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PROPOSAL

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Subject:	New Legislative Framework Alignment Package (Implementation of the Goods Package) - Proposal for a Directive of the European Parliament and of the Council on the harmonisation of the laws of the Member States relating to electromagnetic compatibility

Delegations will find attached a proposal from the Commission, submitted under a covering letter from Mr Jordi AYET PUIGARNAU, Director to Mr Uwe CORSEPIUS, Secretary-General of the Council of the European Union.

Encl.: COM(2011) 765 final

EUROPEAN COMMISSION

Brussels, 21.11.2011
COM(2011) 765 final

2011/0351 (COD)

NEW LEGISLATIVE FRAMEWORK (NLF) ALIGNMENT PACKAGE
(Implementation of the Goods Package)

Proposal for a

DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on the harmonisation of the laws of the Member States relating to electromagnetic compatibility

(Recast)

(Text with EEA relevance)

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE PROPOSAL

General context, reasons for and objectives of this proposal

This proposal is presented in the framework of the **implementation of the "goods package"** adopted in 2008. It is part of a package of proposals aligning ten product directives to Decision No 768/2008/EC establishing a common framework for the marketing of products.

Union (EU) harmonisation legislation ensuring the free movement of products has contributed considerably to the completion and operation of the Single Market. It is based on a high level of protection and provides economic operators with the means to demonstrate conformity, thus ensuring free movement through trust in the products.

Directive 2004/108/EC is an example of that Union harmonisation legislation, ensuring the free movement of apparatus. It sets out essential electromagnetic compatibility requirements that apparatus must comply with in order to be made available on the EU market. These essential requirements also apply to fixed installations. Manufacturers must demonstrate that an apparatus has been designed and manufactured in compliance with the essential requirements and affix the CE marking. The responsible persons for fixed installations must also guarantee that fixed installations comply with the essential requirements.

Experience with the implementation of Union harmonisation legislation has shown – on a cross-sector scale - certain weaknesses and inconsistencies in the implementation and enforcement of this legislation, leading to

– the presence of non-compliant or dangerous products on the market and consequently a certain lack of trust in CE marking

– competitive disadvantages for economic operators complying with the legislation as opposed to those circumventing the rules

– unequal treatment in the case of non-compliant products and distortion of competition amongst economic operators due to different enforcement practices

– differing practices in the designation of conformity assessment bodies by national authorities

– problems with the quality of certain notified bodies

Furthermore the regulatory environment has become more and more complex, as frequently several pieces of legislation apply simultaneously to one and the same product. Inconsistencies in these pieces of legislation make it increasingly difficult for economic operators and authorities to correctly interpret and apply that legislation.

To remedy these horizontal shortcomings in Union harmonisation legislation observed across several industrial sectors, the **"New Legislative Framework"** was adopted in 2008 as part of the **goods package**. Its objective is to strengthen and complete the existing rules and to improve practical aspects of their application and enforcement. The New Legislative Framework (NLF) consists of two complementary instruments, **Regulation (EC) No**

765/2008 on accreditation and market surveillance and **Decision No 768/2008/EC establishing a common framework for the marketing of products**.

The NLF Regulation has introduced rules on accreditation (a tool for the evaluation of competence of conformity assessment bodies) and requirements for the organisation and performance of market surveillance and controls of products from third countries. Since 1 January 2010 these rules apply directly in all Member States.

The NLF Decision sets out a common framework for EU product harmonisation legislation. This framework consists of the provisions which are commonly used in EU product legislation (e.g. definitions, obligations of economic operators, notified bodies, safeguard mechanisms, etc). These common provisions have been reinforced to ensure that the directives can be applied and enforced more effectively in practice. New elements, such as obligations on importers, have been introduced, which are crucial for improving the safety of products on the market.

The provisions of the NLF Decision and those of the NLF Regulation are complementary and closely interlinked. The NLF Decision contains the corresponding obligations for economic operators and notified bodies allowing market surveillance authorities and authorities responsible for notified bodies to properly perform the tasks imposed on them by the NLF Regulation and to ensure an effective and consistent enforcement of EU product legislation.

However, unlike the NLF Regulation, the provisions of the NLF Decision are not directly applicable. To ensure that all economic sectors subject to Union harmonisation legislation benefit from the improvements of the NLF, the provisions of the NLF Decision need to be integrated into the existing product legislation.

A survey after the adoption of the goods package in 2008 showed that a majority of Union harmonisation legislation on products was due to be revised within the following 3 years, not only to address the problems observed throughout all sectors but also for sector-specific reasons. Any such revision would automatically include an alignment of the legislation concerned to the NLF Decision since Parliament, Council and Commission have committed themselves to use its provisions as much as possible in future legislation on products in order to further the utmost coherence of the regulatory framework.

For a number of other Union harmonisation directives, including Directive 2004/108/EC no revision for sector-specific problems had been envisaged within this timeframe. To ensure that the problems in relation to non-compliance and notified bodies are nevertheless addressed in these sectors, and for the sake of consistency of the overall regulatory environment on products, it was decided to align these directives within a package to the provisions of the NLF Decision.

Consistency with other policies and objectives of the Union

This initiative is in line with the Single Market Act[1], which has stressed the need to restore consumer confidence in the quality of products on the market and the importance of reinforcing market surveillance.

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[1] Communication from the Commission to the European Parliament, the Council, the Economic and Social Committee and the Committee of the Regions, COM(2011) 206 final.

Furthermore it supports the Commission's policy on Better Regulation and simplification of the regulatory environment.

2. CONSULTATION OF INTERESTED PARTIES AND IMPACT ASSESSMENT

Consultation of interested parties

The alignment of Directive 2004/108/EC to the NLF Decision has been discussed with national experts responsible for the implementation of this Directive, the notified body group, the administrative cooperation group as well as in bilateral meetings with industry associations.

From June to October 2010 a public consultation was organised that comprised all the sectors involved in this initiative. It consisted of four targeted questionnaires for economic operators, authorities, notified bodies and users and the Commission services received 300 replies. The results are published at:

http://ec.europa.eu/enterprise/policies/single-market-goods/regulatory-policies-common-rules-for-products/new-legislative-framework/index_en.htm

In addition to the general consultation a specific SME consultation was carried out. 603 SMEs were consulted through the Enterprise Europe Network in May/June 2010. The results are available at http://ec.europa.eu/enterprise/policies/single-market-goods/files/new-legislative-framework/smes_statistics_en.pdf

The consultation process revealed widespread support for the initiative. There is unanimity on the need to improve market surveillance and the system for assessing and monitoring Notified Bodies. Authorities fully support the exercise because it will strengthen the existing system and improve cooperation at EU level. Industry expects a more level playing field resulting from more effective actions against products that do not comply with the legislation, as well as a simplification effect from the alignment of legislation. Certain concerns were expressed on some obligations which are, however, indispensable for increasing the efficiency of market surveillance. These measures will not entail significant costs for industry, and the benefits resulting from improved market surveillance should by far outweigh the costs.

Collection and use of expertise

The impact assessment for this implementation package has largely built on the impact assessment carried out for the New Legislative Framework. In addition to the expertise collected and analysed in that context, further consultation of sector-specific experts and interest groups, as well as horizontal experts active in the area of technical harmonisation, conformity assessment, accreditation and market surveillance, has taken place.

Impact assessment

Based on the information collected, the Commission carried out an impact assessment which examined and compared three options.

Option 1 - No changes to the current situation

This option proposes no changes to the current directive and relies exclusively on certain improvements that can be expected from the NLF Regulation.

Option 2 – Alignment to the NLF Decision by non-legislative measures

Option 2 considers the possibility of encouraging a voluntary alignment to the provisions set out in the NLF Decision by, e.g., presenting them as best practices in guidance documents.

Option 3 – Alignment to NLF Decision by legislative measures

This option consists in integrating the provisions of the NLF Decision into the existing directives.

Option 3 was found to be the preferred option because

– it will improve the competitiveness of companies and notified bodies taking their obligations seriously, as opposed to those cheating on the system;

– it will improve the functioning of the internal market by ensuring equal treatment of all economic operators, notably importers and distributors, as well as notified bodies;

– it does not entail significant costs for economic operators and notified bodies; for those who are already acting responsibly, no extra costs or only negligible costs are expected;

– it is considered more effective than option 2: due to the lack of enforceability of option 2 it is questionable that the positive impacts would materialise under that option;

– options 1 and 2 do not provide answers to the problem of inconsistencies in the regulatory framework and therefore have no positive impact on the simplification of the regulatory environment.

3. MAIN ELEMENTS OF THE PROPOSAL

3.1. Horizontal definitions

The proposal introduces harmonised definitions of terms which are commonly used throughout Union harmonisation legislation and should therefore be given a consistent meaning throughout that legislation.

3.2. Obligations of economic operators and traceability requirements

The proposal clarifies the obligations of manufacturers and authorised representatives and introduces obligations for importers and distributors. Importers must verify that the manufacturer has carried out the applicable conformity assessment procedure and has drawn up a technical documentation. They must also make sure with the manufacturer that this technical documentation can be made available to authorities upon request. Furthermore importers must verify that apparatus are correctly marked and accompanied by the required documentation. They must keep a copy of the Declaration of conformity and indicate their name and address on the product, or where this is not possible on the packaging or the accompanying documentation. Distributors must verify that apparatus bear the CE marking,

the name of the manufacturer and of the importer, if relevant, and that it is accompanied by the required documentation and instructions.

Importers and distributors must cooperate with market surveillance authorities and take appropriate actions when they have supplied non-compliant apparatus.

Enhanced traceability obligations are introduced for all economic operators. Apparatus have to bear the manufacturer's name and address and a number allowing to identify and link the apparatus to its technical documentation. When an apparatus is imported the importer's name and address must also be on the apparatus. Furthermore every economic operator must be able to identify towards authorities the economic operator who has supplied him with an apparatus or to whom he has supplied an apparatus.

3.3. Harmonised standards

Compliance with harmonised standards provides a presumption of conformity with the essential requirements. On 1 June 2011 the Commission adopted a proposal for a Regulation on European Standardisation[2] that sets out a horizontal legal framework for European standardisation. The proposal for the Regulation contains inter alia provisions on standardisation requests from the Commission to the European Standardisation Organisations, on the procedure for objections to harmonised standards and on stakeholder participation in the standardisation process. Consequently the provisions of Directive 2004/108/EC which cover the same aspects have been deleted in this proposal for reasons of legal certainty.

The provision conferring presumption of conformity to harmonised standards has been modified to clarify the extent of the presumption of conformity when standards only partially cover the essential requirements.

3.4. Conformity assessment and CE marking

Directive 2004/108/EC has selected the appropriate conformity assessment procedures which manufacturers have to apply in order to demonstrate that their apparatus comply with the essential requirements. The proposal aligns these procedures to their updated versions set out in the NLF Decision maintaining certain specific elements, regarding to the electromagnetic compatibility conformity assessment. The Directive also introduces a model for the EU Declaration of conformity.

General principles of the CE marking are set out in Article 30 of Regulation 765/2008, while the detailed provisions on the affixing of the CE marking to apparatus have been inserted in this proposal.

3.5. Notified Bodies

The proposal reinforces the notification criteria for notified bodies. It clarifies that subsidiaries or subcontractors must also comply with the notification requirements. Specific requirements for notifying authorities are introduced, and the procedure for notification of

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[2] COM(2011) 315 final: Proposal for a Regulation of the European Parliament and of the Council on European Standardisation and amending Council Directives 89/686/EEC and 93/15/EEC and Directives 94/9/EC, 94/25/EC, 95/16/EC, 97/23/EC, 98/34/EC, 2004/22/EC, 2007/23/EC, 2009/105/EC and 2009/23/EC of the European Parliament and of the Council.

notified bodies is revised. The competence of a notified body must be demonstrated by an accreditation certificate. Where accreditation has not been used to evaluate the competence of a notified body, the notification must comprise the documentation demonstrating how the competence of that body has been evaluated. Member States will have the possibility to object to a notification.

3.6. Market surveillance and the safeguard clause procedure

The proposal revises the existing safeguard clause procedure. It introduces a phase of information exchange between Member States, and specifies the steps to be taken by the authorities concerned, when a non-compliant apparatus is found. A real safeguard clause procedure – leading to a Decision at Commission level on whether a measure is justified or not - is only launched when another Member State objects to a measure taken against an apparatus. Where there is no disagreement on the restrictive measure taken, all Member States must take the appropriate action on their territory.

4. LEGAL ELEMENTS OF THE PROPOSAL

Legal basis

The proposal is based on Article 114 of the Treaty on the Functioning of the European Union.

Subsidiarity principle

The internal market is a competence that is shared between the Union and the Member States. The subsidiarity principle arises in particular with regard to the newly added provisions aiming at the improvement of effective enforcement of Directive 2004/108/EC namely, the importer and distributor obligations, the traceability provisions, the provisions on the assessment and notification of notified bodies, and the enhanced cooperation obligations in the context of the revised market surveillance and safeguard procedures.

