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EUROPEAN COMMISSION

Brussels, 21.11.2011 COM(2011) 773 final

2011/0357 (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 Member States relating to the making available on the market of electrical equipment designed for use within certain voltage limits

(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 2006/95/EC is an example of that Union harmonisation legislation, ensuring the free movement of electrical equipment. It sets out the safety objectives that electrical equipment must comply with in order to be made available on the EU market. Manufacturers must demonstrate that electrical equipment has been designed and manufactured in compliance with the safety objectives and affix the CE marking.

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

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, 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 allowing market surveillance authorities 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 2006/95/EC no revision for sector-specific problems had been envisaged within this timeframe. To ensure that the problems in relation to non-compliance 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<sup>1</sup>, which has stressed the need to restore consumer confidence in the quality of products on the market and the importance of reinforcing market surveillance.

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

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.

#### 2. CONSULTATION OF INTERESTED PARTIES AND IMPACT ASSESSMENT

### **Consultation of interested parties**

The alignment of Directive 2006/95/EC to the NLF Decision has been discussed with national experts responsible for the implementation of this Directive, 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-commonrules-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 <a href="http://ec.europa.eu/enterprise/policies/single-market-goods/files/new-legislative-framework/smes\_statistics\_en.pdf">http://ec.europa.eu/enterprise/policies/single-market-goods/files/new-legislative-framework/smes\_statistics\_en.pdf</a>

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 Directive.

Option 3 was found to be the preferred option because

- it will improve the competitiveness of companies 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;
- it does not entail significant costs for economic operators; 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 the electrical equipment is correctly marked and accompanied by the required safety information. They must keep a copy of the EU 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 electrical equipment bears 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 electrical equipment.

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

# **3.3.** Harmonised standards

Compliance with harmonised standard provides a presumption of conformity with the essential requirements. On 1 June 2011 the Commission adopted a proposal for a Regulation on European Standardisation<sup>2</sup> 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 2006/95/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 2006/95/EC has selected the appropriate conformity assessment procedure which manufacturers have to apply in order to demonstrate that their electrical equipment comply with the safety objectives. The proposal aligns these procedures to their updated versions set out in the NLF Decision. It 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 electrical equipment have been inserted in this proposal.

## **3.5.** 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 electrical equipment 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 electrical equipment. Where there is no disagreement on the restrictive measure taken, all Member States must take the appropriate action on their territory.

<sup>&</sup>lt;sup>2</sup> 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.

### 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 2006/95/EC namely, the importer and distributor obligations, the traceability provisions, the provisions on the assessment, 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 2006/95/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<sup>3</sup>.

The changes made to the provisions of Directive 2006/95/EC concern: the definitions, the obligations of economic operators, the presumption of conformity provided by harmonised

<sup>3</sup> 

OJ C 77, 28.3.2002, p. 1.

standards, the declaration of conformity, CE marking, the safeguard clause procedure and the conformity assessment procedures.

The proposal does not change the scope and the safety objectives of Directive 2006/95.

# 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 2006/95/EC.

## **European Economic Area**

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

**↓** 2006/95 (adapted)

2011/0357 (COD)

#### Proposal for a

## DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on the harmonisation of the laws of Member States relating to  $\boxtimes$  the making available on the market of  $\bigotimes$  electrical equipment designed for use within certain voltage limits

(Recast)

## (Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community  $\boxtimes$  on the Functioning of the European Union  $\bigotimes$ , and in particular Article  $\frac{95}{114} \bigotimes 114 \bigotimes$  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<sup>4</sup>,

Acting in accordance with the ordinary legislative procedure,

Whereas:

↓ new

- (1) A number of substantive changes are to be made to Directive 2006/95/EC of the European Parliament and of the Council of 12 December 2006 on the harmonisation of the laws of Member States relating to electrical equipment designed for use within certain voltage limits<sup>5</sup>. 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

<sup>&</sup>lt;sup>4</sup> OJ C [...], [...], p. [...]. <sup>5</sup> OJ L 374, 27.12.2006, p. 10.

the marketing of products and repealing Regulation (EEC) No 339/93<sup>6</sup> lays down rules on the accreditation of conformity assessment bodies, provides a framework for the market surveillance of products and for controls of 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<sup>7</sup> 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 2006/95/EC should therefore be adapted to that Decision.

