

Draft Proposal for a

**REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL  
SETTING UP THE EUROPEAN COMMON LANGUAGE FOR EXPRESSING THE  
PERFORMANCES AND CHARACTERISTICS OF CONSTRUCTION PRODUCTS  
WHEN PLACING THEM ON THE MARKET**

**RATIONALE**

Member States are responsible for ensuring that building and civil engineering works on their territory are designed and executed in a way that does not endanger the safety of persons, domestic animals and property while respecting other basic requirements in the interest of general well-being.

Member States have provisions, including requirements, relating not only to building safety but also to health, durability, energy economy, protection of the environment, aspects of economy, and other aspects important in the public interest.

These requirements, which are often the subject of national provisions laid down by law, regulation or administrative action, have a direct influence on the nature of construction products employed and are reflected in national product standards, national technical approvals and other national technical specifications and provisions which, by their disparity, hinder trade within the Community.

The removal of technical barriers in the construction field, to the extent that they cannot be removed by mutual recognition of equivalence among all the Member States, may only be achieved by the establishment of a common technical language in which manufacturers will express the performance characteristics of the products they place on the market.

This common technical language is constituted by testing, calculation and other means foreseen mainly in the product harmonised standards and European technical assessments for estimate the performance characteristics of the products.

This common language and, in particular harmonised standards and European technical assessments will replace the national product standards, technical assessments and other national technical specifications and provisions without reducing the existing and justified levels of protection in the Member States.

The language used by the Member States when drafting their national basic requirements on works and other regulations and provisions having effects on the required performance characteristics of products, has to be in line with the common language laid down by harmonised standards and other technical specifications adopted at European level.

The fulfilment of this obligation by the Member States is a necessary condition for the achievement of the Internal market for construction products.

The basic requirements on works constitute both the general and specific criteria with which construction works must comply; whereas such requirements are to be understood as requiring that the said works conform with an appropriate degree of reliability with one, some or all of these requirements when and where this is laid down in national regulations.

These basic requirements on works provide the basis for the preparation of harmonized standards at European level for construction products; whereas, in order to achieve the greatest possible advantage for a single internal market, to afford access to that market for as many manufacturers as possible, to ensure the greatest possible degree of market transparency and to create the conditions for a harmonized system of general rules in the construction industry, harmonized standards should be established as far as, and as quickly as, possible; whereas these standards are drawn up by private bodies.

For that purpose, the European Committee for Standardization (CEN) and the European Committee for Electrotechnical Standardization (Cenelec) are recognized as the competent bodies for the adoption of harmonized standards in accordance with the general guidelines for cooperation between the Commission and those two bodies signed on 13 November 1984.

For the purposes of this Regulation, a harmonized standard is a technical specification (European standard or harmonized document) adopted by one or both of those bodies upon a mandate given by the Commission in accordance with the provisions of Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations<sup>1</sup>.

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<sup>1</sup> OJ L 204, 21.7.1998, p. 37–48

The special nature of construction products requires the precise formulation of these harmonized standards which, in particular, have to be expressed, as far as practicable, in terms of product performance.

Standardisation mandates covering all relevant families of construction products, and establishing links between the basic requirements on works and the construction products characteristics, have been addressed to CEN and CENELEC under the Directive 89/106/EEC. Harmonized standards have been or are being elaborated following these mandates.

If new mandates for standards were to be necessary, they shall be elaborated by analogy with the existing ones as far as the link between the basic requirements on works and the product characteristics are concerned, and taking account of the most recent developments of the technology in the related area.

Performance levels and characteristics to be fulfilled by products in future in the Member States shall, as far as possible, be laid down in classes of performance in the harmonized technical specifications in order to take account of different levels of basic requirements for certain works or parts of them and of the differences in climate, geology and geography and other different conditions prevailing in the Member States.

When a construction product is placed on the market, it has to bear the necessary information about its performance levels or classes such that the user can determine which uses such product is fit for. Alternatively, manufacturer can place his product on the market with a declaration stating which use(s) the product has to be considered fit for.

Such information has to be expressed using the technical common language as it is laid down in the harmonised technical specifications or generally accepted and well known principles and uses (conventions).

A product placed on the market shall bear the CE-marking, meaning that the performance related information accompanying its placing on the market, has been obtained by using the common technical language and that it has respected the applicable attestation of conformity procedures. Whereas, therefore, this information has to consider accurate, reliable and stable. Whereas, in addition, CE marking means that the product conforms to all applicable provisions.

In cases where products deviate from existing technical specifications, their performance characteristics/fitness for use shall be demonstrated by recourse to a technical assessment body.

In the case of products where neither European standards nor mandates for standardisation exist, the performance levels or classes or the fitness for use of such products shall be established by recourse to European technical assessments.

In the absence of harmonized standards and European technical assessments the rules of mutual recognition under the Regulation (...) apply for placing the products on the market.