Experience with the enforcement of the legislation has shown that measures taken at national level have led to divergent approaches and to a different treatment of economic operators inside the EU, which undermines the objective of this directive. If actions are taken at national level to address the problems, this risks creating obstacles to the free movement of goods. Furthermore action at national level is limited to the territorial competence of a Member State. In view of the increasing internationalisation of trade, the number of cross-border cases is constantly rising. Coordinated action at EU level can much better achieve the objectives set, and will in particular render market surveillance more effective. Hence it is more appropriate to take action at EU level.

As regards the problem of inconsistencies throughout the directives, this is a problem which can only be solved by the EU legislator.

Proportionality

In accordance with the principle of proportionality, the proposed modifications do not go beyond what is necessary to achieve the objectives set.

The new or modified obligations do not impose unnecessary burdens and costs on industry - especially on small and medium sized enterprises - or administrations. Where modifications

have been identified to have negative impacts, the analysis of the impacts of the option serves to provide the most proportionate response to the problems identified. A number of modifications concern the improvement of clarity of the existing Directive without introducing new requirements that entail added cost.

Legislative technique used

The alignment to the NLF Decision requires a number of substantive amendments to the provisions of Directive 2004/108/EC. To ensure the readability of the amended text the technique of recasting has been chosen in line with the Interinstitutional Agreement of 28 November 2001 on a more structured use of the recasting technique for legal acts[3].

The changes made to the provisions of Directive 2004/108/EC concern: the definitions, the obligations of economic operators, the presumption of conformity provided by harmonised standards, the declaration of conformity, CE marking, notified bodies, the safeguard clause procedure and the conformity assessment procedures.

The proposal does not change the scope of Directive 2004/108/EC and the essential requirements.

5. BUDGETARY IMPLICATIONS

This proposal does not have any implications for the EU budget.

6. ADDITIONAL INFORMATION

Repeal of existing legislation

The adoption of the proposal will lead to repeal of Directive 2004/108/EC.

European Economic Area

The proposal concerns the EEA and should therefore be extended to the European Economic Area.

[3] OJ C 77, 28.3.2002, p. 1.

↓ 2004/108 (adapted)

2011/0351 (COD)

Proposal for a

DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on the~~approximation~~ ⌦ harmonisation ⌫ of the laws of the Member States relating to electromagnetic compatibility~~and repealing Directive 89/336/EEC~~

(Recast)

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty ~~establishing the European Community~~, ⌦ on the Functioning of the European Union, ⌫ and in particular Article ~~95~~ ⌦ 114 ⌫ thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national Parliaments,

Having regard to the opinion of the European Economic and Social Committee[4],

Acting in accordance with the ordinary legislative procedure,

Whereas:

↓ 2004/108 recital 1 (adapted)

~~Council Directive 89/336/EEC of 3 May 1989 on the approximation of laws of the Member States relating to electromagnetic compatibility[5] has been the subject of a review under the initiative known as Simpler Legislation for the Internal Market (SLIM). Both the SLIM process and a subsequent in-depth consultation have revealed the need to complete, reinforce and clarify the framework established by Directive 89/336/EEC.~~

4 OJ C 220, 16.9.2003, p. 13.

5 ~~OJ L 139, 23.5.1989, p. 19. Directive as last amended by Directive 93/68/EEC (OJ L 220, 30.8.1993, p. 1).~~

⇩ new

(1) A number of substantive changes are to be made to Directive 2004/108/EC of the European Parliament and of the Council of 15 December 2004 on the approximation of the laws of the Member States relating to electromagnetic compatibility and repealing Directive 89/336/EEC[6]. In the interests of clarity, that Directive should be recast.

(2) Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93[7] lays down rules on the accreditation of conformity assessment bodies, provides a framework for the market surveillance of products and for controls on products from third countries, and lays down the general principles of the CE marking.

(3) Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products, and repealing Council Decision 93/465/EEC[8] lays down a common framework of general principles and reference provisions intended to apply across the legislation harmonising the conditions for the marketing of products in order to provide a coherent basis for revision or recasts of that legislation. Directive 2004/108/EC should therefore be adapted to that Decision.

⇩ 2004/108 recital 2

(4) Member States are responsible for ensuring that radiocommunications, including radio broadcast reception and the amateur radio service operating in accordance with International Telecommunication Union (ITU) radio regulations, electrical supply networks and telecommunications networks, as well as equipment connected thereto, are protected against electromagnetic disturbance.

⇩ 2004/108 recital 3 (adapted)

(5) Provisions of national law ensuring protection against electromagnetic disturbance~~should~~ ⌦ need to ⌫ be harmonised in order to guarantee the free movement of electrical and electronic apparatus without lowering justified levels of protection in the Member States.

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[6] OJ L 390, 31.12.2004, p. 24
[7] OJ L 218, 13.8.2008, p. 30.
[8] OJ L 218, 13.8.2008, p. 82.

↓ 2004/108 recital 4

(6) Protection against electromagnetic disturbance requires obligations to be imposed on the various economic operators. Those obligations should be applied in a fair and effective way in order to achieve such protection.

↓ 2004/108 recital 5

~~The electromagnetic compatibility of equipment should be regulated with a view to ensuring the functioning of the internal market, that is to say, of an area without internal frontiers in which the free movement of goods, persons, services and capital is assured.~~

↓ 2004/108 recital 6 (adapted)

(7) The equipment covered by this Directive should include both apparatus and fixed installations. However, separate provision should be made for each. This is so because, whereas apparatus as such may move freely within the ⌦ Union ⌫ ~~Community~~, fixed installations on the other hand are installed for permanent use at a predefined location, as assemblies of various types of apparatus and, where appropriate, other devices. The composition and function of such installations correspond in most cases to the particular needs of their operators.

↓ 2004/108 recital 7 (adapted)

(8) Radio equipment and telecommunications terminal equipment should not be covered by this Directive since they are already regulated by Directive 1999/5/EC of the European Parliament and of the Council of 9 March 1999 on radio equipment and telecommunications terminal equipment and the mutual recognition of their conformity[9]. The electromagnetic compatibility requirements in both Directives achieve the same level of protection.

↓ 2004/108 recital 8 (adapted)

(9) Aircraft or equipment intended to be fitted into aircraft should not be covered by this Directive, since they are already subject to special ~~Community~~ ⌦ Union ⌫ or international rules governing electromagnetic compatibility.

[9] OJ L 91, 7.4.1999, p. 10. ~~Directive as amended by Regulation (EC) No 1882/2003 (OJ L 284, 31.10.2003, p. 1).~~

↓ 2004/108 recital 9

(10) This Directive need not regulate equipment which is inherently benign in terms of electromagnetic compatibility.

↓ 2004/108 recital 10 (adapted)

(11) This Directive should not deal with the safety of equipment, since that is dealt with by separate ~~Community~~ ⊠ Union ⊠ or national legislation.

↓ 2004/108 recital 11 (adapted)

(12) Where this Directive regulates apparatus, it should refer to finished apparatus ~~commercially available for the first time on the Community~~ ⊠ placed on the ⊠ market. Certain components or sub-assemblies should, under certain conditions, be considered to be apparatus if they are made available to the end-user.

↓ 2004/108 recital 12 (adapted)

~~The principles on which this Directive is based are those set out in the Council Resolution of 7 May 1985 on a new approach to technical harmonization and standards[10]. In accordance with that approach, the design and manufacture of equipment is subject to essential requirements in relation to electromagnetic compatibility. Those requirements are given technical expression by harmonised European standards, to be adopted by the various European standardisation bodies, European Committee for Standardisation (CEN), European Committee for Electro-technical Standardisation (CENELEC) and European Telecommunications Standards Institute (ETSI). CEN, CENELEC and ETSI are recognised as the competent institutions in the field of this Directive for the adoption of harmonised standards, which they draw up in accordance with the general guidelines for cooperation between themselves and the Commission, and with the procedure laid down in 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 and of rules on Information Society services[11].~~

↓ 2004/108 recital 13 (adapted)

~~Harmonised standards reflect the generally acknowledged state of the art as regards electromagnetic compatibility matters in the European Union. It is thus in the interest of the functioning of the internal market to have standards for the electromagnetic compatibility of~~

[10] ~~OJ C 136, 4.6.1985, p. 1.~~

[11] ~~OJ L 204, 21.7.1998, p. 37. Directive as last amended by the 2003 Act of Accession.~~

~~equipment which have been harmonised at Community level. Once the reference to such a standard has been published in the *Official Journal of the European Union*, compliance with it should raise a presumption of conformity with the relevant essential requirements, although other means of demonstrating such conformity should be permitted. Compliance with a harmonised standard means conformity with its provisions and demonstration thereof by the methods the harmonised standard describes or refers to.~~

↓ 2004/108 recital 14

(13) Manufacturers of equipment intended to be connected to networks should construct such equipment in a way that prevents networks from suffering unacceptable degradation of service when used under normal operating conditions. Network operators should construct their networks in such a way that manufacturers of equipment liable to be connected to networks do not suffer a disproportionate burden in order to prevent networks from suffering an unacceptable degradation of service. The European standardisation organisations should take due account of that objective (including the cumulative effects of the relevant types of electromagnetic phenomena) when developing harmonised standards.

↓ 2004/108 recital 15 (adapted)

~~It should be possible to place apparatus on the market or put it into service only if the manufacturers concerned have established that such apparatus has been designed and manufactured in conformity with the requirements of this Directive. Apparatus placed on the market should bear the 'CE' marking attesting to compliance with this Directive. Although conformity assessment should be the responsibility of the manufacturer, without any need to involve an independent conformity assessment body, manufacturers should be free to use the services of such a body.~~

⇩ new

(14) Economic operators should be responsible for the compliance of products, in relation to their respective roles in the supply chain, so as to ensure a high level of protection of public interests, and the protection of end-users, and to guarantee fair competition on the Union market.

(15) All economic operators intervening in the supply and distribution chain should take appropriate measures to ensure that they only make available on the market products which are in conformity with this Directive. It is necessary to provide for a clear and proportionate distribution of obligations which correspond to the role of each operator in the supply and distribution process.

(16) The manufacturer, having detailed knowledge of the design and production process, is best placed to carry out the complete conformity assessment procedure. Conformity assessment should therefore remain the obligation of the manufacturer alone.

(17) It is necessary to ensure that products from third countries entering the Union market comply with the requirements of this Directive, and in particular that appropriate assessment procedures have been carried out by manufacturers with regard to those products. Provision should therefore be made for importers to make sure that the products they place on the market comply with the requirements of this Directive and that they do not place on the market products which do not comply with such requirements or present a risk. Provision should also be made for importers to make sure that conformity assessment procedures have been carried out and that product marking and documentation drawn up by manufacturers are available for inspection by the supervisory authorities.

(18) The distributor makes a product available on the market after it has been placed on the market by the manufacturer or the importer and should act with due care to ensure that its handling of the product does not adversely affect the compliance of the product.

(19) When placing a product on the market, every importer should indicate on the product his name and the address at which he can be contacted. Exceptions should be provided for in cases where the size or nature of the product does not allow it. This includes cases where the importer would have to open the packaging to put his name and address on the product.

(20) Any economic operator that either places a product on the market under his own name or trademark or modifies a product in such a way that compliance with the requirements of this Directive may be affected should be considered to be the manufacturer and should assume the obligations of the manufacturer.

(21) Distributors and importers, being close to the market place, should be involved in market surveillance tasks carried out by the competent national authorities, and should be prepared to participate actively, providing those authorities with all necessary information relating to the product concerned.

(22) Ensuring traceability of a product throughout the whole supply chain helps to make market surveillance simpler and more efficient. An efficient traceability system facilitates market surveillance authorities' task of tracing economic operators who made non-compliant products available on the market.

↓ 2004/108 recital 18 (adapted)

(23) Fixed installations, including large machines and networks, may generate electromagnetic disturbance, or be affected by it. There may be an interface between fixed installations and apparatus, and the electromagnetic disturbances produced by fixed installations may affect apparatus, and vice versa. In terms of electromagnetic compatibility, it is irrelevant whether the electromagnetic disturbance is produced by apparatus or by a fixed installation. Accordingly, fixed installations and apparatus should be subject to a coherent and comprehensive regime of essential requirements. ~~It should be possible to use harmonised standards for fixed installations in order to demonstrate conformity with the essential requirements covered by such standards.~~

⇩ new

(24) This Directive should be limited to the expression of the essential requirements. In order to facilitate conformity assessment with those requirements it is necessary to provide for presumption of conformity for equipment which is in conformity with harmonised standards that are adopted in accordance with Regulation (EU) No [../..] of the European Parliament and of the Council of […..] on European Standardisation and amending Council Directives 89/686/EEC and 93/15/EEC and Directives 94/9/EC, 94/25/EC, 95/16/EC, 97/23/EC, 98/34/EC, 2004/22/EC, 2007/23/EC, 2009/105/EC and 2009/23/EC of the European Parliament and of the Council[12] for the purpose of expressing detailed technical specifications of those requirements.

