that performance without the need of further tests (other parameters e.g. density, may require testing and controlling). To be taken into account in the harmonised product specifications successful CWFT applications require an EC Decision.

3.5. **Conventionally accepted performance**: provisions presented or referred to in the technical specification that allows manufacturers to declare product performances

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[8] Any other result obtained according to any other technical specification (e.g. national standards or national approval) 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.

[9] Currently applied to fire reaction, fire resistance and/or external fire performance

without the need to perform initial type tests, calculations, etc. Such provisions may be tabulated values, descriptive solutions and alike.

Note: In many cases, product property requirements (e.g. density) are the means to establish the right to use the provisions referred to in 3.4 and 3.5.

3.6. **Approval testing**: set of tests to determine product performances, as included in the Guideline for European Technical Approval (ETAG) or Common Understanding of Assessment Procedure (CUAP), to be performed by the Approval Body authorised to deliver ETAs for the product concerned or under its responsibility (by a Notified Body, a sub-contractor or the manufacturer testing under Approval Body witnessing).

3.7. **Conformity assessment linked to an ETA**. In the attestation of conformity procedure, a Notified Body performs all or part (with another body involved, according to the plan[10] which is part of the confidential files which the ETA is referring to) of the tasks linked to the conformity assessment and required in the ETA. The tests and assessments already performed by the Approval Body or under its responsibility when the ETA has been delivered are to be taken into consideration without a need to repeat them. Approval testing is usually to be considered as ITT as can the Approval Body's initial inspection of factory for the purpose of certification or declaration of conformity with regard to FPC. In this case the tasks undertaken by the Notified Body (or the manufacturer) usually only concern validation and the other aspects (e.g. audit testing or continuous surveillance of FPC, if relevant) of conformity assessment.

4. Initial type testing (ITT)

General

4.1. New Approach directives consider the manufacturer as responsible for designing and manufacturing a product[11] who must take all measures necessary to ensure that the manufacturing process assures compliance of the product, to affix CE marking to the product, to establish a technical documentation and to draw up the EC declaration of conformity.

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[10] control plan / accepted test plan prescribed by the Approval Body

[11] Guide to the implementation of directives based on the New Approach and the Global Approach, clause 3.1 *"The manufacturer is any natural or legal person who is responsible for designing and manufacturing a product with a view to placing it on the Community market under his own name"* and *"the manufacturer has sole and ultimate responsibility for the conformity of the product to the applicable directives, whether he designed and manufacture the product himself or he is considered as a manufacturer because the product is placed on the market under his name"*.
Regarding specifically the CPD, to this add the cases in which a structural component or kit is manufactured in accordance with the design details (drawings, material specifications, etc.) prepared by the designer of the works following national provisions, excluding the design from the manufacturer's factual responsibility.

4.2. For construction products subject to AoC with harmonised technical specifications, the CPD foresees that ITT can be used as a method of control of conformity when determining the procedures of attestation of conformity[12]. In practice this means that harmonised characteristics for which the manufacturer declares performances (see 4.3) are subject to ITT when the manufacturer first declares conformity with a hEN, even for products already placed on the market. In addition, the need to perform ITT applies to all characteristics included in a technical specification when the manufacturer claims conformity, unless the technical specification gives provisions (e.g. use of previously existing data, CWFT and conventionally accepted performance) to declare performances without performing tests.

4.3. In order to take into account existing regulations on products where performance(s) for one or more characteristics may not be required, due to the characteristic(s) for a given intended use that is/are not subject to regulation in the Member State(s) where the product is placed on the market, the NPD-option can always be used by manufacturers (according to the provisions of Guidance Paper E "Levels and classes" clause 4.11 and Guidance Paper D "CE marking" clause 3.6). In these cases, the use of phrases "where required" can be confusing and, therefore, should be avoided[13].

4.4. The term ITT is used to cover not only physical testing but also other means of demonstrating conformity, such as calculation[14], conventionally accepted performance or tabulated reference data. Even when using CWFT or conventionally accepted performances, the manufacturer may need to perform some tests (e.g. of density) to demonstrate that his product meets the definition of the product covered by such provisions. The need to do this, as well as which test method(s) is/are appropriate, has to be made clear in the technical specification.

Test and assessment methods

4.5. Specification writers have to ensure that the technical specification for ITT is explicit on the assessment method, i.e. on how samples are to be taken (either in the technical specification itself or by reference to a test or classification technical specification containing the information), how many specimens are to be tested, their dimensions and how they are to be mounted in the testing equipment.