It is necessary to ensure the reproducibility and the stability of the declared product performances previously determined according to the relevant technical specifications or technical files, by means of appropriate provisions of factory production control with or without intervention of an independent qualified third parties according to the applicable procedure of attestation of conformity.

A Standing Committee shall be set up comprising experts designated by Member States to assist the Commission on questions arising from the implementation and practical application of this Regulation.

The responsibility of Member States for safety, health and other matters covered by the basic requirements on their territory should be recognized in a safeguard clause providing for appropriate protective measures.

In order to minimise for enterprises, and in particular for SME, the cost of placing products on the market, the use of concepts of compliance without testing (WT) and without further testing (WFT) should be promoted; and to facilitate such use, the standardisers should be encouraged to introduce technical classes of performance in the harmonised standards;

With the same purpose, the utilisation of Technical Files for expressing the the performances/fitness for use of the products should be facilitated;

With the aim to prevent double testing and avoid undue burden to enterprises, in particular SME, the situations providing for the sharing of testing results and of benefiting of the testing performed in upstream stages of the manufacturing process, should be defined and facilitated;

# PROVISIONS

## CHAPTER I

### Article 1

#### **Scope and Subject-matter**

This Regulation applies to construction products as referred to in Article {2} hereafter.

The objective of this Regulation is to provide the legal framework for the internal market for construction products.

*Note: This means that under this framework, all national regulatory and technical obstacles to the free circulation and to the appropriate use (appropriate use = in accordance with the applicable provisions on works) of the construction products within the internal market will have been abolished.*

To this aim, this Regulation:

- Lays down the rules and procedures to be followed by manufacturers when placing construction products on the EU market.
- Sets out the obligations to be respected by National authorities when regulating on construction works, and when designating and notifying conformity assessment bodies and technical assessment bodies and exercising the surveillance of the markets in their countries.
- Lays down a common technical language for expressing the level of performance of the “essential” characteristics or the fitness for the intended use of the construction products, related to in article 3.
- Obliges national authorities to exclusively use this common language when expressing the work regulatory requirements having an effect on the product characteristics, and the manufacturers to exclusively use this common language when declaring the performances or the fitness for use of the products they place on the market.

- Identifies the “essential” characteristics of the products, referred to in article 3, as being those laid down in the standardisation mandates issued under the Directive 89/106/EC, and determines the procedures to follow should additional characteristics need to be included.
  - Obliges Member States to give presumption of accuracy, reliability and stability to the declaration of performances/fitness for the intended use made by the manufacturer in accordance with the procedures set down in this regulation.
  - Sets down the procedures for the conformity assessment and the criteria for deciding which specific procedure to be applied in each particular case.
  - Sets down the criteria and the procedures to be followed for the designation and notification of conformity assessment bodies;
- .;.;.;.;.;.;.; Market Surveillance + Safeguard clauses.;.;.;.;.;.;.;
- Sets down the procedures to follow for dealing with innovative products as far as their placing on the market is concerned.

Article 2

**Definitions**

- 1 Construction product means any product which is produced for incorporation in a permanent manner in construction works or parts thereof and whose placing on the market is accompanied by a statement of performance / fitness for use, made by the manufacturer, as referred to in article 3.
- 2 Permanent manner means permanently installed in construction works so as that the dismantling of the product decreases the performance of the work and the dismantling or exchange of the product constitute construction operations.
- 3 Construction works means buildings and civil engineering works.

- 4 Essential characteristics of the product means those characteristics that have an influence on the fulfilment of the Basic Requirements on works referred to in Article 3.1, and therefore their performances can be legally required or required by construction agents, the latter being responsible for the fulfilment of the basic requirements on works.
- 5 Harmonised technical specifications refers to harmonised standards and European Technical Assessments,
- 6 Common technical language means the whole set of tools as established in the harmonised technical specifications: test methods, calculation methods, parameters and all other means, for assessing the performances or the fitness for use of construction products. The conditions for using or applying such tools, e.g. sampling, interpretation of testing results, etc. are also part of the common technical language.
- 7 Making available on the market means any supply of a product for distribution or use on the Community market in the course of a commercial activity, whether in return for payment or free of charge. This excludes the assembling or the using of a product for one's own professional activity.
- 8 Placing on the market means the first making available of a product on the Community market.
- 9 Manufacturer means a natural or legal person who manufactures a product or who has such a product manufactured, under his name or trademark.
- 10 Authorised representative means any natural or legal person established within the Community who has received a written mandate from the manufacturer to act on his behalf for specified tasks with regard to the latter's obligations under the relevant Community legislation.
- 11 Distributor means any natural or legal person in the supply chain, who makes a product available on the market.
- 12 Importer means any natural or legal person established within the Community, who places a product from a third country on the Community market.
- 13 Harmonised standard means a standard adopted by one of the European standardisation bodies listed in Annex I to Directive 98/34/EC in

accordance with Article 6 of Directive 98/34/EC and whose references have been published in the series C of the OJEU.

