GNB-CPD

AG

Guidance from the Group of Notified Bodies for the Construction Products Directive 89/106/EEC

NB-CPD/AG/07/008r1

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APPROVED – GUIDANCE

GNB-CPD position paper

Guidance to NBs on their duties in certifying (system 1+, 1, 2+ and 2) suppliers' own brand labelled products and those involving significant subcontract manufacturing

General scope, limitations and aim of this guidance for notified bodies

This position paper contains guidance for Notified Bodies (NBs) involved in certifying the attestation of conformity of own brand labelled products and those involving significant subcontract manufacturing. The purpose is to help NBs work equivalently and come to common judgments. This guidance contains informative material (which NBs should or may follow) and/or normative guidance (which NBs shall follow or at least work equivalently to as circumstances demand).

This guidance is thought necessary to provide clarity and completeness for NBs so that they can work equivalently. It **supplements and makes practical for NBs** the relevant harmonized technical specifications, and Standing Committee guidance in the form of GPs, which also apply unless otherwise explicitly stated in this guidance. This position paper should **not** contradict nor extend the scope of the work and role of a NB, nor impose additional burdens on the manufacturer, beyond those laid down in the CPD and the relevant technical specifications.

This guidance should be considered valid until the relevant technical specifications are amended to include the guidance; or until guidance from the Commission or SCC has changed on relevant matters. Whereupon, the paper should be considered for withdrawal/revision and be replaced by new guidance as necessary.

This position paper was considered approved in its original form by Advisory Group on 27 July 2007 and in its revised form on 6 October 2009.

This position paper was revised to remove the requirement for the certificate to bear a reference to the document explaining coded references to factories, if these are used. This is an issue applicable to all GNB-CPD certificates, not only those addressed by this paper.

1 Background

This guidance has been developed in the light of the CPD and official guidance (ie Commission Guidance Papers (GPs) and the Blue Guide¹), as well as GNB discussions of the matter, to make

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The Guide to the implementation of directives based on the New Approach and the Global Approach – available from Europa website: http://ec.europa.eu/enterprise/newapproach/legislation/guide/index.htm

practical the work of NBs for CE marking products that are made partly or entirely by one organization and placed on the market by another. It does not imply that SCC or all MSs endorse the view that organizations who subcontract some, most or all of the manufacture of a product to others are approved to CE mark. Until the GNB-CPD is informed otherwise, it should not require its members to repeat work to no end, and NBs should not obstruct those wishing to CE mark products that are made partly or entirely by others by refusing to certify, but make it practical:

- without compromising the integrity of the work of the NBs and CE marking;
- by working equivalently, and;
- by adopting procedures to minimise the costs to all proportionate to the likely risks involved.

Before CE marking became possible it was common practice in most countries for many years for those placing construction products on the market for the first time to comply with national regulations in national ways to address the situation where:

- they subcontract part or all of the manufacture of a product to other organization(s) and brand it as their own and take legal responsibility for its conformity with regulations and specifications (national standards etc), and;
- the *identical* ² product is also placed on the market by others under their own brand, ie all the products are made to the same design and manufactured on the same line(s), under the same FPC and to the same specification.

This is one extreme end of the common situation where key manufacturing stages are subcontracted to others or bought-in.

These situations are not addressed clearly or directly in the CPD, and are only partly addressed in Commission GPs ie GP 'M' §4.13 (cascading and sharing of test reports by manufacturers) and the FPC of kits where components are bought in ie GP 'M' §5.13 & §5.14. GP 'M' (or the CPD) does not explicitly address subcontracted manufacture and the sharing of the **work** a NB does for certification between parties in the manufacturing process and the certification of those wishing to CE mark the products. Without further guidance from the SCC or the Commission, the role of the NB is taken to be to certify for the organization that is placing the product on the market that the actual manufacturing process (FPC) of the product or the product itself is in conformity with the harmonised technical specification (subject to SCC and GNB-CPD guidance) – whether the organization placing the product on the market is actually manufacturing the product itself or subcontracts part or all of the product manufacture.

