

EUROPEAN COMMISSION ENTERPRISE AND INDUSTRY DIRECTORATE-GENERAL

Single Market : regulatory environment, standardisation and New Approach  $\ensuremath{\textbf{Construction}}$ 

December 2004

#### **GUIDANCE PAPER K**

(concerning the Construction Products Directive 89/106/EEC)

#### THE ATTESTATION OF CONFORMITY SYSTEMS AND THE ROLE AND TASKS OF THE NOTIFIED BODIES IN THE FIELD OF THE CONSTRUCTION PRODUCTS DIRECTIVE

#### <u>Preface</u>

Article 20 of the Construction Products Directive (89/106/EC) 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They may be further elaborated, amended or withdrawn by the same procedure leading to their issue

Rue de la Loi 200, B-1049 Bruxelles/Wetstraat 200, B-1049 Brussel - Belgium - Office: SC15; Telephone: Switchboard 299.11.11. Fax: 296.10.65.

#### **GUIDANCE PAPER K**

#### THE ATTESTATION OF CONFORMITY SYSTEMS AND THE ROLE AND TASKS OF THE NOTIFIED BODIES IN THE FIELD OF THE CONSTRUCTION PRODUCTS DIRECTIVE

- This Guidance Paper was originally issued following consultation with the Standing Committee on Construction at the 50th meeting on 5 July 2000, as document CONSTRUCT 00/421.
- It was updated following consultation with the SCC in September 2002.
- It has been revised (in particular addition of Annex 3 concerning specific aspects of the attestation of conformity with regard to performance characteristics determined by calculation) after consultation with the Standing Committee at the 60<sup>th</sup> meeting, on 26 October 2004, as document Construct 04/646.

#### Acronyms used in this Guidance Paper

- 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 in conjunction with 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)
- 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
- GP L: Guidance Paper L issued by the Construction Unit of the European Commission "Application and use of Eurocodes"
- hEN: harmonised European Standard (CPD Chapter II type of "technical specification")
- ITC: Initial Type Calculation
- 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

#### THE ATTESTATION OF CONFORMITY SYSTEMS AND THE ROLE AND TASKS OF THE NOTIFIED BODIES IN THE FIELD OF THE CONSTRUCTION PRODUCTS DIRECTIVE

#### 1. <u>Scope</u>

- 1.1 This Guidance Paper goes into detail on the various attestation of conformity (AoC) systems within the context of the implementation of Council Directive 89/106/EEC (hereafter referred to as the Construction Products Directive or CPD), as amended by Council Directive 93/68/EEC.
- 1.2 It also addresses the relation between the AoC systems and the Notified Bodies. It clarifies the role of the relevant Notified Body/Bodies under the different AoC systems.
- 1.3 The Guidance Paper refers, in particular, to Articles 13 and 18 and to Annex III of the CPD. The full text of these provisions can be found on <a href="http://europa.eu.int/comm/enterprise/construction/index.htm">http://europa.eu.int/comm/enterprise/construction/index.htm</a>.
- 1.4 The Guidance Paper is intended for a number of different audiences, particularly Notified Bodies and Regulators and enforcement authorities within the European Economic Area (EEA). It is also of interest to technical specification writers (CEN/CENELEC and EOTA members), for consideration together with the respective mandates, manufacturers and other users for information purposes.
- 1.5 This document gives information which complements Guidance Paper A<sup>1</sup> because it describes the practical role of the notified bodies. It does not specify the criteria to be used by Member States to examine bodies wishing to be considered for notification (covered by Guidance Paper A).

#### 2. <u>Underlying Principles</u>

- 2.1 The CPD identifies a complete set of attestation of conformity systems including all the actors with their respective roles and tasks. Voluntary European or international standards<sup>2</sup>, or documents produced on a horizontal level<sup>3</sup> for new or global approach directives, describing practices similar to those under the CPD, can be used as a starting point where appropriate but are not obligatory.
- 2.2 This document is limited to aspects relating to CE marking under the Construction Products Directive. Voluntary aspects that might be addressed in the technical specifications are not dealt with.
- 2.3 The producer is <u>fully</u> responsible for the attestation that products are in conformity with the requirements of a technical specification. The involvement of a third party, even to

<sup>&</sup>lt;sup>1</sup> Guidance Paper A: THE DESIGNATION OF NOTIFIED BODIES IN THE FIELD OF THE CONSTRUCTION PRODUCTS DIRECTIVE

<sup>&</sup>lt;sup>2</sup> such as EN 45000 series, EN ISO 17025 or EN ISO 9001

<sup>&</sup>lt;sup>3</sup> CERTIF series, including Guide to the Implementation of Directives based on the New Approach and the Global Approach (2000 edition)

provide an EC certificate of conformity, does not relieve the producer of <u>any</u> of his obligations. However, under the CPD, responsibility for specific actions is given to a third party for all systems of attestation of conformity (AoC) except system 4.

- 2.4 Whether or not there is third party intervention in attestation of conformity, all of the tests and procedures required by the CPD and the technical specifications must be performed and documented correctly. The documentation needs to be available for notifying authorities and surveillance authorities where relevant.
- 2.5 In specifying the systems of AoC it has been recognised that the importance of the part played by a product with respect to the essential requirements will not usually be the same for each ER. Thus, within a given system of AoC certain tests of a product's performance have usually been allocated to the notified bodies and the rest to the producer. Details of this allocation of tests need to be specified in the technical specifications, elaborated on the basis of mandates from the Commission.
- 2.6 In addition, many Commission Decisions relating to the attestation of conformity of construction products are based on a cumulative procedure, in which different systems of AoC are allocated to the various possible intended uses<sup>4</sup> of a product. The type of notified bodies involved, if any, therefore depends upon the range of intended uses that the producer chooses to make his product available for.
- 2.7 The term "Notified Body" is used only for organisations notified under article 18 of the CPD to avoid confusion with the terminology used for organisations designated by member states under article 10 of the CPD (ie EOTA Approval Bodies).