4.6. Some technical specifications may provide little more than a harmonised list of test methods and permit manufacturers to declare whatever performance level the product achieves from the tests (or other assessments). Other technical specifications may set threshold values on some characteristics, or introduce classes (either as a result of the mandate or 'classes of convenience'). Any combination of these three provisions is acceptable, although CEN/TCs and EOTA/WGs have to follow the provisions of Guidance Paper E when setting levels and/or classes.

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[12] CPD article 13.3.b and Annex III

[13] Instead, the requirement clauses relating to harmonized characteristics could start with the text: "This characteristic shall be evaluated when subject to regulatory requirements in the Member State where the product is intended to be placed on the market. It also may be evaluated, when the product is intended to be placed on the market in a country without regulation for this characteristic."

[14] For ITT by calculation refer to Guidance Paper K, in particular point 3.4 and its Annex 3.

CEN/TCs and EOTA/WGs need to ensure that the hEN or ETAG/CUAP is explicit in stating what the compliance criteria are and how the test results are to be expressed. Technical specifications may require one of the following approaches:

- 'pass/fail' (in which case it is common, but not necessarily obligatory, to assume that all products tested 'pass'[15]),
- test results that are used to establish levels or classes that are declared (e.g. fire behaviour classes),
- that the manufacturer states the test result itself, a mean value, or a mean value plus a declared tolerance, according to what is required by the technical specification,
- a 'manufacturer's limiting value' (the value which all products have to meet or exceed in tests),
- other, statistical means of declaration (e.g. characteristic/design value, acceptable or limiting quality levels) [16].

4.7. In some cases, test methods for initial type testing take some time to produce test results upon which the manufacturer's declaration is based. Without further guidance, this might mean that products cannot be CE marked for being placed on the intended market(s). If this situation is likely to occur, the CEN/TC should consider other verification methods or propose proxy characteristics in their responses to the EC mandates.

A further possibility is for a product hEN to foresee a first compliance and verification according to an approach considered sufficient for resulting in a provisional permission, for a limited time, to place products on the market under defined and limited conditions, while full verification is undertaken. When this situation does occur, manufacturers have to initiate ITT well in advance of their intended placing onto the market of the product (e.g. in research and development step). Depending on the case, applying, where this is possible, article 4 (4) of the CPD, or an ETA, can also be an appropriate solution for such specific cases.

4.8. In some cases, a manufacturer might seek ITT results for series production (see 4.9.1 and 4.9.2) before he has established a production run and the product(s) is/are produced in more than just very limited quantities. Where this may happen, because it is not possible to perform normal sampling, the technical specification has to give specific rules related to how products are chosen for ITT, and how these results are then applied to later production.

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[15] e.g. concerning frost resistance requirements: "The product shall pass …"(requiring that, for example, 9 out of 10 products pass). Furthermore, 'pass/fail' requirements do not need to be met if the NPD option is made use of.

[16] Drafters may refer to ISO/TR 13425 "Guide for the selection of statistical methods for standardization and specification", or ISO 12491:1997 "Statistical methods for quality control of building materials and components" in order to find an appropriate statistical method, both for ITT and for FPC testing.

Distinct categories of production

4.9. Guidance on ITT taking into account different categories of production

4.9.1. *Conventional series production*:

Many products placed on the market are manufactured in large volumes of the same product made over time. As long as the product remains unchanged, there is no need to repeat the ITT, and neither technical specifications nor Notified Bodies need to seek to put 'lifetime' limits on ITT reports.

4.9.2. *Series production of products with varying properties*[17]:

In this case of products placed on the market, the technical specifications need to give consideration as to how to perform ITT, because although there is series production, the finished product has potentially different performances (e.g. due to different size). The technical specification shall be specific about whether every product/kit of different size, shape, strength, etc., has to be considered as a different product requiring all characteristics, not covered by a product range, to be initial type tested, or the technical specification shall contain provisions to reduce this testing burden (e.g. the concepts of product range and/or direct or extended application of test results).

If, for justified and accepted reasons[18], the CEN/TC or EOTA/WG is not able to find an appropriate solution to cover this production categories appropriately in the same hEN or ETAG/CUAP, CEN/TC or EOTA/WG may do so separately or at a later date (through an amendment of the published hEN or ETAG). In this case, hENs or ETAGs/CUAPs would have to clearly define and exclude from the scope this production category not covered.

4.9.3. *Individual (and non-series) production* (Article 13(5) of the CPD), insofar required to be CE marked[19]:

(In order to fall into this category, a product must fulfil both criteria, individual and non-series production.)

These are products of individual design that are ordered for and installed in one and the same known work. They should neither be part of a range of equal products, which is manufactured in series of the same kind combining usual components in the same way[20], nor should they and their field of application (e.g. dimensions, weight) be offered on the general initiative of the

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[17] Examples of 'series' products with varying properties are steel structures, where each product/kit is of a different size, shape and strength, and windows manufactured in a wide range, where many products are of the same design, but of different sizes.