This guidance:

- does <u>not</u> permit the actual sharing/cascading of certificates themselves, but requires each organization placing the product on the market for the first time to have a certificate in its own name see §4.
- **does encourage** the **work** the NB does to be easily shared between manufacturers (ie organizations placing *identical* ² products on the market) to reduce costs in an open and transparent manner between the manufacturers concerned, see §5 where the manufacturers wish to share the work of a NB.
- seeks to maintain the credibility of CE marking and the certificates of the NBs by requiring all the places of actual manufacture covered by the scope of the harmonised technical specification and hence NB certificate to be covered by one or more NBs see §6

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The products are manufactured to the same design, on the same production line(s), have the same FPC system and are assessed against the same harmonised technical specification.

and §7, and if necessary the storage and distribution of products susceptible to deterioration before selling – see §8.

NOTE The terminology used to discuss these matters can lead to confusion. This paper follows the "Blue Guide" in using the term "manufacturer" for the organization that places a product on the market, although normal English usage associates a manufacturer with the making of a product. The CPD does not separate the functions of making products and placing them on the market.

The role of the NB is to certify for the organization that is placing the product on the market that the actual manufacturing process (FPC) of the product or the product itself is in conformity with the CPD and the harmonised technical specification

The CPD does not separate the functions of making products and placing them on the market. The role of the NB is to certify that the actual manufacturing process (FPC) of the product, or the product itself, is in conformity with the harmonized specification (subject to SCC and GNB-CPD guidance) – whether the organization placing the product on the market is actually manufacturing the product in its own factory(s) or not.

Hence, the NB's certificate shall show:

- The details for < NAME OF THE PRODUCER (OR ITS AUTHORISED REPRESENTATIVE) > and < FULL ADDRESS > as those of the manufacturer/organization that intends to first place the product on the market whether the organization placing the product on the market is actually manufacturing the product itself or not.
- The < FACTORY > details shall be the details of the site(s) visited by the NB including those of subcontractor(s) who have a significant role in the FPC as required by the harmonised technical specification – see §6 below.

NOTE While GP 'D' §5.4 requires the place of production of the product to be identified for reasons of traceability, it states that this may be in a coded format. (These factory details may identify particular production units, lines or facilities).

3 NBs shall have a contract with each organization that they certify

For each certificate a legal contract shall be in place between the NB and each organization it certifies or issues an inspection report for the full product. Where some of the NB's work is shared between two or more manufacturers marketing identical products, then the NB shall have a separate contract with each manufacturer.

NOTE It is not permissible that a NB effectively issues one certificate to one manufacturer for that manufacturer to provide to others, entitling them to CE mark their identical products. The NB shall have individual contracts with each manufacturer for whom it provides a certificate or inspection report for the full product, even though the costs can be shared between the manufacturers issued with certificates and/or inspection reports – see §5.

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4 The unique certificate number of the NB shall cover only one organization

NBs shall ensure there is only one legal entity as "producer" or manufacturer on its certificates ie each "producer" or manufacturer has their own certificate with a unique number³.

Hence the name and address (or the identifying mark) of the manufacturer (ie the organization that is legally first placing the product on the market) and the certificate number of the NB in the information accompanying CE are uniquely linked and directly relate to the unique certificate number, < NAME OF THE PRODUCER (OR ITS AUTHORISED REPRESENTATIVE) > and < FULL ADDRESS > on the certificate of the NB.

When a NB's work on a product is shared between more than one certificate, the NB's clients should be aware the work is not exclusively for them

NBs should accommodate requests by clients to share work for CE marking purposes for *identical* ² products to reduce overall costs - without compromising the credibility of the CE marking process.