#### 3. <u>Methods of control of conformity</u>

# **3.1** Initial type-testing (ITT) of the product (by the manufacturer or a notified body) applicable to all AoC systems

- (1) An Initial Type test is the complete set of tests or other procedures described in the harmonised technical specification, determining the performance of samples of products representative of the product type.
- (2) An ITT verifies that a product complies with the harmonised technical specification. It defines the performance of all harmonised characteristics to be declared.
- (3) Depending on the limitations of intended uses chosen by, and the specific markets envisaged by the manufacturer, the scope of the ITT could be limited to those applicable to the uses foreseen.
- (4) A product range may cover several versions of the product, provided that the differences between the versions do not affect the level of safety and the other requirements concerning the performance of the product.

<sup>&</sup>lt;sup>4</sup> Intended use is defined in the IDs as referring to the roles(s) that the product is intended to play in the fulfilment of the essential requirements.

- (5) An initial type test (ITT) is not an assessment of the fitness for use of a product. The ITT is rather a determination of the performance of a product, on the basis of tests or other procedures described in the technical specifications.
- (6) The ITT is only one element which determines whether or not a product can be attested to be in conformity with a technical specification. However, the ITT does play a fundamental role under the CPD as it provides the reference for the declared performance of the product.

# **3.2** Audit-testing of samples taken at the factory, on the open market or on a construction site by the manufacturer or an notified body;

- (1) Commission Decisions generally limit audit testing by Notified Bodies, under the attestation of conformity procedures, to the premises of the manufacturer or his authorised representative.
- (2) A proper "audit-test " assumes that:
  - The construction product is tested in accordance with the test methods specified in the technical specification and the initial type test.
  - The test results are compared with the declared performances of the product derived from the initial type test.
  - A test report is delivered, confirming that the findings are in conformity with the technical specifications, the ITT and FPC provisions.

#### **3.3** Factory production control

- (1) In the CPD, factory production control means the permanent internal control of production exercised by the manufacturer. Normally this includes testing by the manufacturer, to assure compliance of the manufactured products with the declared performances of the initial type test.
- (2) Further details on factory production control can be found in Guidance Paper B: "The definition of factory production control in technical specifications for construction products."

## **3.4** Specific aspects of the attestation of conformity with regard to product performances determined by calculation

In some EU countries, building or related regulations stipulate, for certain types of buildings and civil engineering works, in each individual case the structural calculations of the works and/or their parts, or certain other types of calculation, to be verified by engineers approved by the building authorities. This is not a CPD issue and, therefore, this Guidance Paper does not deal with the latter task, but only with the issue of calculation in relation to Attestation of Conformity for CE marked construction products. However, Member State rules relating to the verification of calculations regarding works and/or their parts must provide for this verification taking exclusive account of the declared product performances as stated in the documents accompanying the CE marking. They must not introduce any additional requirements or verification of a

product performance, including for products intended to be used as structural components, other than those defined by the harmonised technical specifications<sup>5</sup>.

- (1) Where feasible, in particular for construction products, which contribute to the mechanical resistance and stability and/or fire resistance of works (structural components and kits), performance characteristics may be determined by calculation (see Guidance Paper L 3.1.2 first dash and 3.3). Such products are distinguished from those products used for structural elements like masonry units, cement, steel reinforcement, etc., for which the performance characteristics are determined by testing (see Guidance Paper L, 3.1, second dash and 3.2).
- (2) The hENs or ETAGs/CUAPs/ETAs need to lay down the methods for determining the performances and to specify all the requirements, including conformity assessment requirements regarding Initial Type Testing (ITT) and Factory Production Control (FPC) in such a way that manufacturers establish and provide the relevant declared performances (values, classes and parameters if relevant) in the information accompanying the CE marking of products (Guidance Paper L 3.3.1).
- (3) Regarding performance characteristics of structural components and kits, for which the performance is established using a calculation method, in particular Eurocodes, the declared performance is obtained by using one of the three methods described in the Guidance Paper L, clause 3.3.
- (4) CE marking and the accompanying documents for such structural products need to provide all of the information necessary to use the product in works, or to integrate the performance characteristics into the structural design of works or parts thereof (see GP L 3.3.1).Related product technical specifications need to require this information relevant for the calculation or the design assumptions of the EN Eurocodes to be part of the information accompanying the CE marking.
- (5) With regard to structural components and kits, as for any other construction product, the technical specifications applicable to the product must provide for the entire conformity assessment to be performed and documented according to the provisions of the Directive (see clause 2.4 above). Therefore, the technical specifications (hENs or ETAs) need to define the tasks linked to the attestation of conformity of the product, also with regard to calculation.
- (6) Since the task of performing conformity assessment by calculation partly requires the availability of proven special technical competence, knowledge and experience in this field, and necessary means and equipment, significantly different from those needed for testing, Member States notifying a body need to indicate, after careful examination, whether conformity assessment by calculation is a task assigned to this approved body (Article 18(3)). They also need to include this availability in their verification according to Annex IV, last paragraph, of the Directive.

<sup>&</sup>lt;sup>5</sup> Including no up-grade of the level of Attestation of Conformity fixed in the relevant Commission Decision.

- (7) Determination of performance by calculation may not give ground to deviate from the procedure of attestation of conformity, as generally provided for.
- (8) Annex 3 is intended to provide to the specification writers for structural components and kits a clarification concerning the specific aspects of the attestation of conformity with regard to performance characteristics which are determined by calculation (see chapter 3.3 of Guidance Paper L). The corresponding requirements should be developed and detailed, when necessary, in the relevant harmonised technical specifications (hENs or ETAs).