[18] In such a case, the CEN/TC or EOTA WG should send to the Commission an amendment to its answer to the mandate, and the Commission will reply in writing whether this amendment is accepted or not.

[19] Article 1 (2) of the CPD defines construction products as those for incorporation in works, and Article 2 (1) refers to them being "placed on the market". Therefore, notwithstanding their responsibilities in this field, Member States are not obliged to take measures for applying CPD provisions and CE marking to building elements made on the works and to those construction products that are manufactured off the works but incorporated in them without beforehand having been placed on the market, i.e. directly by the manufacturer as part of a service comprising more than just manufacturing and delivering the product.

[20] often in automatically operating processes

manufacturer (e.g. by means of published catalogues or other ways of advertising).

Under these conditions, individual (and non-series) production comprises products that are:

– individually designed and manufactured, upon request and for specific purposes, needing to readjust the production machines for their manufacture in order to be used in the work concerned [21]; or

– custom-made for a specific order to obtain one or several end use performances different from products manufactured in series, even if produced according to the same manufacturing process/system design.

Note: According to Statement no. 2. for entry into the Minutes of the Council of 21 December 1988 "The Council and the Commission agree that where a product is intended for a single application, Member States may authorise the use thereof even if it does not comply with the provisions of the Directive" (but without CE marking). In this respect, single-application products are to be considered being those of individual (and non-series) production falling under the first indent above, and manufactured for one single specific case of application that requires one or several individual end use performances.

For individual (and non-series) production, with the exception mentioned hereafter, a declaration of conformity by the manufacturer on the basis of (a) initial type-testing by him that uses conventionally accepted methods of testing/determining performances, and (b) factory production control, is sufficient to attest the conformity with the technical specifications in question and to allow the product to be CE marked. This must not result in reduced performance with regard to the requirements laid down in the technical specifications. For the purpose of control and surveillance, this declaration of conformity should indicate the intended use and the work in which the product is to be incorporated.

In the case that technical specifications are drafted for products which have particularly important implications for health and safety, specification writers need to expressly include a related provision if they consider, for individual (and non-series) production, such a declaration of conformity by the manufacturer (i.e. AoC system 4) as insufficient with regard to these implications. If they do so, the technical specifications in question should contain specific provisions regarding ITT of products resulting from individual (and non-series) production for the performance(s) with important implications for health and safety that permit these products to be CE marked without disproportionate testing (see also 5.12 for FPC aspects).

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[21] A product which is manufactured using the same machines the same components and the same process of manufacture, but changing only the dimensions can generally not be considered as non-series product and, instead, falls under the category 4.11.2 *Series production of products with varying properties*.

Where specification writers consider it possible that technical specifications concern a type of product, for which Member States may authorise the use of single-application products that do not comply (see note above) or may otherwise lawfully regard products not falling under the scope of the directive (see footnote [18]), they should bear this in mind when drafting the technical specifications in question.

Reduction of ITT test costs[22]

4.10. Specification writers should consider using in a hEN or ETAG/CUAP the notion of 'product ranges' which individual manufacturers may define. The product range may differ according to the characteristics in question. Although not always essential, using a 'worst case' scenario is a good way of defining a product range.

4.11. CEN/TCs and EOTA/WGs should also consider introducing, in technical specifications, 'direct' and 'extended' application rules of test results.[23] Such rules in technical specifications are familiar for fire related characteristics[24], but they may also apply to other performance characteristics. They are more likely to be included in clauses on testing (or in test technical specifications themselves) than in those on conformity assessment.

4.12. Where a manufacturer produces the same product on more than one production line or unit, or in more than one factory, there may be no need to repeat ITT for these different production lines or units (the manufacturer takes responsibility for ensuring that the products are indeed the same).

The need to repeat ITT depends on whether the production equipment used in the factory, and/or the production line or unit, might influence the performance declarations forming part of the CE marking. This might be subject to the product or even the production method. Where an influence exists, technical specifications may need to specify that ITT needs to be performed for each factory, production line or unit separately. Otherwise, the individual manufacturer can decide on this issue, being the ultimate responsible for the declarations accompanying the CE Marking. Manufacturers must be conscious that if ITT is performed on samples from various production units, lines or even factories, they will have to ensure that the declarations are valid for all products that rely on that ITT.

4.13. To avoid the repetition of testing, also the use of otherwise already existing transferable test results might be taken into consideration, as presented below.

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[22] As a contribution to further reducing test costs, specification writers should also propose products which play a minor part with respect to health and safety for the application of article 4(5) of the CPD.