There are confidentiality obligations on NBs, but if work carried out for a particular type of certificate or notifiable task (other than testing⁴) is shared between clients marketing different branded versions of *identical* ² products, all clients for the shared work shall be informed that the work is not exclusively for them.

Provided that the NB informs all clients for the shared work that the work is shared, the client (or possibly group of clients) that commissions particular elements of the work, and owns any original reports resulting from the work, shall determine which details, such as costs of the work, numbers or names of organizations involved, shall be passed on to other clients that have been granted permission to use the reports.

If clients do not wish other clients to be aware that work is shared, they shall be treated as separate clients, the work undertaken for them shall not be shared, and they shall not benefit from the work shared between other clients.

To accommodate their clients' wishes a NB may:

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³ This is not explicit in the CPD, GPs or current GNB guidance; but it is a consequence of:

GP 'D' §5.4 regarding the EC Certificate and Declaration of conformity:
... the information provided ... should be identical to that accompanying the CE marking (see GP 'D' §3.3), except in the case of where the manufacturer has expressly designated a legal entity to act on his behalf within the EEA (his authorised representative).'

[•] *GP 'D'* §3.3 regarding the need '... to identify the legal entity responsible for the manufacture of the product.'

[•] to ensure transparency and traceability requirements for products (GP 'D' §3.3 & 3.5, GP 'B' §3.3), and NB certification activity (NB-CPD/AG/03/001 Numbering of certificates of conformity'), and;

[•] the commercial/marketing needs of the clients of NBs to own brand their products.

⁴ The sharing and cascading of ITT is covered by GP 'M' §4.13.

- A] Enter into a contract with the other manufacturer(s), certifying their product(s), certifying their FPC or producing an inspection report itself.
 - Eg 1: The most likely scenario is one where the organization making the product, ie whose factory and FPC is inspected by the NB, wishes to enable others to place that *identical* ² product on the market under their own brand. The NB will have contracts with the other manufacturers and will certificate each of them. Each manufacturer is aware they are sharing the work with others. The organization making the product (ie that had the original contract with the NB and asked the NB to enable others to share the NB's work) is aware of the identity of all manufacturers and agrees to the sharing of the work with all.
- B] Assist the NB that the other manufacturer may choose as his third party for CE marking purposes by undertaking **notifiable task(s)**, or other tasks subject to a contract between the two NBs, to avoid duplicate work whilst respecting Member States' rules on subcontracting by NBs.
 - Eg 2: The most likely scenario is again the one above, ie §5A, except that one (or more) of the other manufacturers wishes to use his/their own NB to certify his products for CE marking purposes. For a product at system 1, where the two (or more) manufacturers agree, the NB for the original manufacturer may assist the NB(s) of the other manufacturer(s) by providing FPC certificates or inspection reports in the name of the other manufacturer by entering into a contract with the other manufacturer(s) or nominated NB(s) if within the original NB's scope of notification. Each manufacturer is aware they are sharing the work with others. The organization making the product (ie who had the original contract with the NB and asked the NB to enable others to share the NB's work) is aware of the identity of all manufacturers and agrees to the sharing of the work with all.

6 NBs shall check that manufacturers and subcontractors have adequate procedures and records to ensure conformity and traceability of products

NBs shall ensure that what is expected of a manufacturer who subcontracts all or most of his manufacturing matches what is expected of a manufacturer who manufactures the product in his own factory and CE marks in his own name. NBs shall expect and actively look for robust procedures or safeguards in the manufacturer-subcontractor relationship, equivalent to those expected in Commission GPs, harmonised technical specifications and GNB approved guidance for manufacturers who manufacture in-house from raw materials to final product. To achieve this, it may be necessary for a NB to inspect the sales and manufacturing records, and the subcontracts, of both manufacturer and subcontractors engaged in manufacturing the product, to assure itself of the overall robustness of the FPC, where this is not fully achieved by direct inspection of the subcontractor's plant or rigorous checking or testing of incoming parts by the manufacturer.