(25) Regulation (EU) No [../..] [on European Standardisation] provides for a procedure for objections to harmonised standards where those standards do not entirely satisfy the requirements of this Directive.

(26) In order to enable economic operators to demonstrate and the competent authorities to ensure that products made available on the market conform to the essential requirements it is necessary to provide for conformity assessment procedures. Decision No 768/2008/EC establishes modules for conformity assessment procedures, which include procedures from the least to the most stringent, in proportion to the level of risk involved and the level of safety required. In order to ensure inter-sectoral coherence and to avoid ad-hoc variants, conformity assessment procedures should be chosen from among those modules.

⇩ 2004/108 recital 16

(27) The conformity assessment obligation should require the manufacturer to perform an electromagnetic compatibility assessment of apparatus, based on relevant phenomena, in order to determine whether or not it meets the protection requirements under this Directive.

⇩ 2004/108 recital 17

(28) Where apparatus is capable of taking different configurations, the electromagnetic compatibility assessment should confirm whether the apparatus meets the protection requirements in the configurations foreseeable by the manufacturer as representative of normal use in the intended applications. ~~.~~ ~~I~~In such cases it should be sufficient to perform an assessment on the basis of the configuration most likely to cause maximum disturbance and the configuration most susceptible to disturbance.

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[12] OJ L […], […], p. […]

↓ 2004/108 recital 20

(29) It is not pertinent to carry out the conformity assessment of apparatus placed on the market for incorporation into a given fixed installation, and otherwise not commercially available, in isolation from the fixed installation into which it is to be incorporated. Such apparatus should therefore be exempted from the conformity assessment procedures normally applicable to apparatus. However, such apparatus should not be permitted to compromise the conformity of the fixed installation into which it is incorporated. Should apparatus be incorporated into more than one identical fixed installation, identifying the electromagnetic compatibility characteristics of these installations should be sufficient to ensure exemption from the conformity assessment procedure.

⇩ new

(30) Manufacturers should draw up an EU declaration of conformity to provide detailed information on the conformity of an apparatus with the requirements of this Directive and of the other relevant Union harmonisation legislation.

(31) The CE marking, indicating the conformity of a product, is the visible consequence of a whole process comprising conformity assessment in a broad sense. General principles governing the CE marking are set out in Regulation (EC) No 765/2008. Rules governing the affixing of the CE marking should be laid down in this Directive.

↓ 2004/108 recital 19 (adapted)

(32) Due to their specific characteristics, fixed installations need not be subject to the~~affixation~~ ⌦ affixing ⌫ of the 'CE' marking or to the ⌦ EU ⌫ declaration of conformity.

⇩ new

(33) One of the conformity assessment procedures set out in this Directive requires the intervention of conformity assessment bodies, which are notified by the Member States to the Commission.

(34) Experience has shown that the criteria set out in Directive 2004/108/EC that conformity assessment bodies have to fulfil to be notified to the Commission are not sufficient to ensure a uniformly high level of performance of notified bodies throughout the Union. It is, however, essential that all notified bodies perform their functions to the same level and under conditions of fair competition. That requires the setting of obligatory requirements for conformity assessment bodies wishing to be notified in order to provide conformity assessment services.

(35) In order to ensure a consistent level of conformity assessment quality it is also necessary to set requirements for notifying authorities and other bodies involved in the assessment, notification and monitoring of notified bodies.

(36) If a conformity assessment body demonstrates conformity with the criteria laid down in harmonised standards, it should be presumed to comply with the corresponding requirements set out in this Directive.

(37) The system set out in this Directive should be complemented by the accreditation system provided for in Regulation (EC) No 765/2008. Since accreditation is an essential means of verifying the competence of conformity assessment bodies, it should also be used for the purposes of notification.

(38) Transparent accreditation as provided for in Regulation (EC) No 765/2008, ensuring the necessary level of confidence in conformity certificates, should be considered by the national public authorities throughout the Union as the preferred means of demonstrating the technical competence of conformity assessment bodies. However, national authorities may consider that they possess the appropriate means of carrying out this evaluation themselves. In such cases, in order to ensure the appropriate level of credibility of evaluations carried out by other national authorities, they should provide the Commission and the other Member States with the necessary documentary evidence demonstrating the compliance of the conformity assessment bodies evaluated with the relevant regulatory requirements.

(39) Conformity assessment bodies frequently subcontract parts of their activities linked to the assessment of conformity or have recourse to a subsidiary. In order to safeguard the level of protection required for the products to be placed on the Union market, it is essential that conformity assessment subcontractors and subsidiaries fulfil the same requirements as notified bodies in relation to the performance of conformity assessment tasks. Therefore, it is important that the assessment of the competence and the performance of bodies to be notified and the monitoring of bodies already notified cover also activities carried out by subcontractors and subsidiaries.

(40) It is necessary to increase the efficiency and transparency of the notification procedure and, in particular, to adapt it to new technologies so as to enable online notification.

(41) Since notified bodies may offer their services throughout the Union, it is appropriate to give the other Member States and the Commission the opportunity to raise objections concerning a notified body. It is therefore important to provide for a period during which any doubts or concerns as to the competence of conformity assessment bodies can be clarified before they start operating as notified bodies.

(42) In the interests of competitiveness, it is crucial that notified bodies apply the conformity assessment procedures without creating unnecessary burdens for economic operators. For the same reason, and to ensure equal treatment of economic operators, consistency in the technical application of the conformity assessment procedures needs to be ensured. That can best be achieved through appropriate coordination and cooperation between notified bodies.

(43) In order to ensure legal certainty, it is necessary to clarify that rules on Union market surveillance and control of products entering the Union market provided for in

Regulation (EC) No 765/2008 apply to equipment covered by this Directive. This Directive should not prevent Member States from choosing the competent authorities to carry out those tasks.

(44) Directive 2004/108/EC already provides for a safeguard procedure. In order to increase transparency and to reduce processing time, it is necessary to improve the existing safeguard clause procedure, with a view to making it more efficient and drawing on the expertise available in Member States.

(45) The existing system should be supplemented by a procedure under which interested parties are informed of measures intended to be taken with regard to products presenting a risk to aspects of public interest protection. It should also allow market surveillance authorities, in cooperation with the relevant economic operators, to act at an earlier stage in respect of such products.

(46) Where the Member States and the Commission agree as to the justification of a measure taken by a Member State, no further involvement of the Commission should be required, except where non-compliance can be attributed to shortcomings of a harmonised standard.

(47) The Member States should lay down rules on penalties applicable to infringements of the national provisions adopted pursuant to this Directive and ensure that they are implemented. Those penalties should be effective, proportionate and dissuasive.

(48) It is necessary to provide for transitional arrangements that allow making available on the market and putting into service of apparatus that has already been placed on the market in accordance with Directive 2004/108/EC.

↓ 2004/108 recital 22 (adapted)

(49) Since the objective of this Directive, namely to ensure the functioning of the internal market by requiring equipment to comply with an adequate level of electromagnetic compatibility, cannot be sufficiently achieved by Member States and can therefore, by reason of its scale and effects, be better achieved at ~~Community~~ ⌦ Union ⌫ level, the ~~Community~~ ⌦ Union ⌫ may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty ⌦ on European Union ⌫ . In accordance with the principle of proportionality, as set out in that Article, this Directive does not go beyond what is necessary in order to achieve that objective.

⇩ new

(50) The obligation to transpose this Directive into national law should be confined to those provisions which represent a substantive change as compared with Directive 2004/108/EC. The obligation to transpose the provisions which are unchanged arises under Directive 2004/108/EC.

(51) This Directive should be without prejudice to the obligations of the Member States relating to the time-limits for transposition into national law and application of Directive 2004/108/EC set out in Annex V.

↓ 2004/108 recital 21 (adapted)

~~A transitional period is necessary in order to ensure that manufacturers and other concerned parties are able to adapt to the new regulatory regime.~~

↓ 2004/108 (adapted)

HAVE ADOPTED THIS DIRECTIVE:

CHAPTER 1~~I~~

GENERAL PROVISIONS

Article 1

Subject matter ~~*and scope*~~

↓ 2004/108

~~1.~~This Directive regulates the electromagnetic compatibility of equipment. It aims to ensure the functioning of the internal market by requiring equipment to comply with an adequate level of electromagnetic compatibility.

↓ 2004/108 (adapted)

Article 2

⌦ *Scope* ⌫

1. This Directive ~~applies~~ ⌦ shall apply ⌫ to equipment as defined in Article ~~2~~3.

2. This Directive shall not apply to ⌦ the following ⌫ :

↓ 2004/108

(a) equipment covered by Directive 1999/5/EC;

(b) aeronautical products, parts and appliances as referred to in Regulation (EC) No ~~1592/2002~~ 216/2008 of the European Parliament and of the Council[13] ~~of 15 July 2002 on common rules in the field of civil aviation and establishing a European Aviation Safety Agency~~[14];

↓ 2004/108 (adapted)

(c) radio equipment used by radio amateurs within the meaning of the Radio Regulations adopted in the framework of the Constitution ⌦ of the International Telecommunication Union ⌫ and ⌦ the ⌫ Convention of the ~~ITU~~ ⌦ International Telecommunication Union ⌫[15], unless the equipment is available commercially~~.~~; ~~Kits of components to be assembled by radio amateurs and commercial equipment modified by and for the use of radio amateurs are not regarded as commercially available equipment.~~

(d) ~~3. This Directive shall not apply to~~ equipment the inherent nature of the physical characteristics of which is such that:

↓ 2004/108

(~~a~~i) it is incapable of generating or contributing to electromagnetic emissions which exceed a level allowing radio and telecommunication equipment and other equipment to operate as intended; and

↓ 2004/108 (adapted)

(~~b~~ii) it ~~will operate~~ ⌦ operates ⌫ without unacceptable degradation in the presence of the electromagnetic disturbance normally consequent upon its intended use.

⌦ For the purposes of point (c) of the first subparagraph, kits of components to be assembled by radio amateurs and commercial equipment modified by and for the use of radio amateurs are not regarded as commercially available equipment. ⌫

13 OJ L 79, 19.3.2008, p. 1

14 ~~OJ L 240, 7.9.2002, p. 1. Regulation as amended by Commission Regulation (EC) No 1701/2003 (OJ L 243, 27.9.2003, p. 5).~~

15 Constitution and Convention of the International Telecommunication Union adopted by the Additional Plenipotentiary Conference (Geneva, 1992) as amended by the Plenipotentiary Conference (Kyoto, 1994).

~~4~~3. Where, for the equipment referred to in paragraph 1, the essential requirements ~~referred to~~ ⌦ set out ⌫ in Annex I are wholly or partly laid down more specifically by other ⌦ Union ⌫ ~~Community~~ directives, this Directive shall not apply, or shall cease to apply, to that equipment in respect of such requirements from the date of implementation of those directives.

↓ 2004/108 (adapted)

~~5~~4. This Directive shall not affect the application of ⌦ Union ⌫ ~~Community~~ or national legislation regulating the safety of equipment.

Article~~3~~2 [Article R1 of Decision No 768/2008/EC]

Definitions

↓ 2004/108 (adapted)

For the purposes of this Directive, the following definitions ~~shall~~ apply:

↓ 2004/108

(~~a~~1) ‘equipment’ means any apparatus or fixed installation;

(~~b~~2) ‘apparatus’ means any finished appliance or combination thereof made commercially available as a single functional unit, intended for the end user and liable to generate electromagnetic disturbance, or the performance of which is liable to be affected by such disturbance;

(~~c~~3) ‘fixed installation’ means a particular combination of several types of apparatus and, where applicable, other devices, which are assembled, installed and intended to be used permanently at a predefined location;

(~~d~~4) ‘electromagnetic compatibility’ means the ability of equipment to function satisfactorily in its electromagnetic environment without introducing intolerable electromagnetic disturbances to other equipment in that environment;

↓ 2004/108 (adapted)

(~~e~~5) ‘electromagnetic disturbance’ means any electromagnetic phenomenon which may degrade the performance of equipment⌦ , including, ⌫ ~~. An electromagnetic disturbance may be~~ electromagnetic noise, an unwanted signal or a change in the propagation medium itself;

↓ 2004/108

(~~f~~6) 'immunity' means the ability of equipment to perform as intended without degradation in the presence of an electromagnetic disturbance;

(~~g~~7) 'safety purposes' means the purposes of safeguarding human life or property;

(~~h~~8) 'electromagnetic environment' means all electromagnetic phenomena observable in a given location~~.~~;

⇩ new

(9) 'making available on the market' means any supply of apparatus for distribution, consumption or use on the Union market in the course of a commercial activity, whether in return for payment or free of charge;

(10) 'placing on the market' means the first making available of apparatus on the Union market;

(11) 'manufacturer' means any natural or legal person who manufactures apparatus or has apparatus designed or manufactured, and markets that apparatus under his name or trademark;

(12) 'authorised representative' means any natural or legal person established within the Union who has received a written mandate from a manufacturer to act on his behalf in relation to specified tasks;

(13) 'importer' means any natural or legal person established within the Union who places apparatus from a third country on the Union market;

(14) 'distributor' means any natural or legal person in the supply chain, other than the manufacturer or the importer, who makes apparatus available on the market;

(15) 'economic operators' means the manufacturer, the authorised representative, the importer and the distributor;

(16) 'technical specification' means a document that prescribes technical requirements to be fulfilled by the equipment;

(17) 'harmonised standard' means harmonised standard as defined in Article 2(1)(c) of Regulation (EU) No [../..] [on European Standardisation];

(18) 'accreditation' means accreditation as defined in Article 2(10) of Regulation (EC) No 765/2008;

(19) 'national accreditation body' means national accreditation body as defined in Article 2(11) of Regulation (EC) No 765/2008;

(20) 'conformity assessment' means the process demonstrating whether the requirements relating to an apparatus have been fulfilled;

(21) 'conformity assessment body' means a body that performs conformity assessment activities including calibration, testing, certification and inspection;

(22) 'recall' means any measure aimed at achieving the return of apparatus that has already been made available to the end user;

(23) 'withdrawal' means any measure aimed at preventing apparatus in the supply chain from being made available on the market;

(24) 'CE marking' means a marking by which the manufacturer indicates that the apparatus is in conformity with the applicable requirements set out in Union harmonisation legislation providing for its affixing;

(25) 'Union harmonisation legislation' means any Union legislation harmonising the conditions for the marketing of products.