[23] *Direct application rules* can be considered to be rules which specify how much products/kits may differ from those tested, while still maintaining the same test result (e.g. "Test results apply to products of the same composition with a density up to 10% greater than tested"). They effectively define product ranges. *Extended application rules* (which may contain calculation procedures) predict test results on the basis of one or more test results for the same test method (e.g. "Where the density differs by more than 10%, but its relationship is not known, a sufficient number of tests is needed to determine the relationship. Once the relationship is established, this may be used to calculate the results for products of intermediate density values.") (note that extended application is often used to derive a direct application rule)

[24] CEN/TCs and EOTA/WGs should refer to the work ongoing in this area.

Specification writers are invited to formulate, as an informal part of harmonised technical specifications, further details and guidance to this end, e.g. parameters for determining whether products have the same characteristics relevant for a given performance and, therefore, can be subject of shared ITT results (see hereafter).

4.13.1. *Shared ITT results (in principle applicable to all AoC systems)*

A manufacturer may use ITT results obtained by someone else (e.g. by another manufacturer, as a common service to manufacturers, or by a product developer), hereafter called 'other party ITT results', to justify his own declaration of conformity regarding a product that is manufactured according to the same design (e.g. dimensions) and with raw materials, constituents and manufacturing methods of the same kind, provided that

– the results are known to be valid for products with the same characteristics relevant for performance;

– in addition to any information essential for confirming that the product has such same characteristics, the other party who has carried out the ITT testing concerned or has had it carried out, has expressly accepted[25] to transmit to the manufacturer the results and the test report to be used for the latter's ITT, as well as information regarding production facilities and the production control process that can be taken into account for FPC;

– the manufacturer using other party ITT results accepts remaining responsible for the product being in compliance with all the provisions of the CPD, including both the design[26] and the manufacture of the product;

– he ensures that the product has the same characteristics relevant for performance as the one that has been subjected to ITT, and that there are no significant differences with regard to production facilities and the production control process compared to that used for the product that was subjected to ITT; and

– he keeps available a copy of the ITT report complying to Guidance Paper K point 6.2 that also contains the information needed for verifying that the product is manufactured according to the same design and with raw materials, constituents and manufacturing methods of the same kind.

Provided that the manufacturer provides the necessary documentation to this end, and that the notified certification body or notified test laboratory asked to undertake ITT under AoC system 1, 1+ or 3 has verified, by appropriate means, that the conditions to do so are fulfilled (see above), the latter may accept, upon request by the manufacturer, to use other party ITT results

[25] The formulation of such an agreement can be done by licence, contract, or any other type of written consent.

[26] For certain products (in particular those, for which the performance is calculated using Eurocodes) special provisions may apply.

under its responsibility[27]. Under AoC system 1 and 1+, the necessary verification includes that there are no significant differences with regard to production facilities and the production control process compared to that used for the product that was subjected to ITT [28].

Note: This does not mean "shared ITT". An ITT concerns the evaluation of a specific production made by a given manufacturer. In the declaration of conformity established by the manufacturer, which is a document which can have legal consequences, the product is identified and the name of the manufacturer is given. Therefore, ITT cannot be shared, but only test results.

4.13.2. *Cascading ITT (to be applied under systems 1, 1+ and 3 only[29])*

For some construction products, there are companies (system houses) which supply or ensure the supply of, on the basis of an agreement[30], some or all of the components (e.g. profiles, gaskets, weather strips for windows)[31] to an assembler who then manufactures the finished product (referred to below as the "assembler") in his factory.

Provided that the activities for which such a system house is legally established include manufacturing/assembling of products as the assembled one, the system house may take the responsibility for the ITT regarding one or several mandated characteristics of an end product which is subsequently manufactured and/or assembled by other firms in their own factory. When doing so, the system house must submit an "assembled product" using components manufactured by it or by others, to initial type testing and then make the ITT report available to the assemblers, i.e. the actual manufacturer of the product placed on the market.

Regardless the AoC system under which ITT is the task of a Notified Body (i.e. 1 and 1+ where the notified certification body is responsible for sampling, or 3 where this is a task of the manufacturer) samples for testing the "assembled product" submitted by the system house need to be taken at the latter.

To take into account such a situation, the concept of cascading ITT might be taken into consideration in the technical specification, provided that this concerns characteristics for which either a product certification body or a notified test laboratory intervene, as presented below.

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[27] Irrespective of the fact that, under system 3, the manufacturer remains responsible for choosing the samples.

[28] This might need the NB to visit the other party's facilities in addition to those of the manufacturer.