- 14 Innovative products means a construction product ..... (to be discussed)
- 15 European Technical Assessment means the harmonised technical specification prepared for and granted to innovative construction products and containing the assessment and the evaluation of the concerned product against the manufacturer claimed performances / characteristics for a specific intended use.
- 16 Conformity assessment means the process whereby demonstration is made that the manufacturer declaration relating to the performance characteristics or the fitness for a specific use of a product, is accurate, reliable and statistically stable.
- 17 Accreditation means a third-party attestation related to a conformity assessment body, conveying formal demonstration of their competence to carry out specific conformity assessment tasks.
- 18 National accreditation body means the sole authoritative body in a Member State that performs accreditation with authority derived from government.
- 19 Recall means any measure aimed at achieving the return of a dangerous or non-conforming product that has already been made available.
- 20 Construction operators means any legal or physical person involved in the construction process for which he assumes the responsibility of fulfilling the national provisions on works including those related to the use of construction products (architects, designers, contractors, installers, owners, etc.).
- 21 Product fit for a specific application/use means a product possessing such performance characteristics that, for a given proper design, it enables works in which it is installed to satisfy the applicable basic requirements, as far as that application/use is concerned. The concept of fitness for use is therefore depending on the work specific design and on possible regulatory provisions applying to the work or/and to the application concerned.
- 22 Deemed to be fit for a specific use without testing (WT) refers to a product for which it has been well established and is sufficiently well known that the fitness for the declared use does not require any testing.

- 23 Deemed to be fit for a specific use without further testing (WFT) refers to a product for which it has been proven, based on stable previous test results and/or existing data, that the fitness for the declared use does not require any further testing.
- 24 Deemed to satisfy a specific level or class of performance WT or WFT according to a given technical specification refers to a product for which it has been proven, based on stable previous test results and/or existing data, that it meets the conditions set out by a technical specification or by a Commission decision taken following the procedure under article {.....} of this regulation, for being presumed to achieve without or without further testing, such level or class of performance.
- 25 Type test (TT) means the testing part, if any, of the process aiming at defining and evaluating the performances (level or classes) of the product-type as declared by the manufacturer when placing the product on the market
- 26 shared TT means the use by a manufacturer of the test results obtained by someone else for a product for which it is established that it shares with the former one all the elements determining the performances.
- 27 Cascading TT means the use by a manufacturer of the test results obtained in an upstream stage of the production process, provided that it is demonstrated that the performance is not modified in the ulterior stages of the manufacturing process.
- 28 Individual product means product of ad hoc design that is ordered for and installed in one and the same known work.

### Article 3

#### **Basic requirements on works and essential characteristics of products**

1. The basic requirements applicable to works which may influence the technical characteristics of a product are set out in terms of objectives in Annex I. One, some or all of these requirements may apply.
2. In order to take account of possible differences in geographical, geological or climatic conditions or in ways of life as well as different levels of

protection that may prevail at national, regional or local level, each basic requirement may give rise to the establishment of classes of performance in the harmonised technical specifications for the requirement to be respected.

3. The links between the basic requirements on works and the essential characteristics of the products have been made explicit with the help of the Interpretative Documents<sup>2</sup> under the Directive 89/106/EEC. Indeed, the essential characteristics of the products have been identified for each basic requirement and for each family of products, and they have been laid down in the standardization mandates and mandates for guidelines for European technical approval delivered<sup>3</sup> under the Directive 89/106/EEC. Should additional essential characteristics be identified, they shall be incorporated, after consultation of the Committee referred to in Art. {.....}, in new or amended standardisation mandates and published in the series C of the OJEU.

## CHAPTER II

### Article 4

#### **Placing on the market and Statement of performance / fitness for use**

1. When placed on the market, construction products shall be accompanied by a statement made by the manufacturer indicating the level or class of performance for all or part of the relevant essential characteristics of the product. Alternatively, the statement will indicate the specific use(s) which the product has to be considered to be fit for.
2. This statement of performance/fitness for the intended use shall be part of the “EC declaration of conformity” referred to in Article 6 bis. In addition, the EC declaration of conformity shall state that the fulfilment of all requirements specified in this regulation has been demonstrated.

The EC declaration of conformity shall have the model structure set out in {Annex....}.

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<sup>2</sup> OJ No C 62, 28.2.1994, p ....

<sup>3</sup> The Commission will publish the list of mandated characteristics in the series C of the OJEU.

3. The evaluation of performance / fitness for the intended use shall be made in accordance with:
  - a) the relevant Harmonised Standard, referred to in Article 10, the references of which have been published in the OJEU;
  - b) a European Technical Assessment delivered according to the procedure described in chapter {.....};
  - c) a Technical File (TF) following the procedures and the conditions described in article {12}.
  