↓ 2004/108 (adapted)

~~2.~~ For the purposes of ~~this Directive~~ ⌦ point (2) of the first subparagraph ⌫ the following shall be ~~deemed to be~~ ⌦ considered ⌫ an apparatus ~~within the meaning of paragraph 1(b)~~ :

↓ 2004/108 (adapted)
⇨ new

(a)‘components’ or ‘sub-assemblies’ intended for incorporation into an apparatus by the end user, which are liable to generate electromagnetic disturbance, or the performance of which is liable to be affected by such disturbance;

(b)‘mobile installations’ defined as a combination of apparatus and, where applicable, other devices, intended to be moved and operated in a range of locations.

Article 4~~3~~

~~Placing~~ ⇨ Making available ⇦ on the market and/or putting into service

Member States shall take all appropriate measures to ensure that equipment is ~~placed~~ ⇨ made available ⇦ on the market and/or put into service only if it complies with the requirements of this Directive when properly installed, maintained and used for its intended purpose.

Article ~~5~~4

Free movement of equipment

1. Member States shall not impede, for reasons relating to electromagnetic compatibility, the ~~placing~~ ⇨ making available ⇦ on the market and/or the putting into service in their territory of equipment which complies with this Directive.

2. The requirements of this Directive shall not prevent the application in any Member State of the following special measures concerning the putting into service or use of equipment:

(a) measures to overcome an existing or predicted electromagnetic compatibility problem at a specific site;

(b) measures taken for safety reasons to protect public telecommunications networks or receiving or transmitting stations when used for safety purposes in well-defined spectrum situations.

Without prejudice to Directive 98/34/EC, Member States shall notify those special measures to the Commission and to the other Member States.

The special measures which have been accepted shall be published by the Commission in the *Official Journal of the European Union*.

3. Member States shall not create any obstacles to the display and/or demonstration at trade fairs, exhibitions or similar events of equipment which does not comply with this Directive, provided that a visible sign clearly indicates that such equipment may not be ~~placed~~ ⇨ made available ⇦ on the market and/or put into service until it has been brought into conformity with this Directive. Demonstration may only take place provided that adequate measures are taken to avoid electromagnetic disturbances.

Article ~~6~~5

Essential requirements

🡻 2004/108 (adapted)

The equipment ~~referred to in Article 1~~ shall meet the essential requirements set out in Annex I.

⇩ new

CHAPTER 2

OBLIGATIONS OF ECONOMIC OPERATORS

Article 7 [Article R2 of Decision No 768/2008/EC]

Obligations of manufacturers

1. When placing their apparatus on the market and/or putting them into service, manufacturers shall ensure that they have been designed and manufactured in accordance with the essential requirements set out in Annex I.

2. Manufacturers shall draw up the technical documentation referred to in Annex II and Annex III and carry out the conformity assessment procedure referred to in Article 15 or have it carried out.

Where compliance of apparatus with the applicable requirements has been demonstrated by that procedure, manufacturers shall draw up an EU declaration of conformity and affix the CE marking.

3. Manufacturers shall keep the technical documentation and the EU declaration of conformity for 10 years after the apparatus has been placed on the market.

4. Manufacturers shall ensure that procedures are in place for series production to remain in conformity. Changes in apparatus design or characteristics and changes in the harmonised standards or in technical specifications by reference to which conformity of apparatus is declared shall be adequately taken into account.

5. Manufacturers shall ensure that their apparatus bear a type, batch or serial number or other element allowing their identification, or, where the size or nature of the apparatus does not allow it, that the required information is provided on the packaging or in a document accompanying the apparatus.

6. Manufacturers shall indicate their name, registered trade name or registered trade mark and the address at which they can be contacted on the apparatus or, where that is not possible, on its packaging or in a document accompanying the apparatus. The address must indicate a single point at which the manufacturer can be contacted.

7. Manufacturers shall ensure that the apparatus is accompanied by instructions and other information referred to in Article 18 in a language which can be easily understood by consumers and other end-users, as determined by the Member State concerned.

8. Manufacturers who consider or have reason to believe that apparatus which they have placed on the market and/or put into service is not in conformity with this Directive shall

immediately take the necessary corrective measures to bring that apparatus into conformity, to withdraw it or recall it, if appropriate. Furthermore, where the apparatus presents a risk, manufacturers shall immediately inform the competent national authorities of the Member States in which they made the apparatus available and/or put it into service to that effect, giving details, in particular, of the non-compliance and of any corrective measures taken.

9. Manufacturers shall, further to a reasoned request from a competent national authority, provide it with all the information and documentation necessary to demonstrate the conformity of the apparatus, in a language which can be easily understood by that authority. They shall cooperate with that authority, at its request, on any action taken to eliminate the risks posed by apparatus which they have placed on the market and/or put into service.

Article 8 [Article R3 of Decision No 768/2008/EC]

Authorised representatives

1. A manufacturer may, by a written mandate, appoint an authorised representative.

The obligations laid down in Article 7(1) and the drawing up of technical documentation shall not form part of the authorised representative's mandate.

2. An authorised representative shall perform the tasks specified in the mandate received from the manufacturer. The mandate shall allow the authorised representative to do at least the following:

(a) keep the EU declaration of conformity and the technical documentation at the disposal of national surveillance authorities for 10 years after the apparatus has been placed on the market;

(b) further to a reasoned request from a competent national authority, provide that authority with all the information and documentation necessary to demonstrate the conformity of the apparatus;

(c) cooperate with the competent national authorities, at their request, on any action taken to eliminate the risks posed by the apparatus covered by the authorised representative's mandate.

Article 9 [Article R4 of Decision No 768/2008/EC]

Obligations of importers

1. Importers shall place only compliant apparatus on the market.

2. Before placing apparatus on the market importers shall ensure that the appropriate conformity assessment procedure has been carried out by the manufacturer. They shall ensure that the manufacturer has drawn up the technical documentation, that the apparatus bears the CE marking and is accompanied by the required documents, and that the manufacturer has complied with the requirements set out in Article 7(5) and (6).

Where an importer considers or has reason to believe that apparatus is not in conformity with essential requirements set out in Annex I, he shall not place the apparatus on the market until it has been brought into conformity. Furthermore, where the apparatus presents a risk, the importer shall inform the manufacturer and the market surveillance authorities to that effect.

3. Importers shall indicate their name, registered trade name or registered trade mark and the address at which they can be contacted on the apparatus or, where that is not possible, on its packaging or in a document accompanying the apparatus.

4. Importers shall ensure that the apparatus is accompanied by instructions and other information referred to in Article 18 in a language which can be easily understood by consumers and other end-users, as determined by the Member State concerned.

5. Importers shall ensure that, while apparatus is under their responsibility, storage or transport conditions do not jeopardise its compliance with the essential requirements set out in Annex I.

6. Importers who consider or have reason to believe that apparatus which they have placed on the market is not in conformity with the requirements of this Directive shall immediately take the corrective measures necessary to bring that apparatus into conformity, to withdraw it or recall it, if appropriate. Furthermore, where the apparatus presents a risk, importers shall immediately inform the competent national authorities of the Member States in which they made the apparatus available to that effect, giving details, in particular, of the non-compliance and of any corrective measures taken.

7. Importers shall, for 10 years after the apparatus has been placed on the market, keep a copy of the EU declaration of conformity at the disposal of the market surveillance authorities and ensure that the technical documentation can be made available to those authorities, upon request.

8. Importers shall, further to a reasoned request from a competent national authority, provide it with all the information and documentation necessary to demonstrate the conformity of apparatus in a language which can be easily understood by that authority. They shall cooperate with that authority, at its request, on any action taken to eliminate the risks posed by apparatus which they have placed on the market.

Article 10 [Article R5 of Decision No 768/2008/EC]

Obligations of distributors

1. When making apparatus available on the market distributors shall act with due care in relation to the requirements of this Directive.

2. Before making apparatus available on the market distributors shall verify that the apparatus bears the CE marking, that it is accompanied by the required documents and by instructions and other information referred to in Article 18 in a language which can be easily understood by consumers and other end-users in the Member State in which the apparatus is to be made available on the market and/or to be put into service, and that the manufacturer and the importer have complied with the requirements set out in Article 7(5) and (6) and Article 9(3).

Where a distributor considers or has reason to believe that apparatus is not in conformity with the essential requirements set out in Annex I, he shall not make the apparatus available on the market until it has been brought into conformity. Furthermore, where the apparatus presents a risk, the distributor shall inform the manufacturer or the importer to that effect as well as the market surveillance authorities.

3. Distributors shall ensure that, while apparatus is under their responsibility, storage or transport conditions do not jeopardise its compliance with the essential requirements set out in Annex I.

4. Distributors who consider or have reason to believe that apparatus which they have made available on the market is not in conformity with the requirements of this Directive shall make sure that the corrective measures necessary to bring that apparatus into conformity, to withdraw it or recall it, if appropriate, are taken. Furthermore, where the apparatus presents a risk, distributors shall immediately inform the competent national authorities of the Member States in which they made the apparatus available to that effect, giving details, in particular, of the non-compliance and of any corrective measures taken.

5. Distributors shall, further to a reasoned request from a competent national authority, provide it with all the information and documentation necessary to demonstrate the conformity of the apparatus. They shall cooperate with that authority, at its request, on any action taken to eliminate the risks posed by apparatus which they have made available on the market.

Article 11 [Article R6 of Decision No 768/2008/EC]

Cases in which obligations of manufacturers apply to importers and distributors

An importer or distributor shall be considered a manufacturer for the purposes of this Directive and he shall be subject to the obligations of the manufacturer under Article 7, where he places apparatus on the market under his name or trademark or modifies apparatus already placed on the market in such a way that compliance with the requirements of this Directive may be affected.

Article 12 [Article R7 of Decision No 768/2008/EC]

Identification of economic operators

Economic operators shall, on request, identify the following to the market surveillance authorities:

(a) any economic operator who has supplied them with apparatus;

(b) any economic operator to whom they have supplied apparatus.

Economic operators shall be able to present the information referred to in the first paragraph for a period of 10 years after they have been supplied with the apparatus and for a period of 10 years after they have supplied the apparatus.

↓ 2004/108 (adapted)

CHAPTER 3~~III~~

⌦ CONFORMITY OF EQUIPMENT ⌫

Article ~~6~~13 [Article R8 of Decision No 768/2008/EC]

~~Harmonised standards~~ ⌦ Presumption of conformity ⌫

↓ 2004/108

~~1. 'Harmonised standard' means a technical specification adopted by a recognised European standardisation body under a mandate from the Commission in conformity with the procedures laid down in Directive 98/34/EC for the purpose of establishing a European requirement. Compliance with a 'harmonised standard' is not compulsory.~~

↓ 2004/108 (adapted)

~~2. The compliance of e~~Equipment ⌦ which is in conformity ⌫ with ~~the relevant~~ harmonised standards ⌦ or parts thereof the ⌫ ~~whose~~ references ⌦ of which ⌫ have been published in the Official Journal of the European Union shall ⌦ be presumed to be in ⌫ ~~raise a presumption, on the part of the Member States, of~~ conformity with the essential requirements ⌦ covered by those standards or parts thereof, set out ⌫ ~~referred to~~ in Annex I ~~to which such standards relate~~. ~~This presumption of conformity is limited to the scope of the harmonised standard(s) applied and the relevant essential requirements covered by such harmonised standard(s).~~

~~3. Where a Member State or the Commission considers that a harmonised standard does not entirely satisfy the essential requirements referred to in Annex I, it shall bring the matter before the Standing Committee set up by Directive 98/34/EC (hereinafter 'the Committee'), stating its reasons. The Committee shall deliver an opinion without delay.~~

~~4. Upon receipt of the Committee's opinion, the Commission shall take one of the following decisions with regard to the references to the harmonised standard concerned:~~

~~(a) not to publish;~~

~~(b) to publish with restrictions;~~

~~(c) to maintain the reference in the *Official Journal of the European Union*;~~

~~(d) to withdraw the reference from the *Official Journal of the European Union*.~~

~~The Commission shall inform the Member States of its decision without delay.~~

⇩ new

[Where a harmonised standard satisfies the requirements which it covers and which are set out in Annex I or Article 24, the Commission shall publish the references of those standards in the Official Journal of the European Union.]