Annex 3 deals with attestation of conformity aspects concerning the calculated performance characteristics of structural components and kits relating to essential requirements  $n^{\circ} 1$  (Mechanical resistance and stability), including such aspects of Essential Requirement  $n^{\circ} 4$  (Safety in use, which relate to mechanical resistance and stability) and 2 (Safety in case of fire). It could also be used as reference for products performance characteristics related to other essential requirements (e.g. essential requirements  $n^{\circ} 5$  – acoustic or  $n^{\circ}6$  – thermal performances) which are determined by calculation; however, in this case, the content of this guidance may need to be adjusted to suit specific aspects of the products and the calculation methods concerned.

Annex 3 refers only to the influence of calculations for the determination of product performance characteristics. It does not deal with the influence of manufacturing quality.

#### 4. <u>Systems of conformity attestation</u>

- (1) According to Article 13 of the CPD, the manufacturer, or his authorised representative established in the Community, is responsible for the attestation that products are in conformity with the requirements of a technical specification within the meaning of Article 4. Conformity needs to be established by means of testing and/or other evidence on the basis of the technical specifications in accordance with Annex III where preference is given to the application of two procedures of conformity attestation, namely:
  - (i) Certification of the conformity of the product by an approved certification body...(on the basis of 2 alternative systems)
  - (ii) Declaration of conformity of the product by the manufacturer...(on the basis of four alternative systems)
- (2) The certification body<sup>6</sup> in procedure (i) has to perform conformity assessment of the product, and in procedure (ii), first possibility, has to do the assessment of the capabilities of the manufacturer to assess ITT and FPC outcomes against the product specifications and, when surveillance is required, periodically review this.
- (3) Under procedure (i) and procedure (ii), first possibility, notified bodies (other than the certification body) may work as sub-contractor to the certification body.

<sup>&</sup>lt;sup>6</sup> The involvement of the certification body is not intended to relieve any of the responsibilities for the manufacturer but to reassure the users and the authorities that everything is satisfactory.

- (4) Under procedure (ii) second possibility, the tests to be carried out in respect of any one Essential Requirement are the responsibility of a notified test laboratory (see 4.2.2 (3) below). However, that laboratory may subcontract specific tests to other laboratories.
- (5) To facilitate referencing the various AoC systems in the Commission Decisions on the Attestation of Conformity and in the corresponding mandates, the systems have been given a number. Annex 1 recapitulates this numbering scheme.

# 4.1 Certification of the conformity of the product by a notified certification body on the basis of different tasks for the manufacturer and notified bodies (CPD Annex III.2(i) (Systems 1 and 1+))

- (1) Under systems 1 and 1+, responsibility for the certification of the conformity of the product (on the basis of tasks by the producer and the notified body) is given to a third party.
- (2) It is normal practice that various parties producer, certification body, inspection body, laboratory carry out the individual tasks required to enable product certification to take place. The certification body is responsible for assembling all of the relevant information, verifying that tasks have been carried out according to the technical specification and assessing and certifying the conformity of the product.
- (3) Product certification can therefore be considered to be an umbrella activity, making use of information from various sources. Within this overall scheme, the producer has a significant role to play, including the testing of certain product characteristics as part of an initial type test (see paragraph 3.1 above). The allocation of such tests to the producer needs to be indicated in the technical specifications, elaborated on the basis of the mandates from the Commission.
- (4) Under systems 1 and 1+, responsibility for product sampling for the ITT, in accordance with the rules laid down in the technical specification, lies with the certification body (often delegated to an inspection body), rather than the producer.
- (5) The result of the actions of the notified body under CPD Annex III.2(i) (*Systems 1 and 1+*) is in all cases a product conformity certificate. The only difference between the commonly used terms 'system 1' and 'system 1+' are the methods used by the notified body to assess the product (ie. 1+ includes audit testing).

# 4.2 Declaration of conformity of the product by the manufacturer (CPD Annex III.2(ii))

(1) Under systems 2, 2+, 3 and 4, the responsibility for product sampling for the ITT test, in accordance with the rules laid down in the technical specification, lies with the manufacturer.

# This second system (Annex III of the CPD) distinguishes between three possibilities:

#### 4.1.1 *first possibility (Systems 2 and 2+)*

- (1) The result of the actions of the notified body under this first possibility is in all cases a factory production control certificate. The only difference between the commonly used terms 'system 2' and 'system 2+' are that whereas both 2 and 2+ involve assessment of Factory Production Control, system 2+ also involves surveillance.
- (2) The certification of factory production control (FPC) refers to an evaluation of the permanent internal control of production exercised by the producer (to enable achievement of the required product characteristics to be checked). Thus, both initial inspection and continuous surveillance are general activities relating to a particular production facility, in order to demonstrate that the FPC is in conformity with the requirements of the technical specification and the CPD.
- (3) Given the general character of FPC certification, there is no one-to-one relationship with the individual product characteristics, even if some aspects of a product's performance may warrant particular attention (to be specified in the technical specifications if this is the case). Hence, the allocation of tasks to the notified body or the producer on the basis of individual product characteristics does not have any practical value. The assessment of FPC concerns all of the elements, requirements and provisions adopted by the producer to fulfil his obligations under the CPD.
- (4) Certification of FPC does not involve assessment of the overall conformity of a product with a technical specification this remains the responsibility of the producer.
- 4.1.2 second possibility (system 3)
  - (1) Under system 3, responsibility for the Initial Type Test (ITT) is given to a third party or parties, rather than to the producer. All other responsibilities fall on the producer.
  - (2) The responsibility for sampling of the products to be tested, in accordance with the rules laid down in the technical specification<sup>7</sup> lies with the producer. The producer has a duty to ensure that the samples are representative of the product to be placed on the market and to keep satisfactory records of this (i.e. as part of his factory production control).
  - (3) Having responsibility for the ITT does not necessarily mean that the third party (or parties) has to carry out all of the tests required for a given product type. It is quite normal for the producer to carry out some of the

<sup>&</sup>lt;sup>7</sup> In the absence of sampling rules (and other initial type testing or factory production control details) in the technical specification, the Group of Notified Bodies shall provide appropriate common instructions to producers. These common instructions will be communicated to the SCC for endorsement. Specification writers could use these as basis for future amendments of the specifications.

testing himself. The technical specifications, elaborated on the basis of the mandates from the Commission, will indicate which of the tests on individual product characteristics may be performed by the producer, as opposed to the notified laboratories (reports will always indicate who has performed the test).