4. In accordance to paragraph 1, the manufacturer could decide not to declare values for some of the essential characteristics applicable to product. This choice shall only be possible for those essential characteristics for which no regulatory requirement exists in the market area in which he intends to place the product.

To obtain the needed information concerning the regulatory provisions and applicable technical rules existing in Member States, manufacturer shall have the possibility of addressing a request to the corresponding national contact point referred to in articles {7 and 8}

5. Without prejudice of article 12, where, for the purposes of the evaluation of the performances / fitness for the intended use of the product, a manufacturer or his agent, established in the Community, has applied only in part the existing technical specifications referred to in paragraph 3 a) and b), his EC declaration of performance/fit for intended use related to the non applied part shall be supported by a technical file established with the intervention of a technical assessment body competent for the related product area, demonstrating the relevancy and the validity of the applied alternative route.
  
6. Products covered by a standardisation mandate which has not yet resulted in a harmonised standard, are included in the scope of the regulation (...) on mutual recognition, until the references of the applicable harmonised standard have been published in the Series C of OJEU.
  
7. If the relevant European technical specifications distinguish between different classes corresponding to different performance levels, Member States may determine the performance level also to be observed in their territory only within the classification adopted at Community level using one, some or all of the established classes.

## Article 5

### **CE marking**

CE marking shall be affixed to all construction products covered by a harmonised technical specification or a technical file and for which a declaration of performance/fitness for intended use is made.

The CE marking may only be affixed by the manufacturer or his authorised representative.

By affixing or having affixed the CE marking the manufacturer shall assume the responsibility for the compliance of the product with the provisions laid down in this Regulation and in particular with the declaration of performance or of fitness for intended use.

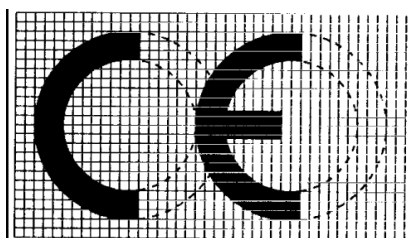
The CE marking shall be the only marking which attests compliance of the product with the applicable requirements and with the declaration of performance/fitness for intended use. Member States shall refrain from introducing into their national regulations or shall withdraw any reference to a conformity marking other than the CE marking in connection with conformity to the provisions contained in the legislation on CE marking.

The affixing on a product of markings, signs and inscriptions which are likely to mislead third parties as to the meaning or form of the CE marking, or both, is prohibited. Any other marking may be affixed to the product provided that the visibility, legibility and meaning of the CE marking are not thereby impaired.

## Article 6

### **Rules and conditions for the affixing of the CE marking**

The CE marking shall consist of the initials “CE” taking the following form:



If the CE marking is reduced or enlarged the proportions given in the graduated drawing in paragraph 1 must be respected.

The CE marking shall be affixed visibly, legibly and indelibly to the product or to its data plate. Where this is not possible or not warranted on account of the nature of the product, it shall be affixed to the packaging or to the accompanying documents.

The CE marking shall be affixed before the product is placed on the market. It may be followed by a pictogram or any other mark indicating a special risk or use.

The CE marking shall be followed by the identification number of the notified body where such body is involved in the production control phase.

The identification number of the notified body shall be affixed by the body itself or under its instructions, by the manufacturer or his authorised representative established within the Community.

As far as practicable, the CE marking shall be followed by the list of the declared characteristics.

Member States shall ensure correct implementation of the regime governing the CE marking and, if they deem adequate, take legal action in case of improper use. Member States shall also put in place penalties, including criminal sanctions for serious infringements that must be proportionate to the seriousness of the offence and constitute an effective deterrent against improper use.

#### Article {6bis}

#### **EC declaration of conformity**

1. The manufacturer shall draw up a written declaration of conformity on the basis of a product-type and keep it with the technical documentation at the disposal of the national authorities for a period of 10 years after the last product has been manufactured. The declaration of conformity shall clearly identify the product for which it has been drawn up.
2. A copy of the declaration of conformity shall be supplied with each product that is made available on the market. However, this requirement

may be interpreted as applying to a batch or consignment rather than to individual products in those cases where a large number of products is delivered to a single user.

3. The manufacturer's obligations contained in paragraphs 1 and 2 may be fulfilled, on his behalf and under his responsibility, by his authorised representative.

## **CHAPTER III**

### Article 7

#### **Product Contact Points**

Each Member State shall designate one or more National Product Contact Points in its territory and shall communicate their contact details to the other Member States and to the Commission.

The Commission shall publish and regularly update the list of National Product Contact Points.