### $\checkmark$ 2006/95 recital 1 (adapted)

Council Directive 73/23/EEC of 19 February 1973 on the harmonisation of the laws of Member States relating to electrical equipment designed for use within certain voltage limits <sup>9</sup> has been substantially amended<sup>9</sup>. In the interests of elarity and rationality the said Directive should be codified.

The provisions in force in the Member States designed to ensure safety in the use of electrical equipment used within certain voltage limits may differ, thus impeding trade.

In certain Member States in respect of certain electrical equipment, the safety legislation takes the form of preventive and repressive measures by means of binding provisions.

**↓** 2006/95 recital 4

In other Member States in order to achieve the same objective, the safety legislation provides for reference to technical standards laid down by Standards Bodies. Such a system offers the advantage of rapid adjustment to technical progress without neglecting safety requirements.

OJ L 218, 13.8.2008, p. 30.

OJ L 218, 13.8.2008, p. 82.

<sup>(3)</sup>OJ L 77, 26.3.1973, p. 29.Directive as amended by Directive 93/68/EEC (OJ L 220, 30.08.1993, p. <del>1).</del>

<sup>(4)</sup>See Annex V, Part A.

◆ 2006/95 recital 5

Certain Member States carry out administrative operations to approve standards. Such approval neither affects the technical content of the standards in any way nor limits their conditions of use. Such approval cannot therefore alter the effects, from a Community point of view, of harmonised and published standards.

# **↓** 2006/95 recital 6

Within the Community, the free movement of electrical equipment should follow when this equipment complies with certain safety requirements recognised in all Member States. Without prejudice to any other form of proof, the proof of compliance with these requirements may be established by reference to harmonised standards which incorporate these conditions. These harmonised standards should be established by common agreement by bodies to be notified by each Member State to the other Member States and to the Commission and should be publicised as widely as possible. Such harmonisation should, for the purposes of trade, eliminate the inconveniences resulting from differences between national standards

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Without prejudice to any other form of proof, the compliance of electrical equipment with the harmonised standards may be presumed from the affixing or issue of marks or certificates by the competent organisations or, in the absence thereof, from a manufacturer's declaration of compliance. In order to facilitate the removal of barriers to trade, the Member States should recognise such marks or certificates or such declaration as elements of proof. With this end in view, the said marks or certificates should be publicised in particular by their publication in the Official Journal of the European Union.

<sup>₽</sup> new

- (4) Economic operators should be responsible for the compliance of electrical equipment in relation to their respective roles in the supply chain, so as to ensure a high level of protection of public interests, such as health and safety, and the protection of consumers and to guarantee fair competition on the Union market.
- (5) All economic operators intervening in the supply and distribution chain should take the appropriate measures to ensure that they only make available on the market electrical equipment which is 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.
- (6) The manufacturer, having detailed knowledge of the design and production process, is best placed to carry out the complete conformity assessment procedure for electrical

equipment. Conformity assessment should therefore remain the obligation of the manufacturer alone.

- (7) Although conformity assessment should be the responsibility of the manufacturer without any need to involve an independent conformity assessment body, in order to facilitate the completion of the conformity assessment procedure, manufacturers should be allowed to seek assistance of an independent conformity assessment laboratory.
- (8) It is necessary to ensure that electrical equipment 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 this electrical equipment. Provision should therefore be made for importers to make sure that electrical equipment they place on the market comply with the requirements of this Directive and that they do not place on the market electrical equipment which does 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.
- (9) The distributor makes electrical equipment 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 electrical equipment does not adversely affect the compliance of the electrical equipment.
- (10) When placing electrical equipment on the market, every importer should indicate on the electrical equipment 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 electrical equipment 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.
- (11) Any economic operator that either places electrical equipment on the market under his own name or trademark or modifies electrical equipment 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.
- (12) 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 electrical equipment concerned.
- (13) Ensuring traceability of electrical equipment 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.
- (14) This Directive should be limited to the expression of the safety objectives. In order to facilitate conformity assessment with those objectives it is necessary to provide for presumption of conformity for electrical 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 for the purpose of expressing detailed technical specifications of those objectives.