🡻 2004/108 (adapted)

Article 14~~7~~

Conformity assessment procedure for apparatus

Compliance of apparatus with the essential requirements ~~referred to~~ ⌦ set out ⌫ in Annex I shall be demonstrated by means of ~~the procedure~~ ⌦ either of the following procedures ⌫: ~~described in Annex II (internal production control). However, at the discretion of the manufacturer or of his authorised representative in the Community, the procedure described in Annex III may also be followed.~~

⌦ (a) internal production control set out in Annex II; ⌫

⌦ (b) EU type examination that is followed by Conformity to type based on internal production control set out in Annex III. ⌫

🡻 2004/108

~~*Article 8*~~

~~**'CE' marking**~~

~~1. Apparatus whose compliance with this Directive has been established by means of the procedure laid down in Article 7 shall bear the 'CE' marking which attests to that fact. The affixing of the 'CE' marking shall be the responsibility of the manufacturer or his authorised representative in the Community. The 'CE' marking shall be affixed in accordance with Annex V~~

~~2. Member States shall take the necessary measures to prohibit the affixing to the apparatus, or to its packaging, or to the instructions for its use, of marks which are likely to mislead third parties in relation to the meaning and/or graphic form of the 'CE' marking~~

~~3. Any other mark may be affixed to the apparatus, its packaging, or the instructions for its use, provided that neither the visibility nor the legibility of the 'CE' marking is thereby impaired~~

~~4. Without prejudice to Article 10, if a competent authority establishes that the 'CE' marking has been unduly affixed, the manufacturer or his authorised representative in the Community shall bring the apparatus into conformity with the provisions concerning the 'CE' marking under conditions imposed by the Member State concerned~~

⇩ new

Article 15 [Article R10 of Decision No 768/2008/EC]

EU declaration of conformity

1. The EU declaration of conformity shall state that the fulfilment of the essential requirements set out in Annex I has been demonstrated.

2. The EU declaration of conformity shall have the model structure set out in Annex IV to this Directive and it shall be continuously updated. It shall be translated into the language or languages required by the Member State in which market the apparatus is placed or made available.

3. Where apparatus is subject to more than one Union act requiring an EU declaration of conformity, a single EU declaration of conformity shall be drawn up in respect of all such Union acts. That declaration shall contain the identification of the acts concerned including the publication references.

4. By drawing up the EU declaration of conformity, the manufacturer shall assume responsibility for the compliance of the apparatus.

Article 16 [Article R11 of Decision No 768/2008/EC]

General principles of the CE marking

The CE marking shall be subject to the general principles set out in Article 30 of Regulation (EC) No 765/2008.

Article 17 [Article R12 of Decision No 768/2008/EC]

Rules and conditions for affixing the CE marking

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

2. The CE marking shall be affixed before the apparatus is placed on the market.

↓ 2004/108 (adapted)

Article 18~~9~~

Other ~~marks and~~ information

↓ 2004/108

~~1. Each apparatus shall be identified in terms of type, batch, serial number or any other information allowing for the identification of the apparatus.~~

~~2. Each apparatus shall be accompanied by the name and address of the manufacturer and, if he is not established within the Community, the name and address of his authorised representative or of the person in the Community responsible for placing the apparatus on the Community market.~~

↓ 2004/108 (adapted)

1~~3~~. The manufacturer shall provide information on any specific precautions that must be taken when the apparatus is assembled, installed, maintained or used, in order to ensure that, when put into service, the apparatus is in conformity with the ~~protection~~ ⌦ essential ⌫ requirements set out in ~~Annex I,~~ point 1 of Annex I.

2~~4~~. Apparatus for which compliance with the ~~protection~~ ⌦ essential ⌫ requirements ⌦ set out in point 1 of Annex I ⌫ is not ensured in residential areas shall be accompanied by a clear indication of ~~this~~ ⌦ such ⌫ restriction of use, where appropriate also on the packaging.

3~~5~~. The information required to enable apparatus to be used in accordance with the intended purpose of the apparatus shall be ~~contained~~ ⌦ included ⌫ in the instructions accompanying the apparatus.

↓ 2004/108

~~*Article 10*~~

~~**Safeguards**~~

~~1. Where a Member State ascertains that apparatus bearing the 'CE' marking does not comply with the requirements of this Directive, it shall take all appropriate measures to withdraw the apparatus from the market, to prohibit its placing on the market or its putting into service, or to restrict the free movement thereof.~~

2. The Member State concerned shall immediately inform the Commission and the other Member States of any such measure, indicating the reasons and specifying, in particular, whether non-compliance is due to:

(a) failure to satisfy the essential requirements referred to in Annex I, where the apparatus does not comply with the harmonised standards referred to in Article 6;

(b) incorrect application of the harmonised standards referred to in Article 6;

(c) shortcomings in the harmonised standards referred to in Article 6.

3. The Commission shall consult the parties concerned as soon as possible, following which it shall inform the Member States whether or not it finds the measure to be justified.

4. Where the measure referred to in paragraph 1 is attributed to a shortcoming in harmonised standards, the Commission, after consulting the parties, shall, if the Member State concerned intends to uphold the measure, bring the matter before the Committee and initiate the procedure laid down in Article 6(3) and (4).

5. Where the non-compliant apparatus has been subject to the conformity assessment procedure referred to in Annex III, the Member State concerned shall take appropriate action in respect of the author of the statement referred to in Annex III, point 3, and shall inform the Commission and the other Member States accordingly.

Article 11

Decisions to withdraw, prohibit or restrict the free movement of apparatus

1. Any decision taken pursuant to this Directive to withdraw apparatus from the market, prohibit or restrict its placing on the market or its putting into service, or restrict the free movement thereof, shall state the exact grounds on which it is based. Such decisions shall be notified without delay to the party concerned, who shall at the same time be informed of the remedies available to him under the national law in force in the Member State in question and of the time limits to which such remedies are subject.

2. In the event of a decision as referred to in paragraph 1, the manufacturer, his authorised representative, or any other interested party shall have the opportunity to put forward his point of view in advance, unless such consultation is not possible because of the urgency of the measure to be taken as justified in particular with respect to public interest requirements.

Article 12

Notified bodies

1. Member States shall notify the Commission of the bodies which they have designated to carry out the tasks referred to in Annex III. When determining the bodies to be designated, Member States shall apply the criteria laid down in Annex VI.

Such notification shall state whether the bodies are designated to carry out the tasks referred to in Annex III for all apparatus covered by this Directive, and/or the essential requirements

~~referred to in Annex I or whether the scope of designation is limited to certain specific aspects and/or categories of apparatus.~~

~~2. Bodies which comply with the assessment criteria established by the relevant harmonised standards shall be presumed to comply with the criteria set out in Annex VI covered by such harmonised standards. The Commission shall publish in the *Official Journal of the European Union* the references of those standards.~~

~~3. The Commission shall publish in the *Official Journal of the European Union* a list of notified bodies. The Commission shall ensure that the list is kept up to date.~~

~~4. If a Member State finds that a notified body no longer meets the criteria listed in Annex VI, it shall inform the Commission and the other Member States accordingly. The Commission shall withdraw the reference to that body from the list referred to in paragraph 3.~~

↓ 2004/108 (adapted)
⇨ new

~~FIXED INSTALLATIONS~~

Article 19~~13~~

Fixed installations

1. Apparatus which has been ~~placed~~ ⇨ made available ⇦ on the market and which may be incorporated into a fixed installation ~~is~~ ⌦ shall be ⌫ subject to all relevant provisions for apparatus set out in this Directive.

However, the ~~provisions~~ ⌦ requirements ⌫ of Articles ~~5, 7, 8 and 9~~ ⌦ 6 to 11 and Articles 15 to 18 ⌫ shall not be compulsory in the case of apparatus which is intended for incorporation into a ~~given~~ ⌦ particular ⌫ fixed installation and is otherwise not ~~commercially~~ ⌦ made ⌫ available ⌦ on the market ⌫.

In such cases, the accompanying documentation shall identify the fixed installation and its electromagnetic compatibility characteristics and shall indicate the precautions to be taken for the incorporation of the apparatus into the fixed installation in order not to compromise the conformity of that installation. It shall ~~furthermore~~ ⌦ also ⌫ include the information referred to in Articles ~~9(1) and (2)~~ 7(5), 7(6) and 9(3).

↓ 2004/108

2. Where there are indications of non-compliance of the fixed installation, in particular, where there are complaints about disturbances being generated by the installation, the competent authorities of the Member State concerned may request evidence of compliance of the fixed installation, and, when appropriate, initiate an assessment.

↓ 2004/108 (adapted)

Where non-compliance is established, the competent authorities may impose appropriate measures to bring the fixed installation into compliance with the ~~protection~~ ⌦ essential ⌫ requirements set out in Annex I~~, point 1~~.

3. Member States shall set out the necessary provisions for identifying the person or persons responsible for the establishment of compliance of a fixed installation with the relevant essential requirements.

⇩ new

CHAPTER 4

NOTIFICATION OF CONFORMITY ASSESSMENT BODIES

Article 20 [Article R13 of Decision No 768/2008/EC]

Notification of Notified Bodies

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

Article 21 [Article R14 of Decision No 768/2008/EC]

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 Article 26.

2. Member States may decide that the assessment and monitoring referred to in paragraph 1 shall be carried out by a national accreditation body within the meaning of and in accordance with Regulation (EC) No 765/2008.

3. Where the notifying authority delegates or otherwise entrusts the assessment, notification or monitoring referred to in paragraph 1 to a body which is not a governmental entity, that body shall be a legal entity and shall comply mutatis mutandis with the requirements laid down in Article 22 (1) to (6). In addition it shall have arrangements to cover liabilities arising out of its activities.

4. The notifying authority shall take full responsibility for the tasks performed by the body referred to in paragraph 3.

Article 22 [Article R15 of Decision No 768/2008/EC]

Requirements relating to notifying authorities

1. A notifying authority shall be established in such a way that no conflict of interest with conformity assessment bodies occurs.

2. A notifying authority shall be organised and operated so as to safeguard the objectivity and impartiality of its activities.

3. A notifying authority shall be organised in such a way that each decision relating to notification of a conformity assessment body is taken by competent persons different from those who carried out the assessment.

4. A notifying authority shall not offer or provide any activities that conformity assessment bodies perform or consultancy services on a commercial or competitive basis.

5. A notifying authority shall safeguard the confidentiality of the information it obtains.

6. A notifying authority shall have a sufficient number of competent personnel at its disposal for the proper performance of its tasks.

Article 23 [Article R16 of Decision No 768/2008/EC]

Information obligation on notifying authorities

Member States shall inform the Commission of their procedures for the assessment and notification of conformity assessment bodies and the monitoring of notified bodies, and of any changes thereto.

The Commission shall make that information publicly available.

Article 24 [Article R17 of Decision No 768/2008/EC]

Requirements relating to notified bodies

1. For the purposes of notification, a conformity assessment body shall meet the requirements laid down in paragraphs 2 to 11.

2. A conformity assessment body shall be established under national law and have legal personality.

3. A conformity assessment body shall be a third-party body independent of the organisation or the apparatus it assesses.

A body belonging to a business association or professional federation representing undertakings involved in the design, manufacturing, provision, assembly, use or maintenance of apparatus which it assesses, may, on condition that its independence and the absence of any conflict of interest are demonstrated, be considered such a body.

4. A 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 apparatus which they assess, nor the authorised representative of any of those parties. This shall not preclude the use of assessed apparatus that are necessary for the operations of the conformity assessment body or the use of such apparatus for personal purposes.

A conformity assessment body, its top level management and the personnel responsible for carrying out the conformity assessment tasks shall not be directly involved in the design, manufacture or construction, the marketing, installation, use or maintenance of those apparatus, or represent the parties engaged in those activities. They shall not engage in any activity that may conflict with their independence of judgement or integrity in relation to conformity assessment activities for which they are notified. This shall in particular apply to consultancy services.

Conformity assessment bodies shall ensure that the activities of their subsidiaries or subcontractors do not affect the confidentiality, objectivity or impartiality of their conformity assessment activities.

5. Conformity assessment bodies and their personnel shall carry out the conformity assessment activities with the highest degree of professional integrity and the requisite technical competence in the specific field and shall be free from all pressures and inducements, particularly financial, which might influence their judgement or the results of their conformity assessment activities, especially as regards persons or groups of persons with an interest in the results of those activities.