### Article 8

1. Each Member State shall ensure that National Product Contact Points provide, upon request, the following information:
  - (a) the technical rules applicable to the incorporating, assembling or installing a specific type of product in the national territory;
  - (b) the contact details of the National authorities enabling them to be contacted directly, including the particulars of the authorities responsible for supervising the implementation of the particular technical rules in the national territory;
  - (c) the remedies generally available in the National territory in the event of a dispute between the competent authorities and a manufacturer or a distributor;

- (d) the contact details of any body other than the national authorities, from which producers or distributors may obtain practical assistance in the national territory;
  - (e) the regulatory provisions, if any, applicable to the incorporating, assembling or installing a specific type of product in the national territory.
2. Member States shall ensure that the National Product Contact Points respond within twenty working days from the receipt of any request to transmit the information referred to in paragraph 1.

Member States shall ensure that the National Product Contact Points can obtain and provide, on request, detailed information about the technical and regulatory situation in their national territory, related to the type of product concerned

## Article 9

### **Internal Market**

Members States and any other party shall presume accurate and stable the declaration of performance / fitness for the intended use made by the manufacturer under the conditions of article 3. They shall not prohibit, restrict or impede the making available on the market and the use within their territories or under their responsibility of products bearing the CE marking.

Member States shall ensure that the use of such products, for the purpose for which they were intended, shall not be impeded by rules or conditions imposed by public bodies or private bodies acting as a public undertaking, as a public body on the basis of a monopoly position or under a public mandate.

Add Article from 7 to 12 on obligation of economic operators (Decision)

## CHAPTER IV

### Article 10

#### **Harmonised Standards**

1. In order to ensure the quality of harmonized standards referred to in article 4.3a, they shall be established by the European standards organizations on the basis of mandates given by the Commission in accordance with the procedure laid down in Directive 98/34/EC<sup>4</sup> and after consulting the Committee referred to in Article {.....}.
2. The resulting harmonised standards shall be expressed, as far as practicable, in product performance terms. They should, as far as practicable, define technical classes of performances for as many as possible of the essential characteristics referred to in the mandates.
3. In order to reduce the economic burden related to the placing the products in the market, harmonised standards shall, as far as possible, determine ways less onerous than tests, for achieving the defined classes of performance.
4. Once the standards have been established by the European standards organizations, the Commission, after analyzing their quality and their conformity with the relevant mandates, will take the decision whether or not publishing their references in the 'C' series of the Official Journal of the European Union.

### Article 11

#### **European Technical Assessment**

1. European technical assessment is a favourable technical assessment of the fitness for use of a product for an intended use, based on fulfilment of the basic requirements for works for which the product is used.

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<sup>4</sup> OJ No

2. European technical assessment shall only be granted to products for which there is neither a harmonized standard, nor a mandate for a harmonized standard.
  3. Nevertheless, without prejudice of article 4 paragraph 6, the granting of European technical assessments, at the request of the manufacturer, is permitted:
    - a) for products for which guidelines referred to in article {.....*transitional arrangements*.....} for such assessment exist;
    - b) in special cases, if the Commission, as a derogation from paragraph 3, authorizes the issue of European technical assessment, for products for which it has been demonstrated that the mutual recognition is not practicable due to technical obstacles.
- Both, a) and b) shall apply until the entry into force of the relevant harmonized standard in the Member States.
5. European technical assessment shall in general be issued for a five-year period. This period may be extended.

## Article 12

European technical assessment shall be issued by reference to the relevant basic requirements where the assessment of the product is adopted under the responsibility of an individual assessment body on the basis of assessment procedures agreed by assessment bodies acting jointly in the organization referred to in Annex {.....}. These procedures shall be referred to in a publicly available document issued by the said organisation and shall be sent to the Commission which will decide whether or not to publish its reference in the Series C of OJEU.

## Article 13

### **European Technical Assessment Bodies**

1. Each Member State shall notify the other Member States and the Commission of the names and addresses of the bodies which it has authorized to issue European technical assessments. It shall whereby communicate the specific product area for which the body is notified.
2. The assessment bodies must satisfy the requirements set out in Article .... of this Regulation. In addition they shall satisfy eligibility criteria and technical criteria set out in Annex .....
3. The list of assessment bodies and the product areas for which are notified to issue European technical assessments, as well as any amendments to that list, shall be published in the Series C of the Official Journal of the European Communities.

## Article 14

### **Technical File**

Technical file, for the purpose of this regulation, is the set of technical documentation provided by the manufacturer to demonstrate:

1. that the product he places on the market fulfils the required conditions for making the statement of performance / fitness for use WT or WFT, according to the relevant technical specification or to the applicable Commission decision, taken according to the art. { .....
2. that the product he places on the market fulfils the necessary technical conditions for sharing all or part of the test results and/or the declared performances of another product already placed on the market by himself or by some else.

This sharing does not modify the level of the attestation of conformity established for the product.

3. that the product he places on the market fulfils the required conditions for using the testing results obtained in upstream stage of the production process.

This sharing does not modify the level of the attestation of conformity established for the product.