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

✓ 2006/95 recital 8 (adapted)
⇒ new

(16) As a transitional measure,  $\underline{tT}$  he free movement of electrical equipment for which harmonised standards do not yet exist <u>shouldmay</u> be achieved by applying the safety provisions or standards already laid down by  $\Rightarrow$  the International Electrotechnical Commission  $\Rightarrow$  other international bodies or by one of the bodies which establish harmonised standards  $\boxtimes$  applying national standards  $\bigotimes$ .

**↓** 2006/95 recital 9

It is possible that electrical equipment may be placed in free circulation even though it does not comply with the safety requirements, and it is therefore desirable to lay down suitable provisions to minimise this danger

**↓** 2006/95 recital 10 (new)

Council Decision 93/465/EEC<sup>49</sup> establishes the modules for the various phases of the conformity assessment procedures which are intended to be used in the technical harmonisation Directives.

**↓** 2006/95 recital 11

The choice of procedures should not lead to a lowering of safety standards of electrical equipment, which have already been established throughout the Community.

<sup>↓</sup> new

(17) In order to enable economic operators to demonstrate and the competent authorities to ensure that electrical equipment made available on the market is in conformity with

<sup>(1)</sup>Council Decision 93/465/EEC of 22 July 1993 concerning the modules for the various phases of the conformity assessment procedures and the rules for the affixing and use of the CE conformity marking, which are intended to be used in the technical harmonisation directives (OJ L 220, 30.08.1993, p. 23).

the safety objectives 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.

- (18) Manufacturers should draw up an EU declaration of conformity to provide detailed information on the conformity of electrical equipment with the requirements of this Directive and of the other relevant Union harmonisation legislation.
- (19) The CE marking, indicating the conformity of electrical equipment, 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.
- (20) 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 electrical equipment. This Directive should not prevent Member States from choosing the competent authorities that carry out those tasks.
- (21) Directive 2006/95/EC already provides for a safeguard procedure which applies only in the event of disagreement between Member States over measures taken by a Member State. 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.
- (22) 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 the health and safety of persons or to other 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.
- (23) 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.
- (24) 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.
- (25) It is necessary to provide for transitional arrangements that allow making available on the market electrical equipment which has already been placed on the market in accordance with Directive 2006/95/EC.
- (26) Since the objective of this Directive, namely to ensure that electrical equipment on the market fulfil the requirements providing a high level of protection of health and safety and other public interests while guaranteeing the functioning of the internal market

cannot be sufficiently achieved by the Member States and can therefore, by reason of its scale and effects, be better achieved at Union level, the 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.

(27) The obligation to transpose this Directive into national law should be confined to those provisions which represent a substantive change as compared with the Directive 2006/95/EC. The obligation to transpose the provisions which are unchanged arises under the earlier Directive.

◆ 2006/95 recital 12 (adapted)

(28) 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 the Directives set out in <u>Part B of</u> Annex V to <u>Directive 2006/95/EC</u>, <u>Part B</u>.

**↓** 2006/95 (adapted)

HAVE ADOPTED THIS DIRECTIVE:

# <u>Chapter 1</u>

# $\boxtimes$ General provisions $\bigotimes$

Article 1

# 🗵 Scope 🖾

For the purposes of  $\underline{\underline{tT}}$  his Directive,  $\underline{\underline{s}}$  shall apply to  $\underline{\underline{s}}$  electrical equipment  $\underline{\underline{t}}$  means any equipment designed for use with a voltage rating of between 50 and 1000 V for alternating current and between 75 and 1500 V for direct current, other than the equipment and phenomena listed in Annex II.