- (4) For the tests to be carried out by a third party, the producer may address to one or more notified laboratories, but the tests regarding the same Essential Requirement must be carried out by the same laboratory (i.e. no more than 6 notified laboratories, one per Essential Requirement). This allows highly specialised laboratories (e.g. for fire or acoustical testing) to be notified and brought within the Group of Notified Bodies co-ordination process. The producer needs to inform each notified laboratory of the identity of any other notified laboratories used and to keep appropriate records.
- (5) It is recalled that also any tests carried out by the manufacturer himself (*or the notified bodies*) must be performed and reported in accordance with the technical specification(s). The test reports need to make reference to the sample identities referred to above.
- (6) The complete ITT Report, assembled by the producer, needs to include all of the test reports from the notified laboratories and the producer. Any notified laboratory involved in the ITT may request to examine the full ITT Report, in order to satisfy himself that all of the sample identities correspond with those provided to it for testing. If they are not from the same batch, identification testing needs to allow the results to be compared with the other parts of the testing<sup>8</sup>.

#### 4.1.3 third possibility (system 4)

(1) No compulsory intervention of a third party in attestation of conformity. This does not, of course, prevent producers from having the necessary tests done by outside laboratories if they so choose (e.g. if they lack the facilities or expertise to carry out the tests and procedures themselves).

#### 5. <u>Notified bodies involved in the Attestation of Conformity</u>

- (1) Currently, different attestation and market surveillance systems are operational in the Member States. Many of the 'third parties' involved in these schemes will become Notified Bodies under article 18 of the Construction Products Directive. In each national system, a certain terminology is used for these bodies.
- (2) Many Commission Decisions relating to the attestation of conformity of construction products are based on a cumulative procedure, in which different systems of AoC are allocated to the various possible intended uses (see footnote <sup>4</sup>) of a product. The type of notified body involved, if any, therefore depends upon

<sup>&</sup>lt;sup>8</sup> This to allow the use of test results from different times during the development of new products

the range of intended uses that the producer chooses to make his product available for.

- (3) It is not relevant to compare the role and tasks of the types of Notified Bodies under the CPD with existing terminology or practices in Member States as the functions of the latter are not necessarily equal to traditions under national systems.
- (4) The Notified Bodies for one and the same product(s) or product characteristic (or type of test) need to regularly exchange their experience and the information necessary to perform their tasks in a way that the procedures are consistent and transparent and that the results are reproducible. This exchange should take place in the respective Sector Group of the Group of Notified Bodies (GNB). Matters of general interest should be put forward to the Advisory Group of the GNB.

#### 5.1 Task sharing (subcontracting)

- (1) For various reasons Notified Bodies can appoint subcontractors that perform tasks on their behalf. Annex 2 details the different types of Notified Bodies as defined in Annex III of the CPD and their roles under the various AoC systems. In many cases, Notified Bodies look for subcontractors to solve isolated problems (lack of capacity in their own laboratories, inspections in a plant across the border...).
- (2) A subcontracting notified body remains responsible for all the activities covered by the notification. Subcontracting does not entail the delegation of powers or responsibilities. Certificates and reports are always issued in the name and under the responsibility of the subcontracting notified body but will indicate who has performed the actual tasks. Serial subcontracting is prohibited in order to avoid undermining the coherence of the system and the confidence in it.
- (3) A notified body can subcontract strictly limited technical tasks (e.g. tests, factory production control audits), as long as these can be defined as substantial and coherent parts of the technical operation.

Two mechanisms for subcontracting can be identified.

#### On basis of a long-term contract:

- (1) Subcontracting is permissible where a body, applying for notification, identifies clearly its sub-contractors and the role these are going to play in the attestation of conformity system.
- (2) This kind of subcontractor does not need notification but should demonstrate to the respective Member State technical competence and impartiality by fulfilling the requirements of annex IV of the CPD for the tasks that are contracted to them.
- (3) The Notified Body needs in all cases to have a direct private-law contractual link with its sub-contractors to ensure the fulfilling of its general responsibilities.

(4) This mechanism provides an answer where notified bodies seek solutions to enable them to give a complete service to Industry. Council Decision 93/465/EC<sup>9</sup> defines a number of conditions on sub-contracting.

Adapting this to the specific case of the CPD this means that the subcontracting of work needs to be subject to certain conditions guaranteeing:

- the competence of the establishment operating as a sub-contractor, on the basis of conformity with the requirements of Annex IV of the CPD, Guidance paper A and the respective harmonised technical specification, and the capability of the Member State that has notified the sub-contracting body to ensure effective monitoring of such compliance
- the ability of the body notified to exercise effective responsibility for the work carried out under sub-contract.

#### Subcontracting to other Notified Bodies

- (1) To perform tasks, Notified Bodies can make use of the services of other Notified Bodies notified in the relevant area. The certificates or reports produced must clearly indicate who has performed a particular task. The overall responsibility remains with the sub-contracting Notified Body.
- (2) This second type of sub-contracting assures transparency by public knowledge of the assessment of all the bodies involved by the respective Member State, involves all actors in the European co-ordination within the GNB and offers more possibilities to Industry.