[29] Contrary to sharing ITT results, which is subject to severe formal rules (see 4.13.1) , in order to ensure sufficient traceability and transparency of responsibility, the legally less formalised cascading ITT should only be applied to AoC systems, under which ITT is a task for Notified Bodies.

[30] This can be, for instance, a contract, licence or whatever kind of written agreement, which should also contain clear provisions with regard to responsibility and liability of the component producer (system house, on the one hand, and the assembler of the finished product, on the other hand.

[31] These companies may produce components but they are not required to do so.

The ITT report that the system house has obtained with regard to tests carried out by a Notified Body, and which is supplied to the assemblers, may be used for CE marking purposes without the assembler having to involve again a Notified Body to undertake ITT of the product's characteristic(s) that were already tested, provided that:

- the assembler manufactures a product which uses the same combination of components (components with the same characteristics), and in the same way, as that for which the system house has obtained an ITT report. If this report is based on a combination of components not representing the final product as to be placed on the market, and/or is not assembled in accordance with the system house's instruction for assembling the components, the assembler needs to subject his finished product to ITT[32];

- the system house has notified to the manufacturer the instructions for manufacturing/assembling the product and installation guidance;

- the assembler (manufacturer) recognises being the one placing the construction product on the EEA Market and assumes the responsibility for the correct assembly of the product in accordance with the instructions for manufacturing/assembling the product and installation guidance notified to him by the system house;

- the instructions for manufacturing/assembling the product and installation guidance notified to the assembler (manufacturer) by the system house are an integral part of the assembler's Factory Production Control system and are referred to in the ITT report[33];

- the assembler is able to provide, to a Notified Body undertaking ITT of the remaining mandated characteristics or any other task needed for the attestation of conformity, and for control and surveillance purposes, documented evidence that the combination of components he is using, and his way of manufacturing, correspond to the one for which the system house has obtained an ITT report (he needs to keep a copy of the system house's ITT report);

- regardless the possibility of referring, on the basis of the agreement signed with the system house, to the latter's responsibility and liability under private law, the assembler remains responsible for the product being in compliance with all the provisions of the CPD, including both the design[34] and the manufacture of the product, which is given when he affixes the CE marking on his product.[35]

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[32] in the case of ETA according to the indications by the Approval Body

[33] or in the system house's ETA when the product is subject to an ETA

[34] For specific products (e.g. for design using Eurocodes) special provisions may apply.

[35] However, in case of failure due to incorrect or insufficient installation guidance, authorities must be able to invoke the liability of the system house or those acting on its behalf. (see also footnote 21)

4.14. The concept of using "previously existing data" is generally introduced by the sentence "Tests previously performed in accordance with the provisions of this standard or ETAG/CUAP (same product, same characteristic(s), same or more technically demanding and appropriate test method, sampling procedure and system of attestation of conformity) may be taken into account.". Introducing this concept may require that the CEN/TC or EOTA/WG determines the limitations of using data from previously performed tests. Such limitations may be related to the characteristic(s) concerned, the version(s) of the test method(s), the sampling procedure used, the sample dimensions, etc. The limitations specified in the standard or ETAG/CUAP cannot be related to the status (notified or not) of the laboratory that performed the test(s) that lead to the previously existing data.

4.15. The concept of product range may also apply, where previously existing data apply only to one or more characteristics of different products within the same range, rather than to the same product.

4.16. Where a product or kit manufacturer uses components which have already been shown (e.g. by CE marking) to comply with one or more requirements of the technical specifications applicable for that product or kit, the ITT which led to such compliance does not need to be repeated (as long as the component's properties or the means of determining them remain unchanged). Technical specifications should allow for this possibility, but shall also require that the component has the necessary performance levels and/or classes to meet the needs of the finished product or kit, taking into account its intended use(s).

Permitted alternatives

4.17. Use of manufacturer's testing facilities by notified testing laboratories**.**

4.17.1. In principle, testing laboratories approved for initial type tests for systems 1, 1+ and 3 and audit testing (1+) should perform their testing using their *own* testing apparatus and personnel.

However, such tests may also be performed using the manufacturer's testing facilities[36], i.e. equipment with or without the manufacturer's testing personnel operating it, for testing in the framework of conformity attestation, provided that:

- the manufacturer's facilities for testing are calibrated,
- the Notified Body agrees to the use of the manufacturer's testing facilities knowing that he retains the responsibility for the test performed and its results,
- the Notified Body conducts the test, and assists to them also in the case they are carried out by the manufacturer's staff,

[36] For instance, if it is excessively complex (e.g. large samples difficult to be transported) or economically disproportionate to perform the tests in the Notified Body's premises.

– the tests at the manufacturer's test facilities are performed in strict conformity with the testing procedure of the relevant test technical specification, including sampling and the preparation of samples, and

– the Notified Body decides whether to take into consideration the test results or not.