<sup>₽</sup> new

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

Definitions

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

- (1) "placing on the market" means the first making available of electrical equipment on the Union market;
- (2) "making available on the market" means any supply of electrical equipment 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;
- (3) "manufacturer" means any natural or legal person who manufactures electrical equipment or has electrical equipment designed or manufactured, and markets that equipment under his name or trademark;
- (4) "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;
- (5) "importer" means any natural or legal person established within the Union who places electrical equipment from a third country on the Union market;
- (6) "distributor" means any natural or legal person in the supply chain, other than the manufacturer or the importer, who makes electrical equipment available on the market;
- (7) "economic operators" means the manufacturer, the authorised representative, the importer and the distributor;
- (8) "technical specification" means a document that prescribes technical requirements to be fulfilled by an electrical equipment;
- (9) "harmonised standard" means harmonised standard as defined in Article 2(1)(c) of Regulation (EU) No [../..] [on European Standardisation];
- (10) "conformity assessment" means the process demonstrating whether the safety objectives relating to electrical equipment have been fulfilled;
- (11) "recall" means any measure aimed at achieving the return of electrical equipment that has already been made available to the end user;
- (12) "withdrawal" means any measure aimed at preventing electrical equipment in the supply chain from being made available on the market;
- (13) "CE marking" means a marking by which the manufacturer indicates that the electrical equipment is in conformity with the applicable requirements set out in Union harmonisation legislation providing for its affixing;
- (14) "Union harmonisation legislation" means any Union legislation harmonising the conditions for the marketing of products.

✓ 2006/95 (adapted)
⇒ new

# Article <u>3</u>₽

## $\boxtimes$ Making available on the market and safety objectives $\bigotimes$

1. The Member States shall take all appropriate measures to ensure that <u>e</u>Electrical equipment may be  $\Rightarrow$  made available  $\Rightarrow$  placed on the market only if, having been constructed in accordance with good engineering practice in safety matters in force in the Community  $\boxtimes$  Union  $\bigotimes$ , it does not endanger the safety of persons, domestic animals or property when properly installed and maintained and used in applications for which it was made.

♦ 2006/95

2. The principal elements of the safety objectives referred to in paragraph 1 are listed in Annex I.

## Article <u>4<del>3</del></u>

# ➢ Free movement <</p>

The Member States shall take all appropriate measures to ensure that if electrical equipment is of such a nature as to comply with Article 2, subject to the conditions laid down in Articles 5,  $\frac{6}{6}$ ,  $\frac{7}{0}$  or  $\frac{8}{10}$  this Directive  $\ll$ , the free movement thereof within the Community  $\approx$  Union  $\ll$  shall not be impeded for reasons of safety  $\approx$  the aspects covered by this Directive  $\ll$ .

## Article <u>54</u>

# Supply of electricity

In relation to electrical equipment, the Member States shall ensure that stricter safety requirements than those laid down in Article m2-3  $\implies$  and Annex I  $\iff$  are not imposed by electricity supply bodies for connection to the grid, or for the supply of electricity to users of electrical equipment.

# Chapter 2

# $\boxtimes$ Obligations of economic operators $\bigotimes$

**↓** 2006/95

#### Article 5

The Member States shall take all appropriate measures to ensure that, in particular, electrical equipment which complies with the safety provisions of harmonised standards shall be regarded by their competent administrative authorities as complying with the provisions of Article 2, for the purposes of placing on the market and free movement as referred to in Articles 2 and 3 respectively.

Standards shall be regarded as harmonised once they are drawn up by common agreement between the bodies notified by the Member States in accordance with Article 11, first paragraph, point (a), and published under national procedures. The standards shall be kept up to date in the light of technological progress and the developments in good engineering practice in safety matters.