6. A conformity assessment body shall be capable of carrying out all the conformity assessment tasks assigned to it by Annex III and in relation to 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 each kind or category of apparatus in relation to which it has been notified, a conformity assessment body shall have at its disposal the necessary:

(a) personnel with technical knowledge and sufficient and appropriate experience to perform the conformity assessment tasks;

(b) descriptions of procedures in accordance with which conformity assessment is carried out, ensuring the transparency and the ability of reproduction of those procedures. It shall have appropriate policies and procedures in place that distinguish between tasks it carries out as a notified body and other activities;

(c) procedures for the performance of activities which take due account of the size of an undertaking, the sector in which it operates, its structure, the degree of complexity of the apparatus technology in question and the mass or serial nature of the production process.

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 conformity assessment activities shall have the following:

(a) sound technical and vocational training covering all the conformity assessment activities in relation to 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 those assessments;

(c) appropriate knowledge and understanding of the essential requirements set out in Annex I, of the applicable harmonised standards and of the relevant provisions of Union harmonisation legislation and national legislation;

(d) the ability to draw up certificates, records and reports demonstrating that assessments have been carried out.

8. The impartiality of the conformity assessment bodies, their top level management and of the assessment personnel shall be guaranteed.

The remuneration of the top level management and assessment personnel of a conformity assessment body shall not depend on the number of assessments carried out or on the results of those assessments.

9. Conformity assessment bodies 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 a conformity assessment body shall observe professional secrecy with regard to all information obtained in carrying out their tasks under Annex III or any provision of national law giving effect to it, except in relation to the competent authorities of the Member State in which its activities are carried out. Proprietary rights shall be protected.

11. Conformity assessment bodies shall participate in, or ensure that their assessment personnel are informed of, the relevant standardisation activities and the activities of the notified body coordination group established under the relevant Union harmonisation legislation and apply as general guidance the administrative decisions and documents produced as a result of the work of that group.

Article 25 [Article R18 of Decision No 768/2008/EC]

Presumption of conformity

Where a conformity assessment body demonstrates its conformity with the criteria laid down in the relevant harmonised standards or parts thereof the references of which have been published in the *Official Journal of the European Union* it shall be presumed to comply with

the requirements set out in Article 24 in so far as the applicable harmonised standards cover those requirements.

Article 26 [Article R20 of Decision No 768/2008/EC]

Subsidiaries of and subcontracting by notified bodies

1. Where a notified body subcontracts specific tasks connected with conformity assessment or has recourse to a subsidiary, it shall ensure that the subcontractor or the subsidiary meets the requirements set out in Article 24 and shall inform the notifying authority accordingly.

2. Notified bodies 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. Notified bodies shall keep at the disposal of the notifying authority the relevant documents concerning the assessment of the qualifications of the subcontractor or the subsidiary and the work carried out by them under Annex III.

Article 27 [Article R22 of Decision No 768/2008/EC]

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. That application shall be accompanied by a description of the conformity assessment activities, the conformity assessment module or modules and the apparatus or apparatuses for which that body claims to be competent, as well as by an accreditation certificate, where one exists, issued by a national accreditation body attesting that the conformity assessment body fulfils the requirements laid down in Article 24.

3. Where the conformity assessment body concerned cannot provide an accreditation certificate, it shall provide the notifying authority with all the documentary evidence necessary for the verification, recognition and regular monitoring of its compliance with the requirements laid down in Article 24.

Article 28 [Article R23 of Decision No 768/2008/EC]

Notification procedure

1. Notifying authorities may notify only conformity assessment bodies which have satisfied the requirements laid down in Article 24.

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 apparatus or apparatuses concerned and the relevant attestation of competence.

4. Where a notification is not based on an accreditation certificate as referred to in Article 27(2), the notifying authority shall provide the Commission and the other Member States with documentary evidence which attests to the conformity assessment body's competence and the arrangements in place to ensure that that body will be monitored regularly and will continue to satisfy the requirements laid down in Article 24.

5. The body concerned may perform the activities of a notified body only where no objections are raised by the Commission or the other Member States within two weeks of a notification where an accreditation certificate is used or within two months of a notification where accreditation is not used.

Only such a body shall be considered a notified body for the purposes of this Directive.

6. The Commission and the other Member States shall be notified of any subsequent relevant changes to the notification.

Article 29 [Article R24 of Decision No 768/2008/EC]

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 Union acts.

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

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

Article 30 [Article R25 of Decision No 768/2008/EC]

Changes to notifications

1. Where a notifying authority has ascertained or has been informed that a notified body no longer meets the requirements laid down in Article 24, or that it is failing to fulfil its obligations, the notifying authority shall restrict, suspend or withdraw notification as appropriate, depending on the seriousness of the failure to meet those requirements or fulfil those obligations. It shall immediately inform the Commission and the other Member States accordingly.

2. In the event of restriction, suspension or withdrawal of notification, or where the notified body has ceased its activity, the notifying Member State shall take appropriate steps to ensure that the files of that body are either processed by another notified body or kept available for the responsible notifying and market surveillance authorities at their request.

Article 31 [Article R26 of Decision No 768/2008/EC]

Challenge of the competence of notified bodies

1. The Commission shall investigate all cases where it doubts, or doubt is brought to its attention regarding, the competence of a notified body or the continued fulfilment by a notified body of the requirements and responsibilities to which it is subject.

2. The notifying Member State shall provide the Commission, on request, with all information relating to the basis for the notification or the maintenance of the competence of the body concerned.

3. The Commission shall ensure that all sensitive 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 accordingly and request it to take the necessary corrective measures, including de-notification if necessary.

Article 32 [Article R27 of Decision No 768/2008/EC]

Operational obligations of notified bodies

1. Notified bodies shall carry out conformity assessments in accordance with the conformity assessment procedure provided for in Annex III.

2. Conformity assessments shall be carried out in a proportionate manner, avoiding unnecessary burdens for economic operators.

Conformity assessment bodies shall perform their activities taking due account of the size of an undertaking, the sector in which it operates, its structure, the degree of complexity of the apparatus technology in question and the mass or serial nature of the production process.

In so doing they shall nevertheless respect the degree of rigour and the level of protection required for the compliance of the apparatus with this Directive.

3. Where a notified body finds that the essential requirements set out in Annex I or corresponding harmonised standards or technical specifications have not been met by a manufacturer, it shall require that manufacturer to take appropriate corrective measures and shall not issue a conformity certificate.

4. Where, in the course of the monitoring of conformity following the issue of a certificate, a notified body finds that an apparatus no longer complies, it shall require the manufacturer to

take appropriate corrective measures and shall suspend or withdraw the 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 33

Appeal against decisions of notified bodies

Member States shall ensure that an appeal procedure against decisions of the notified bodies is available.

Article 34 [Article R28 of Decision No 768/2008/EC]

Information obligation on notified bodies

1. Notified bodies shall inform the notifying authority of the following:

(a) any refusal, restriction, suspension or withdrawal of a certificate;

(b) any circumstances affecting the scope of and conditions for notification;

(c) any request for information which they have received from market surveillance authorities regarding conformity assessment activities;

(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 Directive carrying out similar conformity assessment activities covering the same apparatus with relevant information on issues relating to negative and, on request, positive conformity assessment results.

Article 35[Article R29 of Decision No 768/2008/EC]

Exchange of experience

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

Article 36 [Article R30 of Decision No 768/2008/EC]

Coordination of notified bodies

The Commission shall ensure that appropriate coordination and cooperation between bodies notified under this Directive are put in place and properly operated in the form of a sectoral group of notified bodies.

Member States shall ensure that the bodies notified by them participate in the work of that group, directly or by means of designated representatives.

CHAPTER 5

UNION MARKET SURVEILLANCE AND CONTROL OF APPARATUS ENTERING THE UNION MARKET AND SAFEGUARD PROCEDURES

Article 37

Union market surveillance and control of apparatus entering the Union market

Article 15(3) and Articles 16 to 29 of Regulation (EC) No 765/2008 shall apply to apparatus.

Article 38 [Article R31 of Decision No 768/2008/EC]

Procedure for dealing with apparatus presenting a risk at national level

1. Where the market surveillance authorities of one Member State have taken action pursuant to Article 20 of Regulation (EC) No 765/2008, or where they have sufficient reason to believe that an apparatus covered by this Directive presents a risk to aspects of public interest protection covered by this Directive, they shall carry out an evaluation in relation to the apparatus concerned covering all the requirements laid down in this Directive. The relevant economic operators shall cooperate as necessary with the market surveillance authorities.

Where, in the course of that evaluation, the market surveillance authorities find that the apparatus does not comply with the requirements laid down in this Directive, they shall without delay require the relevant economic operator to take all appropriate corrective action to bring the apparatus into compliance with those requirements, to withdraw the apparatus from the market, or to recall it within a reasonable period, commensurate with the nature of the risk, as they may prescribe.

The market surveillance authorities shall inform the relevant notified body accordingly.

Article 21 of Regulation (EC) No 765/2008 shall apply to the measures referred to in the second subparagraph.

2. Where the market surveillance authorities consider that non-compliance is not restricted to their national territory, they shall inform the Commission and the other Member States of the results of the evaluation and of the actions which they have required the economic operator to take.

3. The economic operator shall ensure that all appropriate corrective action is taken in respect of all the apparatus concerned that it has made available on the market throughout the Union.

4. Where the relevant economic operator does not take adequate corrective action within the period referred to in the second subparagraph of paragraph 1, the market surveillance authorities shall take all appropriate provisional measures to prohibit or restrict the apparatus's being made available on their national market, to withdraw the apparatus from that market or to recall it.

The market surveillance authorities shall inform the Commission and the other Member States, without delay, of those measures.

5. The information referred to in paragraph 4 shall include all available details, in particular the data necessary for the identification of the non-compliant apparatus, the origin of the apparatus, the nature of the non-compliance alleged and the risk involved, the nature and duration of the national measures taken and the arguments put forward by the relevant economic operator. In particular, the market surveillance authorities shall indicate whether the non-compliance is due to either of the following reasons:

(a) failure of the apparatus to meet the requirements relating to aspects of public interest protection covered by this Directive;

(b) shortcomings in the harmonised standards referred to in Article 12 conferring a presumption of conformity.

6. Member States other than the Member State initiating the procedure shall without delay inform the Commission and the other Member States of any measures adopted and of any additional information at their disposal relating to the non-compliance of the apparatus concerned, and, in the event of disagreement with the notified national measure, of their objections.

7. Where, within 2 months of receipt of the information referred to in paragraph 4, no objection has been raised by either a Member State or the Commission in respect of a provisional measure taken by a Member State, that measure shall be deemed justified.

8. Member States shall ensure that appropriate restrictive measures are taken in respect of the apparatus concerned without delay.

Article 39 [Article R32 of Decision No 768/2008/EC]

Union safeguard procedure

1. Where, on completion of the procedure set out in Article 38(3) and (4), objections are raised against a measure taken by a Member State, or where the Commission considers a national measure to be contrary to Union legislation, the Commission shall without delay enter into consultation with the Member States and the relevant economic operator or operators and shall evaluate the national measure. On the basis of the results of that evaluation, the Commission shall decide whether the national measure is justified or not.

The Commission shall address its decision to all Member States and shall immediately communicate it to them and the relevant economic operator or operators.

2. If the national measure is considered justified, all Member States shall take the measures necessary to ensure that the non-compliant apparatus is withdrawn from their market, and shall inform the Commission accordingly. If the national measure is considered unjustified, the Member State concerned shall withdraw the measure.

3. Where the national measure is considered justified and the non-compliance of the apparatus is attributed to shortcomings in the harmonised standards referred to in Article 38(5)(b) of this Directive, the Commission shall apply the procedure provided for in Article [8] of Regulation (EU) No [../..] [on European Standardisation].

Article 40 [Article R34 of Decision No 768/2008/EC]

Formal non-compliance

1. Without prejudice to Article 38, where a Member State makes one of the following findings, it shall require the relevant economic operator to put an end to the non-compliance concerned:

(a) the CE marking has been affixed in violation of Article 30 of Regulation (EC) No 765/2008 or of Article 17 of this Directive;

(b) the CE marking has not been affixed;

(c) the EU declaration of conformity has not been drawn up;

(d) the EU declaration of conformity has not been drawn up correctly;

(e) technical documentation is either not available or not complete.

2. Where the non-compliance referred to in paragraph 1 persists, the Member State concerned shall take all appropriate measures to restrict or prohibit the apparatus being made available on the market or ensure that it is recalled or withdrawn from the market.

↓ 2004/108 (adapted)

CHAPTER ~~IV~~6

⌦ TRANSITIONAL AND⌫ FINAL PROVISIONS

⇩ new

Article 41

Penalties

Member States shall lay down rules on penalties applicable to infringements of the national provisions adopted pursuant to this Directive and shall take all measures necessary to ensure that they are enforced.

The penalties provided for shall be effective, proportionate and dissuasive.

Member States shall notify those provisions to the Commission by [the date set out in the second subparagraph of Article 43(1)] at the latest and shall notify it without delay of any subsequent amendment affecting them.