In case of an individual product, a TF could replace the established applicable attestation of conformity procedures. The TF shall demonstrate the "ad hoc" nature of the production process and the fitness for use of the individual product placed on market. If the type of product belongs to a family who's the applicable attestation of conformity requires the intervention of a competent notified body, then the TF shall be supported by the intervention of such a body.

The TF shall be referred to in the declaration of conformity.

## Article 15

### **Attestation of conformity**

- 1 The attestation of conformity for construction products is obtained by two different but complementary steps:
  - (a) definition of the product-type by carrying out the type tests (TT) or by other means;
  - (b) verification of the constancy of the manufactured products compared to the behaviour of the product-type defined by the type tests or by other means.

The two steps can be undertaken by a conformity assessment body or by the manufacturer himself, depending from the established level of attestation of conformity.

- 3 The attestation of conformity shall be established by means of testing or other evidence on the basis of the technical specifications in accordance with Annex .....
- 4 The attestation of conformity of a product is dependent on:

- (a) the manufacturer having a factory production control system to ensure that production conforms with the relevant technical specifications;
  - (b) for particular products indicated in the relevant technical specifications, in addition to a factory production control system, a conformity assessment body being involved in assessment, evaluation and surveillance of the factory production control or assessment and evaluation of the product itself.
- 5 The choice of the procedure within the meaning of paragraph 1 and 2 for a given product or family of products shall be specified by a Commission, decision adopted following the procedures referred to in Article ....., according to:
- (a) the importance of the part played by the product with respect to the basic requirements on works, in particular those relating to health and safety;
  - (b) the nature of the product;
  - (c) the effect of the variability of the product's characteristics during its service life ;
  - (d) the susceptibility to defects in the product manufacture;

in accordance with Annex .....

In each case, the least onerous possible procedure consistent with safety shall be chosen.

The procedure thus determined shall be indicated in the mandates and in the technical specifications or in the publication thereof.

## **CHAPTER IV**

### **Notifying Authorities and Notified Bodies**

#### Article 16

##### **Notification**

Member States shall notify the Commission and the other Member States of bodies authorised to carry out third-party conformity assessment tasks under this Regulation.

#### Article 17

##### **Notifying authorities**

- 1 Member States shall designate a notifying authority that shall be responsible for setting up and carrying out the necessary procedures for the assessment and notification of conformity assessment bodies and the monitoring of notified bodies, including compliance with the provisions of Article .....
- 2 Member States shall decide that the assessment and monitoring referred to in paragraph 1 shall be carried out by their national accreditation bodies within the meaning of and in accordance with Regulation (EC) No [...].
- 3 Where the notifying authority delegates, subcontracts or otherwise entrusts the assessment, notification or monitoring referred to in paragraph 1 to a body which is not a governmental entity, the delegated, subcontracted or otherwise entrusted body shall be a legal entity and shall have arrangements to cover liabilities arising from its activities.

## Article 18

### **Requirements relating to notifying authorities**

- 1 The notifying authority shall meet the requirements set out in paragraphs 2 to 7.
- 2 The notifying authority shall be established in such a way that no conflicts of interest with conformity assessment bodies occur.
- 3 The notifying authority shall be organised and operated so as to safeguard the objectivity and impartiality of its activities.
- 4 The notifying authority shall be organised in such a way that each decision relating to notification of the conformity assessment body is taken by competent persons different from those who carried out the assessment.
- 5 The notifying authority shall not offer or provide any activities that conformity assessment bodies perform, or consultancy.
- 6 The notifying authority shall have adequate arrangements to safeguard the confidentiality of the information obtained.
- 7 The notifying authority shall have a sufficient number of competent personnel at its disposal for the proper performance of its tasks.

## Article 19

### **Information obligation for the notifying authorities**

Member States shall inform the Commission and the other Member States of their national procedures for the assessment and notification of conformity assessment bodies and the monitoring of notified bodies, and of any changes to that information.

The Commission shall make that information publicly available.

## Article 20

### **Requirements for notified bodies**

1. For the purposes of notification, a conformity assessment body shall meet the requirements set out in paragraphs 2 to 11 of this Article.
2. The conformity assessment body shall be established under national law and have legal personality.
3. The conformity assessment body shall be a third-party body independent from the organisation or the product it assesses.
4. The conformity assessment body, its top level management and the personnel responsible for carrying out the conformity assessment tasks shall not be the designer, manufacturer, supplier, installer, purchaser, owner, user or maintainer of the products which they assess, nor the authorised representative of any of those parties.

Nor shall they become directly involved in the design, manufacture or construction, the marketing, installation, use or maintenance of those products, nor represent the parties engaged in those activities.

They shall not provide consultancy related to the conformity assessment activities for which they are notified and relating to products intended to be placed on the Community market. This shall not preclude the possibility of exchanges of technical information between the manufacturer and the conformity assessment body and the use of assessed products that are necessary for the operations of the conformity assessment body.