Regarding FPC matters, flexibility is required of the NB, eg it may be that thorough checking of part finished goods by a manufacturer as part of its FPC is sufficient to avoid visiting subcontractors. The key factor shall be the level of confidence in the characteristics of the product being the same for all conceivable manufacturing/subcontracting situations – see GP 'B' §4 (which is directed towards technical specification writers). However, the NB shall always ensure that the provisions of the harmonized technical specification are followed.

Where a manufacturer uses multiple subcontractors for the same key process(es) or component(s), or even different suppliers of the complete product; then the NB should be satisfied regarding all of the manufacturer's manufacturing routes, and its certificate entitling him to CE mark should cover this specific fact – see §2 footnote 3 and §7. The NB should aim to match for all the manufacturing routes, but not exceed, what it expects of a *'full'* manufacturer (a manufacturer who makes his product in his own factory and places it on the market) regarding:

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- A] Product traceability from manufacturing to first sales after CE marking.
 - GP 'B' §3.3 '... It is the manufacturer's, or his agent's, responsibility to keep full records of individual products or product batches, including their related manufacturing details and characteristics, and to keep records of to whom these products or batches were first sold. Individual products or batches of products and the related manufacturing details must be completely identifiable and retraceable.'
- B] Packing, storage and handling conditions of products once manufactured shall be sufficient to ensure they remain in conformity.
 - GP 'B' §3.1.3 '...where there is no control of finished products [by testing of finished products] at the time they are placed on the market, the manufacturer must ensure that packaging, and reasonable conditions of handling and storage do not damage products and the product remains in conformity with the technical specification.'
- C] The contractual relationship between the manufacturer and subcontractor shall be examined to ensure that the obligations to inform the NB of changes in FPC, factory equipment etc are safeguarded at all times.

7 NBs shall visit the places of manufacture

NBs (and/or their long term subcontractors approved by their MS) shall visit all the places of manufacture, ie the factories, required to comply with the harmonised technical specification, CPD and any GNB guidance.

There is no guidance at present that permits a NB generally to issue a certificate to a manufacturer based only on finished product testing without visiting the manufacturing facilities used to produce the product according to the harmonised technical specification and inspecting the FPC (the 'Rotterdam scenario'⁵). A NB should only certify without inspection of the key manufacturing facilities if either:

- A] the technical specification specifically addresses this scenario, or;
- B] the Sector Group has an approved position paper covering the scenario, with clear support from the CEN Technical Committee.
- NOTE This requirement for inspection of factories need not necessarily extend to those where components parts are produced (see GP 'M' §5.14) unless the harmonised technical specifications are specific on the matter.

8 NBs may need to visit the manufacturer's offices/warehouses etc

Even if all manufacture is subcontracted and is in conformity, NBs may need to visit the manufacturer's offices/warehouses etc if risks to the credibility of the CE marking process remain.

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⁵ The 'Rotterdam scenario' is the situation, permitted in some MSs prior to the introduction of CE marking, where a product is allowed on the market which has no documented production history, but has undergone extensive testing to show it can satisfy the MS's requirements eg reinforcing bar (1+) is off-loaded from a ship at Rotterdam (say) and a sample from each coil is tested to show it has the declared values.

The NB should aim to match the confidence it has in certifying a 'full' manufacturer. Some of the reasons why a NB shall visit a manufacturer's offices/warehouses include:

- there is the risk that products have limited shelf life and/or are particularly sensitive to handling damage and so may no longer be in conformity before they are sold, or;
- there is the risk that products may loose their traceability from manufacture to being first sold eg be wrongly labelled and packaged by the manufacturer if ready manufactured products are delivered in bulk from subcontractors and broken down into smaller lots for sale, or;
- there is a SG position paper requiring such visits.

SGs shall consider the matter at the request of any member who asks for advice. If the risks are generally considered real then a short paper shall be prepared instructing its members to visit in such circumstances.

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