↓ 2004/108 (adapted)
⇨ new

Article ~~42~~15

Transitional provisions

Member States shall not impede the ~~placing~~ ⇨ making available ⇦ on the market and/or the putting into service of equipment ~~which is in compliance with the provisions of Directive 89/336/EEC and which was placed on the market before 20 July 2009.~~ ⇨ covered by Directive 2004/108/EC which is in conformity with that Directive and which was placed on the market before [the date set out in the second subparagraph of Article 43(1)] ⇦ .

↓ 2004/108 (adapted)

Article ~~43~~ ~~16~~

Transposition

1. Member States shall adopt and publish ⌦ by [insert date - 2 years after adoption] at the latest ⌫ , the laws, regulations and administrative provisions necessary to comply with ~~this Directive~~ ⌦ Article 3 first subparagraph points (9) to (25), Article 4, Article 5(1), Articles 7 to 12, Articles 15 to 17, Article 19 (1) first subparagraph, Articles 20 to 42, and Annexes II, III and IV. ⌫ ~~by 20 January 2007~~. They shall forthwith ~~inform~~ ⌦ communicate to ⌫ the Commission ~~thereof~~ ⌦ the text of those provisions and a correlation table between those provisions and this Directive ⌫.

They shall apply those provisions ~~as~~ from ~~20 July 2007~~ ⌦ [day after date mentioned in first subparagraph] ⌫.

When Member States adopt those provisions, they shall contain a reference to this Directive or ~~shall~~ be accompanied by such reference on the occasion of their official publication. ~~The methods of making such reference shall be laid down by Member States.~~ ⌦ They shall also include a statement that references in existing laws, regulations and administrative provisions to the directive repealed by this Directive shall be construed as references to this Directive. Member States shall determine how such reference is to be made and how that statement is to be formulated. ⌫

2. Member States shall communicate to the Commission the texts of the ⌦ main ⌫ provisions of national law which they adopt in the field covered by this Directive.

Article ~~44~~ ~~14~~

Repeal

Directive ~~89/336/EEC~~ 2004/108/EC is ~~hereby~~ repealed ~~as from 20 July 2007~~ ⌦ with effect from [the date set out in the second subparagraph of Article 43(1)], without prejudice to the obligations of the Member States relating to the time-limit for transposition into national law and application of the said Directive set out in Annex V. ⌫

References to ⌦ the repealed ⌫ Directive ~~89/336/EEC~~ shall be construed as references to this Directive and ~~should~~ ⌦ shall ⌫ be read in accordance with the correlation table ~~set out~~ in Annex VI~~I~~.

Article 45~~17~~

Entry into force

This Directive shall enter into force on the twentieth day ~~after~~ ⌦ following that of ⌫ its publication in the *Official Journal of the European Union*.

↓

Article 1, Article 2, Article 3 first subparagraph, points (1) to (8) and second subparagraph, Article 5(2) and (3), Article 6, Article 13 first subparagraph, Article 19 (3) and Annex I shall apply from [the date set out in the second subparagraph of Article 43(1)].

↓ 2004/108

Article 46~~18~~

Addressees

This Directive is addressed to the Member States.

Done at […],

For the European Parliament	*For the Council*
The President	*The President*

↓ 2004/108 (adapted)

ANNEX I

ESSENTIAL REQUIREMENTS ~~REFERRED TO IN ARTICLE 5~~

1. ~~PROTECTION~~ ⌦ ESSENTIAL ⌫ REQUIREMENTS

↓ 2004/108

Equipment shall be so designed and manufactured, having regard to the state of the art, as to ensure that:

(a) the electromagnetic disturbance generated does not exceed the level above which radio and telecommunications equipment or other equipment cannot operate as intended;

(b) it has a level of immunity to the electromagnetic disturbance to be expected in its intended use which allows it to operate without unacceptable degradation of its intended use.

2. SPECIFIC REQUIREMENTS FOR FIXED INSTALLATIONS

Installation and intended use of components

↓ 2004/108 (adapted)

A fixed installation shall be installed applying good engineering practices and respecting the information on the intended use of its components, with a view to meeting the ~~protection~~ ⌦ essential ⌫ requirements set out in ~~P~~point 1. Those good engineering practices shall be documented and the documentation shall be held by the person(s) responsible at the disposal of the relevant national authorities for inspection purposes for as long as the fixed installation is in operation.

↓ 2004/108 (adapted)

ANNEX II

~~**CONFORMITY ASSESSMENT PROCEDURE REFERRED TO IN ARTICLE 7**~~

↓ 2004/108

~~(~~INTERNAL PRODUCTION CONTROL~~)~~

~~1. The manufacturer shall perform an electromagnetic compatibility assessment of the apparatus, on the basis of the relevant phenomena, with a view to meeting the protection requirements set out in Annex I, point 1. The correct application of all the relevant harmonised standards whose references have been published in the *Official Journal of the European Union* shall be equivalent to the carrying out of the electromagnetic compatibility assessment.~~

~~2. The electromagnetic compatibility assessment shall take into account all normal intended operating conditions. Where the apparatus is capable of taking different configurations, the electromagnetic compatibility assessment shall confirm whether the apparatus meets the protection requirements set out in Annex I, point 1, in all the possible configurations identified by the manufacturer as representative of its intended use.~~

~~3. In accordance with the provisions set out in Annex IV, the manufacturer shall draw up technical documentation providing evidence of the conformity of the apparatus with the essential requirements of this Directive.~~

~~4. The manufacturer or his authorised representative in the Community shall hold the technical documentation at the disposal of the competent authorities for at least ten years after the date on which such apparatus was last manufactured.~~

~~5. The compliance of apparatus with all relevant essential requirements shall be attested by an EC declaration of conformity issued by the manufacturer or his authorised representative in the Community.~~

~~6. The manufacturer or his authorised representative in the Community shall hold the EC declaration of conformity at the disposal of the competent authorities for a period of at least ten years after the date on which such apparatus was last manufactured.~~

~~7. If neither the manufacturer nor his authorised representative is established within the Community, the obligation to hold the EC declaration of conformity and the technical documentation at the disposal of the competent authorities shall lie with the person who places the apparatus on the Community market.~~

~~8. The manufacturer must take all measures necessary to ensure that the products are manufactured in accordance with the technical documentation referred to in point 3 and with the provisions of this Directive that apply to them.~~

~~9. The technical documentation and the EC declaration of conformity shall be drawn up in accordance with the provisions set out in Annex IV.~~

⇩ new

1. Internal production control is the conformity assessment procedure whereby the manufacturer performs an electromagnetic compatibility assessment of the apparatus, on the basis of the relevant phenomena, with a view to meeting the essential requirements set out in point 1 of Annex I and fulfils the obligations laid down in points 2, 3 and 4, and ensures and declares on his sole responsibility that the apparatus concerned satisfy the requirements of this Directive.

The electromagnetic compatibility assessment shall take into account all normal intended operating conditions. Where the apparatus is capable of taking different configurations, the electromagnetic compatibility assessment shall confirm whether the apparatus meets the essential requirements set out in point 1 of Annex I in all the possible configurations identified by the manufacturer as representative of its intended use.

The correct application of all the relevant harmonised standards whose references have been published in the *Official Journal of the European Union* shall be equivalent to the carrying out of the electromagnetic compatibility assessment.

2. Technical documentation

The manufacturer shall establish the technical documentation. The documentation shall make it possible to assess the apparatus conformity to the relevant requirements, and shall include an adequate analysis and assessment of the risk(s).

The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture and operation of the apparatus. The technical documentation shall, wherever applicable, contain at least the following elements:

— a general description of the apparatus;

— a list of the harmonised standards and/or other relevant technical specifications the references of which have been published in the *Official Journal of the European Union*, applied in full or in part, and descriptions of the solutions adopted to meet the essential requirements of this Directive where those harmonised standards have not been applied. In the event of partly applied harmonised standards, the technical documentation shall specify the parts which have been applied;

— results of design calculations made, examinations carried out, etc; and

— test reports.

3. Manufacturing

The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure compliance of the manufactured apparatus with the technical documentation referred to in point 2 and with the requirements of the legislative instruments that apply to them.

4. CE marking and EU declaration of conformity

4.1. The manufacturer shall affix the CE marking to each individual apparatus that satisfies the applicable requirements of this Directive.

4.2. The manufacturer shall draw up a written EU declaration of conformity for an apparatus model and keep it together with the technical documentation at the disposal of the national authorities for 10 years after the apparatus has been placed on the market. The declaration of conformity shall identify the apparatus for which it has been drawn up.

A copy of the EU declaration of conformity shall be made available to the relevant authorities upon request.

5. Authorised representative

The manufacturer's obligations set out in point 4 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.

↓ 2004/108

ANNEX III

~~CONFORMITY ASSESSMENT PROCEDURE REFERRED TO IN ARTICLE 7~~

~~1. This procedure consists of applying Annex II, completed as follows:~~

~~2. The manufacturer or his authorised representative in the Community shall present the technical documentation to the notified body referred to in Article 12 and request the notified body for an assessment thereof. The manufacturer or his authorised representative in the Community shall specify to the notified body which aspects of the essential requirements must be assessed by the notified body.~~

~~3. The notified body shall review the technical documentation and assess whether the technical documentation properly demonstrates that the requirements of the Directive that it is to assess have been met. If the compliance of the apparatus is confirmed, the notified body shall issue a statement to the manufacturer or his authorised representative in the Community confirming the compliance of the apparatus. That statement shall be limited to those aspects of the essential requirements which have been assessed by the notified body.~~

~~4. The manufacturer shall add the statement of the notified body to the technical documentation.~~

⇩ new

Part A

EU-TYPE EXAMINATION

1. EU-type examination is the part of a conformity assessment procedure in which a notified body examines the technical design of an apparatus and verifies and attests that the technical design of the apparatus meets the requirements of this Directive.

2. EU-type examination shall be carried out by assessment of the adequacy of the technical design of the apparatus through examination of the technical documentation and supporting evidence referred to in point 3, without examination of a specimen (design type). It may be restricted to some aspects of the essential requirements as specified by the manufacturer or his authorised representative in the Union.

3. The manufacturer shall lodge an application for EU-type examination with a single notified body of his choice.

The application shall include:

(a) the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address as well;

(b) a written declaration that the same application has not been lodged with any other notified body;

(c) the technical documentation. The technical documentation shall make it possible to assess the apparatus conformity with the applicable requirements of this Directive and shall include an adequate analysis and assessment of the risk(s). The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture and operation of the apparatus. The technical documentation shall contain, wherever applicable, at least the following elements:

(i) a general description of the apparatus;

(ii) a list of the harmonised standards and/or other relevant technical specifications the references of which have been published in the Official Journal of the European Union, applied in full or in part, and descriptions of the solutions adopted to meet the essential requirements of this Directive where those harmonised standards have not been applied. In the event of partly applied harmonised standards, the technical documentation shall specify the parts which have been applied;

(iii) results of design calculations made, examinations carried out, etc.; and

(iv) test reports;

(d) the supporting evidence for the adequacy of the technical design solution. This supporting evidence shall mention any documents that have been used, in particular where the relevant harmonised standards and/or technical specifications have not been applied in full. The supporting evidence shall include, where necessary, the results of tests carried out by the appropriate laboratory of the manufacturer, or by another testing laboratory on his behalf and under his responsibility.

4. The notified body shall examine the technical documentation and supporting evidence to assess the adequacy of the technical design of the apparatus.

5. The notified body shall draw up an evaluation report that records the activities undertaken in accordance with point 4 and their outcomes. Without prejudice to its obligations vis-à vis the notifying authorities, the notified body shall release the content of that report, in full or in part, only with the agreement of the manufacturer.

6. Where the type meets the requirements of this Directive that apply to the apparatus concerned, the notified body shall issue an EU-type examination certificate to the manufacturer. The certificate shall contain the name and address of the manufacturer, the conclusions of the examination, the conditions (if any) for its validity and the necessary data for identification of the approved type. The certificate may have one or more annexes attached.

The certificate and its annexes shall contain all relevant information to allow the conformity of manufactured apparatus with the examined type to be evaluated and to allow for in-service control.

Where the type does not satisfy the applicable requirements of this Directive, the notified body shall refuse to issue an EU-type examination certificate and shall inform the applicant accordingly, giving detailed reasons for its refusal.

7. The notified body shall keep itself apprised of any changes in the generally acknowledged state of the art which indicate that the approved type may no longer comply with the applicable requirements of this Directive, and shall determine whether such changes require further investigation. If so, the notified body shall inform the manufacturer accordingly.

The manufacturer shall inform the notified body that holds the technical documentation relating to the EU-type examination certificate of all modifications to the approved type that may affect the conformity of the apparatus with the essential requirements of the legislative instrument or the conditions for validity of the certificate. Such modifications shall require additional approval in the form of an addition to the original EU-type examination certificate.

8. Each notified body shall inform its notifying authorities concerning the EU-type examination certificates and/or any additions thereto which it has issued or withdrawn, and shall, periodically or upon request, make available to its notifying authorities the list of certificates and/or any additions thereto refused, suspended or otherwise restricted.