#### 6. <u>Sample marking and Reporting</u>

#### 6.1 Marking of samples

- (1) All samples to be used for testing purposes need to be suitably marked to allow a subsequent verification that the producer has fulfilled his obligations. This demonstrates that the manufacturer has followed the rules in the harmonised EN or ETA, that all tests have been carried out on the same batch of samples, if this is specified, and that the samples are representative for the product to be placed on the market.
- (2) Sample-marking on the product will at least include production line, date and time of the taking of the sample. The sample identity needs to be recorded in all test reports to enhance trace ability.
- (3) Products declared by the manufacturer to be defective may only be excluded from sampling if they have been set aside and marked accordingly.

<sup>&</sup>lt;sup>9</sup> Council decision 93/465/EC concerning the modules for the various phases of the conformity assessment procedures and the rules for affixing and use of the CE conformity marking, which are intended to be used in the technical harmonisation directives.

- (4) In the case of sampling by a Notified Body, the sampler needs to prepare and sign a record on sampling that needs to be countersigned by the manufacturer or his representative (when relevant). The record should at least include the following information:
  - Manufacturer and manufacturing plant
  - Place of sampling
  - If necessary, stock or batch quantity (from which the samples have been taken)
  - Number or quantity of samples
  - Identification of the construction product in accordance with the technical specification
  - Marking of the product by the manufacturer
  - Marking of the samples by the sampler (when relevant)
  - Where necessary, properties to be tested
  - Place and date
  - Signatures
  - Registration number of the Notified Body

#### 6.2 Test Reports

- (1) The results of each test, independent of whether this test is part of the initial type test or audit testing by the manufacturer or a third party, need to be recorded in a *"test report"*. The test report should at least include the following information:
  - Manufacturer and manufacturing plant
  - Identification of the construction product in accordance with the relevant technical specification
  - Information about
    - sampling
    - date of testing
    - involved personnel
    - applied testing methods according the relevant technical specification
  - Identification of the organisation and personnel executing the test
  - Place and date
  - The results of the test, including analysis of these when relevant.
  - Place and date of the delivery of the test report
  - Registration number of the Notified Body (when relevant)
  - Signature of the head of the testing laboratory and stamp (when relevant).

The test report must comply with the relevant clauses of the technical specifications. The complete set of test reports will be kept by the manufacturer and

the certification body (when relevant) and will be made available to the inspection body (where relevant) and market surveillance authorities on demand.

Test laboratories will keep the test reports that they have issued.

#### 6.3 Note

Where possible, model reports and other model documentation should be developed by the specification writers and should be included in the technical specifications.

As an interim solution and to avoid extra work for the specification writers, the test reports may need to appear as separate documents developed by the relevant sector groups and/or the Advisory Group of the Group of Notified Bodies. Suitable common presentation should be assured by close collaboration between specification writers and the GNB.

#### 7. <u>References</u>

Construction Products Directive.

CONSTRUCT 99/345 REV.3: Third party intervention in AoC

CONSTRUCT 99/342: Discussion paper on the notification of bodies by Member States and the relation with sub-contracting of tasks by Notified Bodies

- Guidance paper A: The Designation of Notified Bodies in the field of the Construction Products Directive.
- Guidance Paper B: The definition of Factory Production Control in technical specifications for construction products.

Guidance Paper D: CE marking under the construction products directive

Guidance Paper L: Application and use of Eurocodes

Guide to the implementation of Directives based on the New Approach and the Global Approach.

-----

#### Annex 1: Attestation of Conformity Systems.

System	Task for manufacturer	Task for notified body	Basis for CE marking
4	Initial type testing of product Factory production control		
3	Factory production control	Initial type of testing of product	Manufacturers conformity Declaration
2	Initial type of testing of product Factory production control	Certification of factory production control on basis of initial inspection	Manufacturers conformity Declaration +
2+	Initial type testing of product Factory production control Testing of samples according prescribed test plan	Certification of factory production control on basis of initial inspection continuous surveillance, assessment and approval of production control	certification of factory production control
1	factory production control Further testing of samples according prescribed test plan	Certification of product conformity on basis of tasks of the notified body and the tasks assigned to the manufacturer	
		Tasks for notified body: initial type-testing of the product; initial inspection of factory and of factory production control; continuous surveillance, assessment and approval of factory production control;	Manufacturers Conformity <sup>10</sup> Declaration accompanied by Certificate of product conformity
1+	Factory production control Further testing of samples according prescribed test plan	Certification of product conformity on basis of tasks of the notified body and the tasks assigned to the manufacturer Tasks for notified body: initial type-testing of the product; initial inspection of factory and of factory production control; continuous surveillance, assessment and approval of factory production control;	
		audit-testing of samples taken at the factory, on the market or on the construction site	

<sup>&</sup>lt;sup>10</sup> A declaration of conformity is always required (see Guidance paper D).

#### Annex 2

Text extract from CPD Annex III	Tasks	Attestation systems			stems	Certification		
Preference is given to application of the following systems of co attestation	onformity	1+	1	2+	2	3	4	required
<ul><li>(i) Certification of the conformity of the product by an notif of:</li></ul>	fied cert	ifica	tion	body	' on	the L	asis	
(a) (tasks for the manufacturer)								
(1) factory production control;	1	М	М					
(2) further testing of samples taken at the factory by the manufacturer in accordance with a prescribed test plan;	2	М	Μ					
(b) (tasks for the notified body)								
(3) initial type-testing of the product;	3	А	А					СР
(4) initial inspection of factory and of factory production control;	4	A	A					CP
(5) continuous surveillance, assessment and approval of factory production control;	5	A	A					CP
(6) audit-testing of samples taken at the factory , on the open market or on a construction site	6	А						СР
First possibility:								
(a) (tasks for the manufacturer)								
(1) initial type-testing of the product;	7			м	М			
(2) factory production control;	8			М	М			-
(3) testing of samples taken at the factory in accordance with a prescribed test plan (*);	9			М				
(b) (tasks for the notified body)								
(4) certification of factory production control on the basis of:								
initial inspection of factory and of factory production control,	10			А	A			CF
continuous surveillance, assessment and approval of factory production control.	11			A				CF
Second possibility:								
<ol> <li>initial type-testing of the product by an notified laboratory;</li> </ol>	12					L		Report onl by L
(2) factory production control	13					м		
Third possibility:							N.4	
Third possibility: (a) initial type-testing by the manufacturer;	14						Μ	