For purposes of information the list of harmonised standards and their references shall be published in the *Official Journal of the European Union*.

₽ new

Article 6 [Article R2 of Decision No 768/2008/EC]

## **Obligations of manufacturers**

1. When placing electrical equipment on the market, manufacturers shall ensure that it has been designed and manufactured in accordance with Article 3 and Annex I.

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

Where compliance of electrical equipment with the applicable requirements has been demonstrated by the procedure referred to in the first subparagraph, 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 a period of 10 years after the electrical equipment has been placed on the market.

4. Manufacturers shall ensure that procedures are in place for series production to remain in conformity. Changes in product design or characteristics and changes in the harmonised

standards or in technical specifications by reference to which conformity of electrical equipment is declared shall be adequately taken into account.

When deemed appropriate with regard to the risks presented by electrical equipment, manufacturers shall, to protect the safety of consumers, carry out sample testing of electrical equipment made available on the market, investigate, and, if necessary, keep a register of complaints, of non-conforming electrical equipment and electrical equipment recalls, and shall keep distributors informed of any such monitoring.

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

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

7. Manufacturers shall ensure that the electrical equipment is accompanied by safety information 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 electrical equipment which they have placed on the market is not in conformity with this Directive shall immediately take the necessary corrective measures to bring that electrical equipment into conformity, to withdraw it or recall it, if appropriate. Furthermore, where the electrical equipment presents a risk, manufacturers shall immediately inform the competent national authorities of the Member States in which they made the electrical equipment available 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 electrical equipment, 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 electrical equipment which they have placed on the market.

# Article 7 [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 6(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 a

period of 10 years after the electrical equipment 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 electrical equipment;
- (c) cooperate with the competent national authorities, at their request, on any action taken to eliminate the risks posed by electrical equipment covered by the authorised representative's mandate.

# Article 8 [Article R4 of Decision No 768/2008/EC]

## **Obligations of importers**

1. Importers shall place only compliant electrical equipment on the market.

2. Before placing electrical equipment 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 electrical equipment bears the CE marking and is accompanied by the required documents, and that the manufacturer has complied with the requirements set out in Article 6(5) and (6).

Where an importer considers or has reason to believe that electrical equipment is not in conformity with Article 3 and Annex I, he shall not place the electrical equipment on the market until it has been brought into conformity. Furthermore, where the electrical equipment 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 electrical equipment or, where that is not possible, on its packaging or in a document accompanying the electrical equipment.

4. Importers shall ensure that the electrical equipment is accompanied by safety information 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 electrical equipment is under their responsibility, storage or transport conditions do not jeopardize its compliance with the safety objectives set out in Article 3 and Annex I.

6. When deemed appropriate with regard to the risks presented by electrical equipment, importers shall, to protect the safety of consumers, carry out sample testing of electrical equipment made available on the market, investigate and, if necessary, keep a register of complaints, of non-conforming electrical equipment and electrical equipment recalls, and shall keep distributors informed of such monitoring.

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

8. Importers shall, for a period of 10 years after the electrical equipment 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.

9. 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 electrical equipment 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 electrical equipment which they have placed on the market.

## Article 9[Article R5 of Decision No 768/2008/EC]

## **Obligations of distributors**

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

2. Before making electrical equipment available on the market distributors shall verify that the electrical equipment bears the CE marking, that it is accompanied by the safety information in a language which can be easily understood by consumers and other end-users in the Member State in which the electrical equipment is to be made available on the market, and that the manufacturer and the importer have complied with the requirements set out in Article 6(5) and 6(6) and Article 8 (3).

Where a distributor considers or has reason to believe that electrical equipment is not in conformity with the requirements set out in Article 3 and Annex I, he shall not make the electrical equipment available on the market until it has been brought into conformity. Furthermore, where the electrical equipment 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 electrical equipment is under their responsibility, storage or transport conditions do not jeopardise its compliance with the requirements set out in Article 3 and Annex I.