The conformity assessment body shall ensure that activities of its subsidiaries or subcontractors do not affect the confidentiality, objectivity and impartiality of its conformity assessment activities.

5. The conformity assessment body and its personnel shall carry out the conformity assessment activities with the highest degree of professional integrity and requisite technical competence in the specific field and must be free from all pressures and inducements, particularly financial, which might influence their judgement or the results of their conformity assessment activities, especially from persons or groups of persons with an interest in the results of those activities.
6. The conformity assessment body shall be capable of carrying out all the conformity assessment tasks assigned to such a body by the provisions of

article .... of this regulation and for which it has been notified, whether those tasks are carried out by the conformity assessment body itself or on its behalf and under its responsibility.

At all times and for each conformity assessment procedure and for each kind or category of products, characteristics and tasks for which it is notified, the conformity assessment body shall have at its disposal the necessary personnel with technical knowledge and sufficient and appropriate experience to perform the conformity assessment tasks.

It shall have the means necessary to perform the technical and administrative tasks connected with the conformity assessment activities in an appropriate manner and shall have access to all necessary equipment or facilities.

7. The personnel responsible for carrying out the conformity assessment activities shall have the following:
  - (a) sound technical and vocational training covering all the conformity assessment activities of the relevant scope for which the conformity assessment body has been notified;
  - (b) satisfactory knowledge of the requirements of the assessments they carry out and adequate authority to carry out such operations;
  - (c) appropriate knowledge and understanding of the essential requirements, of the applicable harmonised standards and of the relevant provisions of the relevant Community legislation and relevant implementing regulations;
  - (d) the ability required to draw up the certificates, records and reports to demonstrate that the assessments have been carried out.
8. The impartiality of the conformity assessment body, its top level management and assessment personnel shall be guaranteed.

The remuneration of the conformity assessment body's top level management and assessment personnel shall not depend on the number of assessments carried out or on the results of such assessments.
9. The conformity assessment body shall take out liability insurance unless liability is assumed by the State in accordance with national law, or the Member State itself is directly responsible for the conformity assessment.
10. The personnel of the conformity assessment body shall be bound to observe professional secrecy with regard to all information gained in

carrying out its tasks under article..... or any provision of national law giving effect to it, except in relation to the competent administrative authorities of the Member State in which its activities are carried out. Proprietary rights shall be protected.

11. The conformity assessment body shall cooperate in, or ensure that its assessment personnel is informed of, the relevant standardisation activities and the activities of the notified body co-ordination group established under the relevant Community legislation and apply as general guidance the administrative decisions and documents produced as a work result of that group.

## Article 21

### **Subsidiaries and subcontracting of notified bodies**

- 1 Where the conformity assessment body subcontracts specific tasks connected with the assessment of conformity or has recourse to a subsidiary, it shall ensure that the subcontractor or the subsidiary meets the requirements set out in Article [20].
- 2 The conformity assessment body shall take full responsibility for the tasks performed by subcontractors or subsidiaries wherever these are established.
- 3 Activities may be subcontracted or carried out by a subsidiary only with the agreement of the client.
- 4 The conformity assessment body shall keep at the disposal of the national authorities the relevant documents concerning the assessment of the subcontractor's or subsidiary's qualifications and the work carried out by the subcontractor or the subsidiary under ... [reference to the relevant part of the legislation].

## Article 22

### **Accredited in-house bodies**

- 1 For the purpose of conformity assessment procedures set out in Annex ..., an accredited in-house body, which forms a separate and identifiable part of an undertaking involved in the design, manufacture, supply, installation, use or maintenance of the products that it assesses and which has been established to supply conformity assessment services to the undertaking of which it forms a part, may be used.
- 2 The in-house body shall meet the following criteria:
  - (a) it shall be accredited in accordance with Regulation (EC) No [...].;
  - (b) the body and its personnel shall be organisationally identifiable and have reporting methods within the undertaking of which it forms a part, which ensure its impartiality and demonstrate it to the relevant national accreditation body;
  - (c) the body and its personnel must not be responsible for the design, manufacture, supply, installation, operation or maintenance of the products which they assess, and must not engage in any activities that might conflict with their independence of judgment and integrity in relation to their assessment activities;
  - (d) the body shall supply its services exclusively to the undertaking of which it forms a part.
- 3 Accredited in-house bodies shall not be notified to the Member States or the Commission, but information about their accreditation shall be provided to the notifying authority, on request.

## Article 23

### **Application for notification**

- 1 A conformity assessment body shall submit an application for notification to the notifying authority of the Member State in which it is established.

- 2 The application shall be accompanied by a description of the conformity assessment activities, the conformity assessment procedures for which the body claims to be competent, as well as by an accreditation certificate, delivered by the national accreditation body within the meaning of Regulation (EC) No [...],attesting that the conformity assessment body meets the requirements laid down in Article.....