4.17.2. Insofar testing laboratories use manufacturer's testing facilities, it must be assured that they are and must remain third parties independent of their clients and other interested parties[37].

The use of the manufacturer's testing facilities does not mean any sub-contracting (Guidance Paper A clause 3.4). It does not give to the manufacturer the status of a notified body.

4.17.3. When facilities of the manufacturer are used by a Notified Body to perform all or part of testing this shall be noted in the test report.

4.18. Under AoC systems 2+, 2 and 4, for which ITT is a task for the manufacturer, the latter may entrust this task or parts of it to any party equipped and qualified to undertake correct ITT for the product concerned, provided that all rules relevant for the AoC system in question will be properly applied.

4.19. As far as establishing the fitness for use of products for which the existing technical specifications have not been applied, or only in part, attention is drawn to Guidance Paper I "The application of Article 4(4) of the Construction Products Directive".

5. Factory Production Control (FPC)

5.1. In the CPD, factory production control means the permanent internal control of production exercised by the manufacturer. FPC is the means by which a manufacturer ensures that the performances declared by him (obtained on the basis of ITT) continue to be valid for all subsequent products. This generally involves ensuring that subsequent products remain substantially the same as those submitted to ITT (i.e. having the same characteristics), although the concept of product range may also be applied to FPC. Where the manufacturer involves intermediaries (e.g. his agent established in the EU) for placing the product on the market, this control might also need to include the latter's facilities, i.e. by controlling there those features of this stage that could affect the product characteristics.

5.2. In general FPC is relevant to all characteristics. However, this does not mean that all characteristics have to be subject to verification and/or evaluation, or that the same methods used for ITT have to be used for FPC. FPC may involve control by indirect means (for example by control of incoming raw materials and control of the production process) or may involve the use of methods different (usually simpler

[37] See Guidance Paper A, point 3.5, in particular 3.5 (b).

and cheaper) from those used for ITT[38] but for which there is a relationship between the FPC method and the ITT one, at least for the individual product or range of products from each manufacturer. The technical specification should require that such a relationship is established, and indicate how it is established and documented, but the relationship itself does not have to be given in the technical specification. Even when the manufacturer uses CWFT or conventionally accepted performance, and the conformity to these is determined by indirect testing (see note below 3.5), the FPC system may need to require checks that the product continues to conform to the requirements for using such provisions (e.g. if the thermal conductivity is a tabulated value based on density, FPC may require that density be controlled).

5.3. Where different manufacturers may use different methods of control (e.g. some use process control while others use finished product testing), the hEN or ETAG/CUAP needs to provide for these equally, and may not distort conditions in favour of one or the other. In addition, technical specifications may not give preferential treatment to manufacturers operating an EN ISO 9001 quality management system, whether 3rd party certified or not (see 5.4 below on the use of EN ISO 9001). Usually, FPC combines both, i.e. frequent process control and infrequent finished product testing. In addition, care needs to be taken when drafting clauses on process control, so as not to directly or indirectly imply or require a specific manufacturing method, as this is not permitted.

5.4. FPC should, in general, be included in the normative part of the technical specification, but may be the subject of a separate annex or even a separate technical specification. Clauses on FPC for CE marking have to be written taking into account Guidance Paper B, and shall be referred to from Annex ZA. It is not permissible to make conformity with the whole of EN ISO 9001 (or earlier versions of the EN ISO 9000 series of standards) normative, but technical specifications may require conformity with those clauses of that standard which correspond to the requirements of Guidance Paper B as part of the overall FPC system. Moreover, manufacturers voluntarily running an EN ISO 9001 compliant quality management system may have a favourable presumption from the Notified Body (under its responsibility), provided the terms and conditions of the technical specification are covered by this EN ISO system.

5.5. The specification writers should consider how much detail to give on FPC[39]. They should recognise that the provisions on FPC are binding on both manufacturers and any notified bodies, and that they therefore need to be carefully drafted so as not to distort the market in favour or against a particular manufacturer, manufacturing method, quantity of production, type of production control, or any notified body. One way of ensuring this is to write FPC provisions in performance based, rather than prescriptive, terms. It is, of course, possible to combine both the performance

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[38] These methods allow the same characteristic or product property to be verified ensuring that the performances declared by the manufacturer continue to be valid for all subsequent products, but using equipment and conditions adapted to the means of the manufacturers and the production environment. Regarding FPC related to calculations, see Annex 3 of Guidance Paper K, in particular its items (11), (14), (18) and (22) as far as the tasks of Notified Bodies are concerned.