4. Distributors who consider or have reason to believe that electrical equipment which they have made available on the market is not in conformity with this Directive shall make sure that the corrective measures necessary to bring that equipment into conformity, to withdraw it or recall it, if appropriate, are taken. Furthermore, where the electrical equipment presents a risk, distributors shall immediately inform the competent national authorities of the Member States in which they made the electrical equipment 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 electrical equipment. They shall cooperate with that authority, at its request, on any action taken to eliminate the risks posed by electrical equipment which they have made available on the market.

Article 10 [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 6, where he places electrical equipment on the market under his name or trademark or modifies electrical equipment already placed on the market in such a way that compliance with the requirements of this Directive may be affected.

Article 11 [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 electrical equipment;

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

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 electrical equipment and for a period of 10 years after they have supplied the electrical equipment.

# Chapter 3

# Conformity of the electrical equipment

Article 12 [Article R8 of Decision No 768/2008/EC]

## Presumption of conformity with harmonised standards

Electrical equipment which is in conformity with harmonised standards or parts thereof the references of which have been published in the *Official Journal of the European Union* shall be presumed to be in conformity with the safety objectives covered by those standards or parts thereof, set out in Article 3 and Annex I.

[Where a harmonised standard satisfies the requirements which it covers and which are set out in Article 3 and Annex I, the Commission shall publish the references of those standards in the *Official Journal of the European Union*.]

✓ 2006/95 (adapted)
⇒ new

## Article <u>13<del>6</del></u>

## $\boxtimes$ Presumption of conformity with international standards $\bigotimes$

1. Where harmonised standards as defined  $\boxtimes$  referred to  $\bigotimes$  in Article <u>125</u> have not <del>yet</del> been drawn up and published, the Member States shall take all appropriate measures to ensure that, for the purposes of <del>placing</del>  $\Rightarrow$  making available  $\Leftrightarrow$  on the market or free movement as referred to in Articles <u>23</u> and <u>34</u> respectively, their competent administrative authorities shall also regard as complying with the provisions of Article <u>32</u>  $\boxtimes$  and Annex I  $\bigotimes$  electrical equipment which complies with the safety provisions of the International Commission on the Rules for the Approval of Electrical Equipment (CEE) or of the International Electrotechnical Commission (IEC) in respect of which the publication procedure laid down in paragraphs 2 and 3 of this Article has been applied

2. The safety provisions referred to in paragraph 1 shall be notified to the Member States by the Commission as from the entry into force of this Directive, and thereafter as and when they are published. The Commission, after consulting the Member States, shall state the provisions and in particular the variants which it recommends to be published.

3. The Member States shall inform the Commission within a period of three months of such  $\boxtimes$  any  $\bigotimes$  objections as they may have to the provisions thus notified  $\boxtimes$  in accordance with paragraph 2  $\bigotimes$ , stating the safety grounds on account of which the provisions should not be recognised.

For purposes of information those  $\boxtimes$  the  $\bigotimes$  safety provisions against which no objection has been raised shall be published in the Official Journal of the European Union.

# Article <u>14<del>7</del></u>

# $\boxtimes$ Presumption of conformity with national standards $\bigotimes$

Where harmonised standards within the meaning of  $\boxtimes$  referred to in  $\bigotimes$  Article  $\frac{5}{2}$  12 or safety provisions published in accordance with  $\boxtimes$  referred to in  $\bigotimes$  Article  $\frac{613}{2}$  are not yet in existence, the Member States shall take all appropriate measures to ensure that, for the purpose of placing  $\Rightarrow$  making available  $\Leftrightarrow$  on the market or free movement as referred to in Articles  $\frac{23}{23}$  and  $\frac{24}{24}$  respectively, their competent administrative authorities shall also regard as complying with the provisions of Article  $\frac{23}{23}$  and Annex I  $\bigotimes$  electrical equipment manufactured in accordance with the safety provisions of the standards in force in the Member State of manufacture, if it ensures a safety level equivalent to that required in their own territory.