CP -certification body required for certification of the conformity of the product CF - certification body required for certification of the factory production control A - certification body or, when acting on behalf of a certification body, an inspection body and/or testing laboratory. L - testing laboratory M – manufacturer

(\*) when required

Table 2: Bodies involved in Attestation of Conformity and their functions										
Text extract from CPD Annex III	Tasks		Attestation systems							
BODIES INVOLVED IN THE ATTESTATION OF CONFORMITY		1	1+	2	2+	3	4			
With respect to the function of the bodies involved in the attestation of conformity, distinction needs to be made between										
<ul> <li>(i) certification body, which means an impartial body, governmental or non-governmental, possessing the necessary competence and responsibility to carry out product conformity certification or FPC certification according to given rules of procedure and management;</li> </ul>	3 to 6, 10 and 11	Y	Y	Y	Y					
(ii) inspection body, which means an impartial body having the organization, staffing, competence and integrity to perform according to specified criteria functions such as assessing, recommending for acceptance and subsequent audit of manufacturers' factory production control system		S	S	S	S					
(iii) testing laboratory, which means a laboratory which measures,examines,tests,calibrates or otherwise determines the characteristics or performance of materials or products.	3, 6 and 12	S	S			Y				
In case (i) and (ii) (first possibility) of paragraph 2, the three functions 3 (i) to (iii) may be performed by one and the same body or by different bodies, in which case the inspection body and/or the testing laboratory involved in the attestation of conformity carries out its function on behalf of the certification body.	Note: Inspection Bodies and Testing Laboratories can undertake the tasks but under systems 1, 1+, 2 and 2+ they do so on behalf of the certification body.									
KEY: Y - Body is involved in these tasks or in certification based on them. s - Body can undertake these tasks on behalf of a certification body.										

#### ANNEX 3

Specific aspects of attestation of conformity with regard to product performance characteristics determined by structural calculation.<sup>11</sup>

#### 1. Calculation results accompanying CE marking of structural components and kits

- (1) Regarding the performance characteristics relating to the essential requirements  $N^{\circ}$  1 (including such aspects of essential requirement  $N^{\circ}$  4 which relate to mechanical resistance and stability) and aspects of essential requirement  $N^{\circ}$  2 (resistance to fire) of the product, the manufacturer needs to provide, in accordance with the provisions of hEN/ETA, the declared performance(s) or values in the information accompanying the CE marking according to one of the following methods detailed in the Guidance Paper L, clause 3.3:
  - <u>Method 1</u>, which is as follows:

The "declared information" consists of geometrical data of the component and / or kits and of properties of the materials and constituent products used (see Guidance paper L – clause 3.3.2)

What geometrical data and properties of material and constituent products are necessary to perform calculations of works and/or parts of them is listed in the product hEN or ETAG/CUAP/ETA. Related product information provided in the information accompanying the CE marking.

The calculation method of the structural characteristics is not relevant for the CE marking. The information accompanying the CE marking does not include performance characteristics based on calculation results. Instead, design calculations for specific works or parts of them, which are based on the information accompanying the CE marking, comply with the procedures implemented by the Member States in which the work is to be erected. They are performed by those who are entitled to do so, under these procedures.

– <u>Method 2</u>, which is as follows:

The mechanical resistance of the components or kits is determined by means of the calculation methods (e.g. Eurocodes) laid down in the hEN or ETAG/CUAP/ETA. The results are expressed as characteristic values or design values<sup>12</sup>, and the information accompanying the CE marking includes all relevant parameters (e.g. characteristics of material and constituent products, partial factors) used to perform the calculation (see Guidance Paper L, 3.3.3).

The calculation method to obtain the structural performance characteristics and the results or the calculation is of relevance for the CE marking.

<sup>&</sup>lt;sup>11</sup> This Annex could also be used as reference for products performance characteristics related to other essential requirements (e.g. essential requirements  $n^{\circ} 5$  – acoustic or  $n^{\circ}6$  – thermal performances) which are determined by calculation; however, in this case, the content of this guidance may need to be adjusted to suit specific aspects of the products and the calculation methods concerned.

<sup>&</sup>lt;sup>12</sup> Characteristic and design values are defined in the Eurocodes.

- <u>Method 3</u>, which is as follows:

The declared information is presented by reference to design documents of the works or client's order (see Guidance Paper L, 3.3.4), regardless whether the harmonised technical specification prescribes a calculation method to be used or not.

The manufacturer decides whether or not to accompany the CE marking with information regarding the product performance characteristics, by reference to the respective design documents (which may be based on harmonised calculation methods, i.e. Eurocodes, applied by the designer of the works or the product manufacturer, as agreed between the client and the manufacturer). If he does so, he is also responsible and liable for the performance of the product with regard to its design, which might mean that he ensures a verification of the design if he has doubts about its correctness. If he does not, the responsibility regarding the design of the product needs to be determined in the contract between the manufacturer and the one who orders the manufacturing of the product (the user or the designer, according to the given contractual relation) and/or, if relevant, according to the national legal requirements applicable.

- (2) The decision to include one, two, or all these three methods in technical specification, is up to the specification or ETAG/CUAP writers. Nevertheless, they may exclude a method, if this is duly justified for technical reasons. The conditions to be applied for anyone of these methods need to be specified in the product hEN or ETAG/CUAP.
- (3) This annex considers "initial type calculation" (ITC) as being performed on representative types of the product and part of the ITT (i.e. the product performance characteristics is determined by calculation and not by testing), while calculation performed on individual manufactured product may be part of the factory production control in analogy to "testing of samples taken at the factory" included in the Annex III of the CPD as a control method for AoC systems 1+, 1 and, where relevant, 2+.
- (4) The product hEN or ETAG/CUAP should indicate which parts of calculations and input data have to be verified in the framework of the conformity assessment, and by whom, and in which cases it is necessary to be done for individual manufactured products.