Each notified body shall inform the other notified bodies concerning the EU-type examination certificates and/or any additions thereto which it has refused, withdrawn, suspended or otherwise restricted, and, upon request, concerning the certificates and/or additions thereto which it has issued.

The Commission, the Member States and the other notified bodies may, on request, obtain a copy of the EU-type examination certificates and/or additions thereto. On request, the Commission and the Member States may obtain a copy of the technical documentation and the results of the examinations carried out by the notified body. The notified body shall keep a copy of the EU-type examination certificate, its annexes and additions, as well as the technical file including the documentation submitted by the manufacturer, until the expiry of the validity of the certificate.

9. The manufacturer shall keep a copy of the EU-type examination certificate, its annexes and additions together with the technical documentation at the disposal of the national authorities for 10 years after the apparatus has been placed on the market.

10. The manufacturer's authorised representative may lodge the application referred to in point 3 and fulfill the obligations set out in points 7 and 9, provided that they are specified in the mandate.

Part B

CONFORMITY TO TYPE BASED ON INTERNAL PRODUCTION CONTROL

1. Conformity to type based on internal production control is the part of a conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2 and 3, and ensures and declares that the apparatus concerned are in conformity with the type described in the EU-type examination certificate and satisfy the requirements of this Directive that apply to them.

2. Manufacturing

The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure conformity of the manufactured apparatus with the approved type described in the EU-type examination certificate and with the requirements of this Directive that apply to them.

3. CE marking and EU declaration of conformity

3.1. The manufacturer shall affix the required CE marking set out in this Directive to each individual apparatus that is in conformity with the type described in the EU-type examination certificate and satisfies the applicable requirements of this Directive.

3.2. The manufacturer shall draw up a written EU declaration of conformity for an apparatus model and keep it at the disposal of the national authorities for 10 years after the apparatus has been placed on the market. The EU declaration of conformity shall identify the apparatus model for which it has been drawn up.

A copy of the EU declaration of conformity shall be made available to the relevant authorities upon request.

4. Authorised representative

The manufacturer's obligations set out in point 3 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.

↓ 2004/108 (adapted)

ANNEX IV

~~TECHNICAL DOCUMENTATION AND EC~~ ⌦ EU ⌫ DECLARATION OF CONFORMITY

↓ 2004/108

~~1. TECHNICAL DOCUMENTATION~~

~~The technical documentation must enable the conformity of the apparatus with the essential requirements to be assessed. It must cover the design and manufacture of the apparatus, in particular:~~

~~– a general description of the apparatus;~~

~~– evidence of compliance with the harmonised standards, if any, applied in full or in part;~~

~~– where the manufacturer has not applied harmonised standards, or has applied them only in part, a description and explanation of the steps taken to meet the essential requirements of the Directive, including a description of the electromagnetic compatibility assessment set out in Annex II, point 1, results of design calculations made, examinations carried out, test reports, etc.;~~

~~– a statement from the notified body, when the procedure referred to in Annex III has been followed.~~

~~2. EC DECLARATION OF CONFORMITY~~

~~The EC declaration of conformity must contain, at least, the following:~~

~~– a reference to this Directive,~~

~~– an identification of the apparatus to which it refers, as set out in Article 9(1),~~

~~– the name and address of the manufacturer and, where applicable, the name and address of his authorised representative in the Community,~~

~~– a dated reference to the specifications under which conformity is declared to ensure the conformity of the apparatus with the provisions of this Directive,~~

~~– the date of that declaration,~~

~~– the identity and signature of the person empowered to bind the manufacturer or his authorised representative.~~

⇩ new

1. No … (unique identification of the apparatus):

2. Name and address of the manufacturer or his authorised representative:

3. This declaration of conformity is issued under the sole responsibility of the manufacturer (or installer):

4. Object of the declaration (identification of apparatus allowing traceability. It may include a photograph, where appropriate):

5. The object of the declaration described above is in conformity with the relevant Union harmonisation legislation:

6. References to the relevant harmonised standards used, including the date of the standard, or references to the specifications, including the date of the specification, in relation to which conformity is declared:

7. Where applicable, the notified body ... (name, number) … performed … (description of intervention) … and issued the certificate: …

8. Additional information:

Signed for and on behalf of: ……

(place and date of issue):

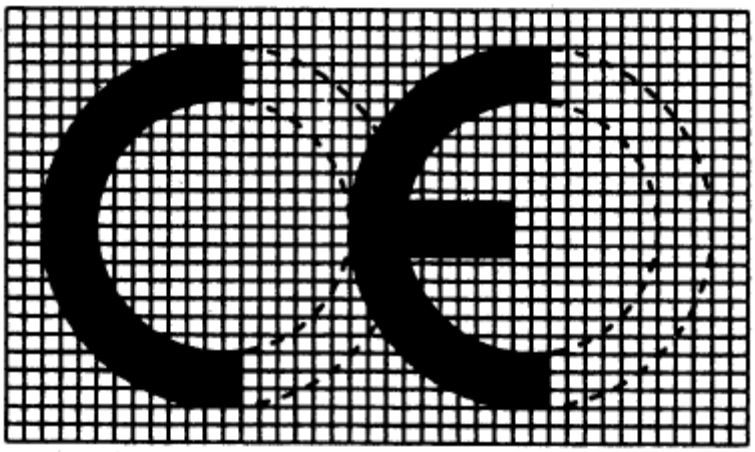
(name, function) (signature):

↓ 2004/108 (adapted)

~~ANNEX V~~

~~'CE' MARKING REFERRED TO IN ARTICLE 8~~

~~The 'CE' marking shall consist in the initials 'CE' taking the following form:~~



~~The 'CE' marking must have a height of at least 5 mm. If the 'CE' marking is reduced or enlarged the proportions given in the above graduated drawing must be respected.~~

~~The 'CE' marking must be affixed to the apparatus or to its data plate. Where this is not possible or not warranted on account of the nature of the apparatus, it must be affixed to the packaging, if any, and to the accompanying documents.~~

~~Where the apparatus is the subject of other Directives covering other aspects and which also provide for the 'CE' marking, the latter shall indicate that the apparatus also conforms with those other Directives.~~

~~However, where one or more of those Directives allow the manufacturer, during a transitional period, to choose which arrangements to apply, the 'CE' marking shall indicate conformity only with the Directives applied by the manufacturer. In that case, particulars of the Directives applied, as published in the *Official Journal of the European Union*, must be given in the documents, notices or instructions required by the Directives and accompanying such apparatus.~~

↓ 2004/108

~~**ANNEX VI**~~

~~CRITERIA FOR THE ASSESSMENT OF THE BODIES TO BE NOTIFIED~~

~~1. The bodies notified by the Member States shall fulfil the following minimum conditions:~~

~~(a) availability of personnel and of the necessary means and equipment;~~

~~(b) technical competence and professional integrity of personnel;~~

~~(c) independence in preparing the reports and performing the verification function provided for in this Directive;~~

~~(d) independence of staff and technical personnel in relation to all interested parties, groups or persons directly or indirectly concerned with the equipment in question;~~

~~(e) maintenance of professional secrecy by personnel;~~

~~(f) possession of civil liability insurance unless such liability is covered by the Member State under national law.~~

~~2. Fulfilment of the conditions laid down in point 1 shall be verified at intervals by the competent authorities of the Member State.~~

↓

ANNEX V

LIST OF TIME-LIMITS FOR TRANSPOSITION INTO NATIONAL LAW AND APPLICATION (REFERRED TO IN ARTICLE 44)

Directive	Time-limit for transposition	Date of application
2004/108/EC	20.1.2007	20.7.2007

↓ 2004/108 (adapted)

ANNEX VII

CORRELATION TABLE	
Directive ~~89/336/EEC~~ ⌦2004/108/EC⌫	This Directive
~~Article 1, point 1~~	~~Article 2(1)(a), (b) and (c)~~
~~Article 1, point 2~~	~~Article 2(1)(e)~~
~~Article 1, point 3~~	~~Article 2(1)(f)~~
~~Article 1, point 4~~	~~Article 2(1)(d)~~
~~Article 1, points 5 and 6~~	~~-~~
~~Article 2(1)~~	~~Article 1(1)~~
~~Article 2(2)~~	~~Article 1(4)~~
~~Article 2(3)~~	~~Article 1(2)~~
~~Article 3~~	~~Article 3~~
~~Article 4~~	~~Article 5 and Annex I~~
~~Article 5~~	~~Article 4(1)~~
~~Article 6~~	~~Article 4(2)~~
~~Article 7(1)(a)~~	~~Article 6(1) and (2)~~
~~Article 7(1)(b)~~	~~-~~
~~Article 7(2).~~	~~-~~
~~Article 7(3)~~	~~-~~
~~Article 8(1)~~	~~Article 6(3) and (4)~~
~~Article 8(2)~~	~~-~~
~~Article 9(1)~~	~~Article 10(1) and (2)~~
~~Article 9(2)~~	~~Article 10(3) and (4)~~
~~Article 9(3)~~	~~Article 10(5)~~

~~Article 9(4)~~	~~Article 10(3)~~
~~Article 10(1), first sub-paragraph~~	~~Article 7, Annexes II and III~~
~~Article 10(1), second sub-paragraph~~	~~Article 8~~
~~Article 10(2)~~	~~Article 7, Annexes II and III~~
~~Article 10(3)~~	~~-~~
~~Article 10(4)~~	~~-~~
~~Article 10(5)~~	~~Article 7, Annexes II and III~~
~~Article 10(6)~~	~~Article 12~~
~~Article 11~~	~~Article 14~~
~~Article 12~~	~~Article 16~~
~~Article 13~~	~~Article 18~~
~~Annex I, point 1~~	~~Annex IV, point 2~~
~~Annex I, point 2~~	~~Annex V~~
~~Annex II~~	~~Annex VI~~
~~Annex III, last paragraph~~	~~Article 9(5)~~

⌦ Article 1(1) ⌫	⌦ Article 1 and Article 2(1) ⌫
⌦ Article 1(2) ⌫	⌦ Article 2(2) ⌫
⌦ Article 1(3) ⌫	⌦ Article 2(2)(d) ⌫
⌦ Article 1(4) ⌫	⌦ Article 2(3) ⌫
⌦ Article 1(5) ⌫	⌦ Article 2(4) ⌫
⌦ Article 2(1)(a) ⌫	⌦ Article 3(1) ⌫
⌦ Article 2(1)(b) ⌫	⌦ Article 3(2) ⌫
⌦ Article 2(1)(c) ⌫	⌦ Article 3(3) ⌫
⌦ Article 2(1)(d) ⌫	⌦ Article 3(4) ⌫

⌦ Article 2(1)(e) ⌫	⌦ Article 3(5) ⌫
⌦ Article 2(1)(f) ⌫	⌦ Article 3(6) ⌫
⌦ Article 2(1)(g) ⌫	⌦ Article 3(7) ⌫
⌦ Article 2(1)(h) ⌫	⌦ Article 3(8) ⌫
⌦ Article 2(2) ⌫	⌦ Article 3, last paragraph ⌫
⌦ Article 3 ⌫	⌦ Article 4 ⌫
⌦ Article 4 ⌫	⌦ Article 5 ⌫
⌦ Article 5 ⌫	⌦ Article 6 ⌫
⌦ Article 6 ⌫	⌦ Article 13 ⌫
⌦ Article 7 ⌫	⌦ Article 14 ⌫
⌦ Article 8 ⌫	⌦ Article 16 and Article 17 ⌫
⌦ Article 9(1) ⌫	⌦ Article 7(5) ⌫
⌦ Article 9(2) ⌫	⌦ Article 7(6) ⌫
⌦ Article 9(3) ⌫	⌦ Article 18(1) ⌫
⌦ Article 9(4) ⌫	⌦ Article 18(2) ⌫
⌦ Article 9(5) ⌫	⌦ Article 18(3) ⌫
⌦ Article 10 and Article 11 ⌫	⌦ Article 37, Article 38, and Article 39⌫
⌦ Article 12 and Annex VI ⌫	⌦ Chapter IV ⌫
⌦ Article 13 ⌫	⌦ Article 19 ⌫
⌦ Article 14 ⌫	⌦ Article 44 ⌫
⌦ Article 15 ⌫	⌦ Article 42 ⌫
⌦ Article 16 ⌫	⌦ Article 43 ⌫
⌦ Article 17 ⌫	⌦ Article 45 ⌫
⌦ Article 18 ⌫	⌦ Article 46 ⌫
⌦ Annex I ⌫	⌦ Annex I ⌫

⌦ Annex II ⌫	⌦ Annex II ⌫
⌦ Annex III ⌫	⌦ Annex III ⌫
⌦ Annex IV ⌫	⌦ Annex IV ⌫
⌦ Annex V ⌫	⌦ Article 16 and Article 17 ⌫
⌦ Annex VI ⌫	⌦ Chapter 4 ⌫
⌦ Annex VII ⌫	⌦ Annex VI ⌫