♦ 2006/95

#### Article 8

 Before being placed on the market, the electrical equipment must have affixed to it the CE marking provided for in Article 10 attesting to its conformity to the provisions of this Directive, including the conformity assessment procedure described in Annex IV.

2. In the event of a challenge, the manufacturer or importer may submit a report, drawn up by a body, which is notified in accordance with Article 11, first paragraph, point (b), on the conformity of the electrical equipment with the provisions of Article 2.

3. Where electrical equipment is subject to other Directives concerning other aspects which also provide for the affixing of the CE marking, the latter shall indicate that the equipment in question is also presumed to conform to the provisions of those other Directives.

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

### Article 9

1. If, for safety reasons, a Member State prohibits the placing on the market of any electrical equipment or impedes its free movement, it shall immediately inform the other Member States concerned and the Commission, indicating the grounds for its decision and stating in particular:

(a) whether its non-conformity with Article 2 is attributable to a shortcoming in the harmonised standards referred to in Article 5, the provisions referred to in Article 6 or the standards referred to in Article 7;

(b) whether its non-conformity with Article 2 is attributable to faulty application of such standards or publications or to failure to comply with good engineering practice as referred to in that Article.

2. If other Member States raise objections to the decision referred to in paragraph 1, the Commission shall immediately consult the Member States concerned.

3. If an agreement has not been reached within three months from the date of communication of the information as laid down in paragraph 1, the Commission shall obtain the opinion of one of the bodies notified in accordance with Article 11, first paragraph, point (b), having its registered office outside the territory of the Member States concerned and which has not been involved in the procedure provided for in Article 8. The opinion shall state the extent to which the provisions of Article 2 have not been complied with. 4. The Commission shall communicate the opinion of the body referred to in paragraph 3 to all Member States which may, within a period of one month, make their observations known to the Commission. The Commission shall at the same time note any observations by the parties concerned on that opinion.

5. Having taken note of these observations the Commission shall, if necessary, formulate the appropriate recommendations or opinions.

#### Article 10

1. The CE conformity marking referred to in Annex III shall be affixed by the manufacturer or his authorised representative established within the Community to the electrical equipment or, failing that, to the packaging, the introduction sheet or the guarantee certificate so as to be visible, easily legible and indelible.

2. The affixing on electrical equipment of any markings liable to deceive third parties as to the meaning and form of the CE marking shall be prohibited. However, any other marking may be affixed to the electrical equipment, its packaging, the instruction sheet or the guarantee certificate provided that the visibility and legibility of the CE marking is not thereby reduced.

#### 3. Without prejudice to Article 9:

- (a) where a Member State establishes that the CE marking has been affixed unduly, the manufacturer or his authorised representative established within the Community shall be obliged to make the electrical equipment comply as regards the provisions concerning the CE marking and to end the infringement under conditions imposed by the Member State;
- (b) where non-compliance continues, the Member State shall take all appropriate measures to restrict or prohibit the placing on the market of the electrical equipment in question or to ensure that it is withdrawn from the market in accordance with Article 9.

#### Article 11

Each Member State shall inform the other Member States and the Commission of the following:

(a) the bodies referred to in Article 5, second paragraph;

(b) the bodies which may make a report in accordance with Article 8(2) or give an opinion in accordance with Article 9;

(c) the publication reference referred to in the second paragraph of Article 5.

Any amendment to the above shall be notified by each Member State to the other Member States and to the Commission.

#### Article 12

#### This Directive shall not apply to electrical equipment intended for export to third countries.

₽ 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 safety objectives set out in Article 3 and Annex I has been demonstrated.

2. The EU declaration of conformity shall have the model structure set out in Annex IV of this Directive, shall contain the elements specified in the Module A as set out in Annex III of this Directive and shall be continuously updated. It shall be translated into the language or languages required by the Member State in which market the electrical equipment is placed or made available.