#### 2. Principles

- (5) Within the systems of attestation of conformity referred to in Annex III of the CPD, for the "initial type testing" (ITT) of the product, calculations are to be considered as a part of the ITT. ITC can usually be performed for a product range<sup>13</sup>. However, where applicable, the product hEN or ETAG/CUAP should define small series production, for which ITC should be limited to the demonstration of the manufacturer's ability to perform the calculations specified in the harmonised technical specifications and his ability to take into account parameters that may change with new (small) series.
- (6) Similarly, calculation might be part of "audit testing" in system 1+, although in many cases, performing new calculations by Notified Bodies should only be considered if

<sup>&</sup>lt;sup>13</sup> 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

technically relevant, i.e. in case calculation methods, instruments or procedures changed since ITC.

- (7) Document procedures regarding calculation should also be covered in the manufacturer's FPC system, similar to the provisions that apply when performances are determined by testing.
- (8) The performance characteristics of products may be determined by calculation or testing. Both methods have the same status (see Guidance Paper L, clause 3.1.2). Therefore, calculation methods have to be considered as supporting tools (e.g. Eurocodes have to be considered as supporting standards) when they are referred to in harmonised technical specifications.

# **3.** Specific tasks to be carried out according to the applicable system of Attestation of Conformity

#### 3.1 Certification of conformity of the product (CPD III.2(i) - AoC systems 1 and 1+)

(9) Under the system of attestation of conformity 1 and 1+ of attestation of conformity, the responsibility for the Initial Type Testing, including ITC, lies with the Notified Body.

# 3.1.1 Methods 1 and 3 (when the calculation method is not covered by the harmonised technical specification):

- (10) Regarding ITT, the Notified Body is responsible, in addition to performing tests, for verifying that the manufacturer has used correct methods and procedures for the determination of geometrical data of the product, and of the properties of the materials and constituent products used, including sampling (where relevant) in accordance with the provisions of the hEN or ETAG/CUAP..
- (11) Regarding the initial inspection of the factory and of FPC and continuous surveillance, assessment and approval of FPC, the Notified Body evaluates the permanent internal control of production exercised by the producer.
- (12) Regarding audit verification by/of calculation in place of audit testing (only system 1+), the Notified body is responsible for regular determination of geometrical data of the product, and of the properties of the materials and constituent products used, including sampling (where relevant).

# 3.1.2 Methods 2 and 3 (when the calculation method is covered by the harmonised technical specification):

(13) The Notified Body is responsible for the ITC according to the method given in the hEN or ETAG/CUAP. It checks and validates the calculation (tools and results) used by the manufacturer to design the product, by any appropriate means included in the hEN or ETAG/CUAP, judging and, if deemed appropriate, performing independent calculations for validation (see footnote <sup>14</sup>, next page)and issuing the CE certificate of conformity. The Notified Body must be qualified for structural calculations by using the methods laid down in the technical specification and/or may be assisted by somebody who is so, provided that it maintains responsibility and liability for this task.

In more detail, regarding ITT and, in particular Initial Type Calculation (ITC), the Notified Body:

- (a) Is responsible for the determination of geometrical data of the product, and of the properties of the materials and constituent products used, including sampling (where relevant). This provides input data for the calculations;
- (b) Verifies that the calculation method used to determine the declared performances of mechanical properties for a product range complies with the requirements given in the hEN or ETAG/CUAP;
- (c) Validates the input data used for the calculations (material and constituent product properties, applied partial factors, etc.) and, where relevant, that it has been processed with the correct tools (e.g. correct computer software);
- (d) Endorses, by means of validation<sup>14</sup>, the results of the ITC;
- (e) Provides an ITC report in accordance with item 6.2 of this Guidance Paper, so that the certificate of conformity of the product can relate to the ITC report, which is a part of the ITT report.
- (14) Regarding the initial inspection of the factory and of FPC and continuous surveillance, assessment and approval of FPC, the tasks of the Notified Body are those carried out under system 2 or 2+ (see § 3.2 below), notwithstanding (13) and (15).
- (15) Regarding audit verification by/of calculation in place of audit testing (only system 1+), the Notified body:
  - (a) Is responsible for regular determination of geometrical data of the product, and of the properties of the materials and constituent products, including sampling (where relevant). This provides input data for the calculations;
  - (b) Verifies that the calculation method, applied to determine the declared mechanical performances, by type of product, continues to comply with the requirements of the hEN or ETAG/CUAP. This is of particular relevance in case the calculation method referred to or the calculation instrument or procedures change, and might be not necessary in other cases;
  - (c) Checks the constant compliance of input data for calculations (material and constituent product properties, assumed actions, partial factors) and, where relevant, of tools (e.g. computer software) to process them;
  - (d) Provides an audit report.

# **3.2** Declaration of conformity of the product (CPD III.2(ii) first possibility - AoC systems 2 and 2+).

<sup>&</sup>lt;sup>14</sup> Taking into consideration manufacturers' wishes resulting from those of stakeholders on a given market, or according to an identified need, a Notified Body may perform itself a complete calculation or verification by partial calculation or needs to do so.

(16) Under the systems of attestation of conformity 2 and 2+, the responsibility for Initial Type Testing, including the ITC, lies with the manufacturer. The Notified Body does not validate the related calculation.