[39] For standards, the 'minimum' specification given in the CEN Model Product Standard (document CEN BT N888 and Supplement No.2) is no longer considered to be sufficient.

based approach and a more prescriptive element, using wording such as "The performance requirement is … . A sampling system complying with the frequency of testing provisions and conformity criteria of Table X is deemed to meet this performance requirement."

For technical specifications prepared by EOTA, see 2.2.

5.6. Where FPC requires the satisfaction of certain statistical criteria, and these take some time to be established, the technical specification should indicate how the manufacturer can demonstrate satisfactory FPC before having performed a sufficient number of tests to meet longer-term statistical criteria. It should also be borne in mind that the statistical approach is only practicable for those characteristics which are tested frequently. For characteristics which are tested only infrequently (e.g. once per year) or are not directly tested at all for FPC purposes, alternative requirements have to be provided.

5.7. For products under Attestation of Conformity (AoC) systems 1+, 1, 2+ or 2, if the technical specification does not contain sufficient detail, or has already progressed too far, to enable all Notified Bodies (CPD art. 18) to work consistently with each other, the Group of Notified Bodies (GNB) will develop these clauses, which will then be offered to the CEN/TC or EOTA for subsequent inclusion in the hEN or ETAG/CUAP/ETAs, so that they take on a normative status.[40] These clauses will be used by the NBs, until the technical specification is revised. CEN/TC or EOTA/WG should liaise with the relevant Sector Group of the GNB.

5.8. It is permissible to fix, in technical specifications, minimum frequencies for assessing (maybe fixing higher and lower minimum frequencies depending on results), which methods to be used, and details of other aspects of FPC, such as defective products and control of incoming raw materials. The use of frequencies (which generally should not be in terms of time, but in terms of quantity of production, e.g. once per 1000 m², or in terms of production time, e.g. once per production day) may not, however, be such as to disadvantage manufacturers who invest in more sophisticated methods of FPC control. The use of statistical methods to control production (e.g. control charts)[41] may be more appropriate for certain characteristics. All these are technical items for the CEN/TCs or EOTA/WGs to include, if they decide to do so, in the harmonised standard or the ETAG/CUAP and the Control Plan which is part of the confidential files the ETA is referring to.

5.9. In application of the CPD Annex III, Attestation of Conformity systems 1+, 1 and 2+ include "Further testing of products in accordance with a prescribed test plan". This is generally assumed to cover FPC testing of finished products[42]. The CEN/TC or EOTA/WG should liaise with the GNB to establish what is necessary to satisfy this requirement, which may then be presented either as a sub-clause in its own

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[40] For harmonised standards for which attestation systems 3 and 4 apply, i.e. where FPC is not subject to any third party evaluation, specification writers cannot rely on the GNB for support to include sufficient detail.

[41] Information on control charts can be found in ISO 7870:1993 "control charts – General guide and instruction", ISO 7966:1993 "Acceptance control chart" and ISO 8258:1991 "Shewhart control chart"

[42] Regarding FPC related to calculations, see Annex 3 of Guidance Paper K.

right, or be included as part of normal FPC testing of finished products. However, where the nature of the product or the method applied is such that no testing of the finished product is performed, this requirement may be excluded (and Table(s) ZA.3 in Annex ZA of harmonised standards, or similar information in an ETAG/CUAP, would be correspondingly adapted).

5.10. Where a manufacturer operates different production lines or units in the same factory, or production lines or units in different factories, and these are covered by a single, overall FPC system, the manufacturer still has to keep control records for each separate production line or unit (and this shall be made a requirement of the technical specification). However, when performing FPC inspections, although the product specific aspects need always to be evaluated, the Notified Body does not have to repeat systematically the assessment of 'general' FPC provisions which apply to all lines/units.

5.11. In some cases, a manufacturer may seek CE marking for an innovative or similar product[43], for which he does not yet have a fully operational FPC system. For such cases, the technical specification should specify the requirements that apply before the FPC system is fully operational, in order to allow the manufacturer to claim conformity to the technical specification, and what requirements apply once the system is fully operational.

5.12. In the case of single-application products (see 4.11.3), some of the aspects of FPC used for series production (e.g. finished product sampling) do not apply. The manufacturer will, however, still have to have an FPC system, for example controlling raw materials and keeping records. Where products covered by a hEN or ETA may be produced as single-application, the FPC clauses need to be written in a way which gives exemptions from those requirements which apply to series production only; however, the specification writers should be aware that the requirements for all products covered by one harmonised technical specification have to be equivalent.

5.13. In the case of kits, a number of different options may exist.

5.13.1. The kit manufacturer manufactures all components, in which case he takes full responsibility for the FPC regarding the kit, including its components (which may, where required by the technical specifications for the kit, go beyond the requirements laid down in the specification for that component as a single product, even if CE marked).

