



EUROPEAN COMMISSION
ENTERPRISE DIRECTORATE-GENERAL

Single Market : regulatory environment, standardisation and New Approach
Construction

Brussels,
September 2002
ENTR/G5 Fy

GUIDANCE PAPER B

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

THE DEFINITION OF FACTORY PRODUCTION CONTROL IN TECHNICAL SPECIFICATIONS FOR CONSTRUCTION PRODUCTS

(Revision Sep 2002)

*(originally issued following consultation of the Standing Committee on Construction at the 29th meeting on 29 May 1995, as document CONSTRUCT 95/135 Rev.1.
Updated following consultation of SCC Sep 02)*

Preface

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They may be further elaborated, amended or withdrawn by the same procedure leading to their issue.

THE DEFINITION OF FACTORY PRODUCTION CONTROL IN TECHNICAL SPECIFICATIONS FOR CONSTRUCTION PRODUCTS

Introduction

Article 13 3(a) of Council Directive 89/106/EC of 21 December 1988 on the Approximation of Laws, Regulations and Administrative Provisions of the Member States relating to Construction Products (referred to below as "the Directive") lays down that manufacturers may only affix the EC conformity marking on their construction products if they have "a factory production control system to ensure that production conforms with the relevant technical specifications".

This Guidance Paper (GP) centres on the factory production control system considered as a means of ensuring that products placed on the market conform with the technical specifications. Technical specifications are those set out in Article 4.1 of the Directive.

It is mainly intended for those drafting harmonised technical specifications (harmonised standards and ETAs [European Technical Approvals]) and those drafting ETA guidelines. It applies whatever system of attestation of conformity is adopted. It may also be relevant, however, to manufacturers making declarations and enforcement authorities.

The writers of technical specifications and guidelines for European technical approvals should also take into account that the manufacturer's compliance with the EN ISO 9000 series of standards is not a mandatory requirement in the framework of the Construction Products Directive and should not be included as such in harmonised technical specifications or guidelines for ETAs¹.

1. Objective and scope

This GP is intended to provide a common basis for understanding factory production control systems required by the Directive in support of its legal requirements.

The GP is not itself directly applicable. But its provisions could apply following their introduction in harmonised technical specifications.

2. Background

Factory production control

The purpose of factory production control is defined in the Directive. Attestation of conformity cannot be achieved in the absence of such a control.

"Factory production control" is defined by Annex III of the Directive as "the permanent internal control of production exercised by the manufacturer. All the

¹ Manufacturers having an FPC system which complies with EN ISO 9001/2 and which addresses the requirements of the appropriate harmonised standard are recognised as satisfying the FPC requirements of the Directive.

elements, requirements and provisions adopted by the manufacturer shall be documented in a systematic manner in the form of written policies and procedures. This production control system documentation shall ensure a common understanding of quality assurance and enable the achievement of the required product characteristics and the effective operation of the production control system to be checked".

Factory production control therefore brings together operational techniques and all measures allowing maintenance and control of the conformity of the product with technical specifications. Its implementation may be achieved by controls and tests on measuring equipment, raw materials and constituents, processes, machines and manufacturing equipment and finished products, including material properties in products, and by making use of the results thus obtained.

3. Requirements for factory production control

3.1 General comments

3.1.1. The manufacturer is responsible for organising the effective implementation of the factory production control system. Tasks and responsibilities in the production control organisation should be documented and this documentation should be kept up-to-date. In each factory the manufacturer may delegate the action to a person having the necessary authority to:

- (a) identify procedures to demonstrate conformity of the product at appropriate stages;
- (b) identify and record any instance of non-conformity;
- (c) identify procedures to correct instances of non conformity.

3.1.2. The manufacturer should draw up and keep up-to-date documents defining the factory production control which he applies. The manufacturer's documentation and procedures should be appropriate to the product and manufacturing process. All FPC systems should achieve an appropriate level of confidence in the conformity of the product. This involves :

- (a) the preparation of documented procedures and instructions relating to factory production control operations, in accordance with the requirements of the reference technical specification (see paragraph 3.1.3);
- (b) the effective implementation of these procedures and instructions;
- (c) the recording of these operations and their results;
- (d) the use of these results to correct any deviations, repair the effects of such deviations, treat any resulting instances of non-conformity and, if necessary, revise the FPC to rectify the cause of non-conformity.

3.1.3. Production control operations include some or all of the following operations:

- (a) the specification and verification of raw materials and constituents;
- (b) the controls and tests to be carried out during manufacture according to a frequency laid down;

- (c) the verifications and tests to be carried out on finished products according to a frequency which may be laid down in the technical specifications and adapted to the product and its conditions of manufacture.