*(NB. It is reminded that this draft regulation foresees a compulsory accreditation system for the conformity assessment bodies to be notified)*

## Article 24

### **Notification procedure**

- 1 Notifying authorities may notify only conformity assessment bodies which have satisfied the requirements laid down in Article ...[22].
- 2 They shall notify the Commission and the other Member States using the electronic notification tool developed and managed by the Commission.
- 3 The notification shall include full details of the conformity assessment activities, the conformity assessment module or modules and product or products concerned and the relevant attestation of competence.
- 4 Notification is based on an accreditation certificate referred to in Article ...
- 5 The body concerned may perform the activities of a notified body only where no objections have been raised by the Commission and the other Member States within two months following that notification.  
  
Only such a body shall be considered as a notified body for the purpose of this Regulation.
- 6 The Commission and the other Member States shall be notified of any subsequent relevant changes to the notification.

## Article 25

### **Identification numbers and lists of notified bodies**

1. The Commission shall assign an identification number to a notified body.

It shall assign a single such number even where the body is notified under several Community acts.

2. The Commission shall make publicly available the list of the bodies notified under this ... [act] , including the identification numbers that have been allocated to them and the activities for which they have been notified.

The Commission shall ensure that this list is kept up to date.

## Article 26

### **Changes to the notification**

1. Where a notifying authority has ascertained or has been informed that a notified body no longer meets the requirements referred to in Article ...[22], or that it is failing to fulfil its obligations, the notifying authority shall restrict, suspend or withdraw the notification as appropriate. It shall immediately inform the Commission and the other Member States thereof.
2. In the case of withdrawal, restriction or suspension of notification or where the notified body has ceased activity, the notifying Member State concerned shall take the appropriate steps to ensure that the files are either processed by another notified body or kept available for the responsible notifying and market surveillance authorities on request.

## Article 27

### **Challenge of the competence of notified bodies**

1. The Commission shall investigate all cases where it doubts or doubt is brought to its attention as to the competence of a notified body or the

continued fulfilment by a notified body of the requirements and responsibilities placed on it.

2. The notifying Member State shall provide the Commission, on request, with all information related to the basis for notification or the maintenance of the competence of the body concerned.
3. The Commission shall ensure that all information obtained in the course of its investigations is treated confidentially.
4. Where the Commission ascertains that a notified body does not meet, or no longer meets, the requirements for its notification, it shall inform the notifying Member State thereof and request it to take the necessary corrective measures, including de-notification, if necessary.

## Article 28

### **Operational obligations for notified bodies**

1. Notified bodies shall carry out conformity assessments in accordance with the conformity assessment procedures provided for in ...[the relevant part of the legislation].
2. Conformity assessments shall be carried out in a proportionate manner, avoiding unnecessary burden for economic operators, in particular taking into consideration the size of companies and the relative complexity of the technology used by the products.
3. Where a notified body finds that requirements laid down in ... this regulation...] or corresponding harmonised standards or other applicable technical specifications have not been met by the manufacturer, it shall require the manufacturer to take appropriate corrective measures and it shall not deliver any conformity certificate.
4. Where, in the course of the monitoring of conformity following the delivery of certificate, a notified body finds that a product no longer complies, it shall require the manufacturer to take appropriate corrective measures and shall suspend or withdraw its certificate if necessary.

5. Where corrective measures are not taken or do not have the required effect, the notified body shall restrict, suspend or withdraw any certificates, as appropriate.

## Article 29

### **Information obligation for notified bodies**

1. Notified bodies shall inform the notifying authority of the following:
  - (a) any refusal, restriction, suspension or withdrawal of certificates;
  - (b) any circumstances affecting the scope of and conditions for notification;
  - (c) any request for information which they have received from market surveillance authorities;
  - (d) on request, conformity assessment activities performed within the scope of their notification and, any other activity performed, including, cross-border activities and subcontracting.
2. Notified bodies shall provide the other bodies notified under this ... [act] carrying out similar conformity assessment activities and covering the same products with relevant information on issues relating to negative and, on request, positive conformity assessment results.

## Article 30

### **Exchange of experience**

The Commission shall provide for the organisation of exchange of experience between the Member States' national authorities responsible for policy on notification.

## Article 31

### **Coordination of notified bodies**

The Commission shall ensure that appropriate coordination and cooperation between bodies notified under ... [the relevant act or other Community legislation] is put into place and properly operated in the form of (a) ... [sectoral or cross sectoral] group(s) of notified bodies.

Member States shall ensure that the bodies notified by them participate in the work of that (those) group(s).

## **CHAPTER V**

## Article 32

### **Market surveillance and safeguard procedures**

*Basically by referencing the horizontal regulation and by taking article 35 and ss from the horizontal decision.*