5.13.2. The kit manufacturer puts a kit on the market, for which he manufactures some components only and buys in other components[44]. In this case, the kit manufacturer is responsible for the FPC of the kit as a whole, including the components which he manufactures (see 5.13.1 above), also as far as

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[43] Usually, such products are outside the scope of hENs and, to be CE marked, require technical specifications in the form of an ETA. When production and FPC are not (fully) running, the demonstration of the conformity of the product shall be mainly done operating control/tests on the final product (final control/test).

[44] to be considered "incoming materials/products"

required by any other technical specification applicable to these components. Furthermore, regarding the component(s) that he buys in, he is responsible, where required by the technical specifications for the kit, for defining any necessary FPC requirement beyond those applicable to them as a single construction product. The following principles apply to the bought in components:

– The kit manufacturer enters into a contract with the component manufacturer, obliging the latter to perform FPC in accordance with the provisions of the technical specification applicable to the kit, to be subjected to third party assessment according to the rules to be applied if required so by the AoC system applicable, and to submit the required FPC records to the kit manufacturer.

– The kit manufacturer purchases one or several components on the open market (CE marked or not) or from a component manufacturer. In this case, the kit manufacturer has to take full responsibility for demonstrating the conformity of the kit as a whole, and all its components, with the technical specification, and, therefore, needs to operate a FPC system ensuring that conformity is maintained, in total. However, since the kit manufacturer, in this case, does not manufacture all kit components, the FPC cannot be entirely based on process control in his premises, so that normally it has to be based on finished product testing. Where this applies, the technical specification will need to include this possibility, and may be different from the FPC requirements for kit manufacturers that manufacture all components themselves[45].

5.13.3. The kit manufacturer uses only bought in components, in which case he is responsible for the FPC of the kit as a whole, and the principles of 5.13.2 apply accordingly for the bought in components.

Note: The guidance regarding kit components applies only to components that play a key role in the performance of the kit as defined in the technical specifications applicable. Technical specifications of the kit should identify which components play such a key role and specify applicable FPC requirements. For those playing a minor role, FPC based on identifying that they comply with the specification given by the manufacturer of the kit will be adequate.

5.14. It can be that the manufacturer of a single construction product or a kit, hereafter called "the basic product", expressly prescribes or requires a specific additional product to be applied for the intended end use (e.g. for fixing or site applied finishing), which plays a key role in the end use performance of the basic product as defined in the technical specifications applicable, but is not part of the basic product, although it constitutes with the latter a "virtual kit", and whose manufacturer does not need to operate a FPC system complying with the provisions of the technical specification for the basic product.

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[45] ISO 3951 and ISO 2859, which define receiving inspection, may form part of such a control process specified in the standard.

In this case, the manufacturer of the basic product should, where relevant, identify any necessary FPC requirement beyond those applicable to this key additional product as a single construction product and ensure himself that this is observed. Furthermore, he may be required to include in his FPC the indications needed to verify whether any potential change in the characteristics of this key additional product risks to reduce the end use performance of the basic product concerned. Where AoC system 1, 1+ or 2+ apply, the specifications for the basic product concerned may include provision to have this appropriately verified under the continuous surveillance of the manufacturer's FPC undertaken by a Notified Body.

Note: Technical specifications of the basic product should identify which additional product(s) play(s) such a key role and specify applicable FPC requirements.

5.15. When drafting FPC clauses, it may be useful to separate them into 'FPC requirements for all manufacturers' (e.g. frequency of FPC testing) and 'Manufacturer-specific FPC system requirements' (e.g. personnel and equipment). Because these latter are manufacturer-specific, it may not be appropriate for the text of the EN to define their details[46].

6. Additional remarks

As far as the responsibilities of a manufacturer, Notified Body and any other body acting in the attestation of conformity systems need to be clarified, information can be found in the *Guide to the implementation of directives based on the New Approach and the Global Approach*, available from the European Commission.

Because of issues such as batch sizes related to sampling (e.g. batches become smaller as they pass through the supply chain), specification writers may add, as an informal part of harmonised technical specifications, an additional clause dealing separately with sampling, testing and compliance criteria beyond those relevant for conformity assessment [47].

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[46] For products subject to ETAs, the details are given in the control plan which is part of the confidential files attached to the ETA., on the basis of the corner stones provided in the ETAG-CUAP

[47] Such clauses could also be helpful for other purposes, including those to which technical specifications do not apply, for instance for market surveillance by public authorities. It may be, for example, that the number of tests needed for market surveillance is significantly smaller than those required for initial type testing and FPC purposes.