N.B.- Depending on the specific case, it may be necessary to carry out i) the operations referred to under (b) and (c), ii) only the operations under (b) or iii) only those under (c).

- The operations under (b) centre as much on the intermediate states of the product as on manufacturing machines and their adjustment, and equipment etc. These controls and tests and their frequency are chosen based on product type and composition, the manufacturing process and its complexity, the sensitivity of product features to variations in manufacturing parameters etc.
- With regard to operations under (c), where there is no control of finished products at the time that they are placed on the market, the manufacturer must ensure that packaging, and reasonable conditions of handling and storage, do not damage products and that the product remains in conformity with the technical specification.
- The appropriate calibrations must be carried out on defined measuring and test instruments.

3.2 Verifications and tests

3.2.1. General comments

The manufacturer must have or have available the installations, equipment and personnel which enable him to carry out the necessary verifications and tests. He may, as may his agent, meet this requirement by concluding a sub-contracting agreement with one or more organisations or persons having the necessary skills and equipment.

The manufacturer must calibrate or verify and maintain the control, measuring or test equipment in good operating condition, whether or not it belongs to him, with a view to demonstrating conformity of the product with its technical specification. The equipment must be used in conformity with the specification or the test reference system to which the specification refers.

3.2.2. Monitoring of conformity

If necessary, monitoring is carried out of the conformity of intermediate states of the product and at the main stages of its production.

This monitoring of conformity focuses where necessary on the product throughout the process of manufacture, so that only products having passed the scheduled intermediate controls and tests are dispatched.

3.2.3. Tests

Tests should be in accordance with the test plan and be carried out in accordance with the methods indicated in the technical specification.

These methods should generally be direct methods.

It is however possible, in the case of certain characteristics, that the prescribed specification gives the possibility of using indirect test methods if a definite correlation or relationship can be established and if possible verified between specified characteristic X - the characteristic to be verified - and another characteristic Y which is easier or safer to measure than characteristic X. Indirect test methods may be retained when available and appropriate.

Depending on the system of attestation of conformity adopted for the product or the product family, initial type tests on the product may be carried out by the manufacturer himself or must be carried out or validated by an notified body.

In the latter case, this obligation only applies to tests to determine characteristics for which the choice of attestation of conformity system requires the intervention of an notified body or laboratory. These characteristics are given in Annex 3 of the mandates.

The same is true for audit tests on samples taken from the factory, market or site when the system of attestation of conformity adopted is the certification of the product and includes the carrying out or validation of these tests by the notified body concerned.

Test Records

The manufacturer should establish and maintain records which provide evidence that the product has been tested. These records should show clearly whether the product has satisfied the defined acceptance criteria. Where the product fails to satisfy the acceptance measures, the provisions for non-conforming products should apply.

3.2.4. Treatment of products which do not conform.

If control or test results show that the product does not meet the requirements, for example if the statistical variation of test results exceeds the limits allowed by the technical specification, the necessary corrective action must immediately be taken. Products or batches not conforming must be isolated and properly identified. Once the fault has been corrected, the test or verification in question must be repeated.

If products have been delivered before the results are available, a procedure and record should be maintained for notifying customers.

3.2.5. Recording of verifications and tests (manufacturer's register).

The results of factory production controls must be properly recorded in the manufacturer's register. The product description, date of manufacture, test method adopted, test results and acceptance criteria must be entered in the register under the signature of the person responsible for control who carried out the verification.

With regard to any control result not meeting the requirements of the technical specification, the corrective measures taken to rectify the situation (e.g. a further

test carried out, modification of manufacturing process, throwing away or putting right of product) must be indicated in the register.

3.3. Traceability

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. In certain cases, for example for bulk products, a rigorous traceability is not possible. The expression of the requirement in the relevant technical specifications should be realistically adapted keeping in view a traceability as complete as possible.

4. **Contents of the technical specifications on products**

Technical specifications specify in the appropriate chapter(s) the elements and requirements either mandatory or informative referred to in Chapter 3 above.

Everything comprising the necessary provisions of factory production control and the attestation of conformity adopted for the product to which the specification relates has a mandatory character.

Where possible, the elements mentioned and the requirements set out must be adapted or adaptable:

- to the particular features of the manufacturing processes. In particular, production control must be able to be adapted depending on the degree of automation of the manufacturing chain, adjustment devices, self adjustment, which manufacture may comprise.
- to the performance level the product is intended to have where the technical specification of the product provides for a range of performance levels and where the risk resulting from not achieving the intended performance varies with the level.

The adaptation procedures must be chosen in the interests of ensuring that the level of confidence obtained by the production control is effectively the same for all conceivable situations of manufacture.