# 3.2.1 Methods 1 and 3 (when the calculation method is not covered by the harmonised technical specification):

- (17) Regarding ITT, the manufacturer is responsible, for the methods and procedures used for the determination of geometrical data of the product and of the properties of the materials and constituent products, including sampling, and their indication as information accompanying the CE marking, in accordance with the provisions of the technical specification (hEN or ETA).
- (18) Regarding initial inspection of the factory and of FPC (AoC system 2 and 2+) and continuous surveillance, assessment and approval of FPC (only AoC system 2+), the Notified Body evaluates the permanent internal control of production exercised by the producer, in particular with regard to documented procedures for the selection of representative samples according to the provisions of the hEN or ETAG/CUAP and the determination of product and material properties necessary as input for calculations. He checks whether the conditions of manufacturing the product allow the indications made by the manufacturer as information accompanying the CE marking to comply with the provisions of the technical specification.

# 3.2.2 Methods 2 and 3 (when the calculation method is covered by the harmonised technical specification):

- (19) The Notified Body is only responsible for certifying that Factory Production Control complies with the requirements laid down in the product hEN or governing the ETA, on the basis of an initial inspection of the factory and factory production control and, in the case of system 2+, continuous surveillance, assessment and approval of the factory production control. Part of the initial inspection of the factory is also to verify that the manufacturer has undertaken an initial type calculation in accordance with the provisions of the hEN or ETAG/CUAP.
- (20) Regarding ITT and related sampling, including the necessary ITC for the product range (as defined in hEN or ETA) and the determination of the input data for calculations (material and constituent product properties, partial factors, etc.), are under the responsibility of the manufacturer.
- (21) Regarding the initial inspection of factory and of the Factory Production Control, the Notified Body evaluates whether the production system enables the achievement of the required product characteristics and the effective operation of FPC. In addition to checking whether the ITC has been performed and whether the method and the calculation process are documented<sup>15</sup>, when the FPC includes calculation of the mechanical properties for the manufactured products (samples), the Notified body verifies that the manufacturer established, uses and maintains a documented FPC system in accordance with the product hEN or ETAG/CUAP ensuring:

<sup>&</sup>lt;sup>15</sup> see Guidance Paper K, clause 2.4

- (a) the correct selection of representative samples;
- (b) for the various products manufactured, the correct determination of product and material properties necessary as input for calculations, for the individual products;
- (c) adequate equipment and competent personnel to perform correct calculations;
- (d) that the calculation has been performed, that its basis (e.g. safety factors used) is correct, and that the method, process and results used as a basis for performance declarations are adequately documented and registered;
- (e) that, in the case of electronic processing and reporting, only sufficiently documented and validated software and properly functioning computer equipment are used, and adequate measures of data protection and integrity are in place.
- (22) Regarding the continuous surveillance, assessment and approval of FPC (only system 2+) the tasks of the Notified Body are, with an appropriate frequency as specified in the product hEN or ETAG/CUAP, to verify that the documentation regarding the calculation method is still valid (regardless whether modified or not) and to check the continued use and maintenance of a documented FPC system in accordance with the product hEN or ETAG/CUAP ensuring (a) to (e) as listed in (21).
- 3.3. Declaration of conformity of the product, (CPD III.2(ii) second possibility AoC system 3)

# 3.3.1 Methods 1 and 3 (when the calculation method is not covered by the harmonised technical specification):

(23) Regarding ITT, the Notified Body is responsible for the determination of geometrical data of the product and of the properties of the materials and constituent products used to manufacture the product. The manufacturer is responsible for sampling (if relevant).

## 3.3.2 Methods 2 and 3 (when the calculation method is covered by the harmonised technical specification):

- (24) Regarding ITT, the Notified Body:
  - (a) Is responsible for the determination of geometrical data of the product and of the properties of the materials and constituent products used. This provides input data for the calculations;
  - (b) Verifies that the calculation method, applied to determine the declared performances of mechanical strength for a product range complies with the requirements given in the hEN or ETAG/CUAP;
  - (c) Validates the input data for calculations (material and constituent product properties, partial factors for materials applied in resistance calculation) and, where relevant, that it has been processed with the correct tools (e.g. correct computer software);

- (d) Validates for endorsement<sup>16</sup> the results of the Initial Type Calculation;
- (e) Provides an ITC report in accordance with item 6.2 of this Guidance Paper, so that the certificate of conformity of the product can relate to the ITC report, which is a part of the ITT report.

#### 3.4. Declaration of conformity of the product, (CPD III.2(ii) third possibility - AoC system 4)

- (25) Under AoC system 4, no compulsory intervention of a third party in attestation of conformity is required. This does not prevent producers from outsourcing the necessary calculations if they so choose (e.g. if they lack the facilities or expertise to carry out the calculations themselves). Therefore:
  - (a) The ITT, including the Initial Type Calculation, is the task of the manufacturer.
  - (b) Structural calculations for the individual products manufactured on the basis of the ITC, used for the evaluation of performances (declared values and classes accompanying the CE marking) are part of the Factory Production Control.

# 4. Specific aspects of control of conformity with technical specifications developed in European Technical Approvals (ETAs)

- (26) In the case of an ETA, with or without guideline, the Approval Body will usually have validated the calculation method to be used, by using it directly to determine the product characteristics when it undertakes the tasks to issue the ETA itself. Then, the role of the Notified Body is restricted to assess, depending on the AoC system involved, the conformity of the product and / or production with what has been specified in the ETA, but it does not need to validate the calculation method used.
- (27) In cases, where the manufacturer presents to the Approval Body a large range of products, the Approval Body might include in the ETA itself the calculation method it judges suitable, allowing the manufacturer to calculate himself product performances for the entire product range. In this case the Approval Body already validates the calculation method and the conditions under which it should be used, by introducing it in the ETA. The role of the Notified Body is then limited to verifying that the manufacturer uses the calculation method as indicated for determining the relevant product performance, but does not need to validate the calculation method as such.

<sup>16</sup> The Notified Body may also perform itself, if he wishes, independent partial or complete calculations.