3. Where the electrical equipment 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 electrical equipment.

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 electrical equipment or to its data plate. Where that is not possible or not warranted on account of the nature of the electrical equipment, it shall be affixed to the packaging and to any accompanying documents.

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

# Chapter 4

# Union market surveillance, control of products entering the Union market and safeguard procedures

# Article 18

# Union market surveillance and control of products entering the Union market

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

## Article 19 [Article R31 of Decision No 768/2008/EC]

## Procedure for dealing with electrical equipment 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 electrical equipment covered by this Directive presents a risk to the safety of persons, domestic animals or property, they shall carry out an evaluation in relation to the electrical equipment 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 electrical equipment 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 electrical equipment into compliance with those requirements, to withdraw the electrical equipment from the market, or to recall it within a reasonable period, commensurate with the nature of the risk, as they may prescribe.

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 electrical equipment 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 electrical equipment's being made available on their national market, to withdraw the electrical equipment from that market or to recall it.

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

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 electrical equipment, the origin of the electrical equipment, 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:

(a) failure of the electrical equipment to meet requirements relating to the safety of persons, domestic animals or property ;

(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 electrical equipment concerned, and, in the event of disagreement with the notified national measure, of their objections.

7. Where, within two 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 electrical equipment concerned without delay.

## Article 20 [Article R32 of Decision No 768/2008/EC]

## Union safeguard procedure

1. Where, on completion of the procedure set out in Article 19(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 electrical equipment 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 electrical equipment is attributed to shortcomings in the harmonised standards referred to in Article 19(5)(b) of this Directive, the Commission shall apply the procedure provided for in Article 8 of Regulation (EU) No [../..] [on European Standardisation].

# Compliant electrical equipment which present a risk to safety

1. Where, having performed an evaluation under Article 19(1), a Member State finds that although electrical equipment is in compliance with this Directive, it presents a risk to the safety of persons, it shall require the relevant economic operator to take all appropriate measures to ensure that the electrical equipment concerned, when placed on the market, no longer presents that risk, to withdraw the electrical equipment from the market or to recall it within a reasonable period, commensurate with the nature of the risk, as it may prescribe.

2. The economic operator shall ensure that corrective action is taken in respect of electrical equipment concerned that he has made available on the market throughout the Union.

3. The Member State shall immediately inform the Commission and the other Member States of the corrective action taken. That information shall include all available details, in particular the data necessary for the identification of the electrical equipment concerned, the origin and the supply chain of the electrical equipment, the nature of the risk involved and the nature and duration of the national measures taken.

4. The Commission shall without delay enter into consultation with the Member States and the relevant economic operator or operators and shall evaluate the corrective measures taken. On the basis of the results of that evaluation, the Commission shall decide whether the measure is justified or not, and where necessary, propose appropriate measures.

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

# Article 22 [Article R34 of Decision No 768/2008/EC]

## Formal non-compliance

1. Without prejudice to Article 19, 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 electrical equipment being made available on the market or ensure that it is recalled or withdrawn from the market.

# Chapter 5

# Transitional and final provisions

# Article 23

# Penalties

Member States shall lay down rules on penalties for economic operators, 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 [insert date – the date set out in the second subparagraph of Article 25(1)] at the latest and shall notify it without delay of any subsequent amendment affecting them.

# Article 24

## Transitional provisions

Member States shall not impede the making available on the market of electrical equipment covered by Directive 2006/95/EC which is in conformity with that Directive and which was placed on the market before [date set out in the second subparagraph of Article 25(1)].

 $\mathbf{4}$ 

Article 25

## 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 Articles 2, 3(1), 6, 7, 8, 9, 10, 11, 12, 13(1), 14, 15, 16, 17, 18, 19, 20, 21, 22, 23 and 24 and Annexes III and IV. They shall forthwith communicate to the Commission the text of those provisions and a correlation table between those provisions and this Directive.

They shall apply those provisions from [day after the date set out in the first subparagraph].

When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. 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.

**↓** 2006/95 (adapted)

# Article 13

<u>2.</u> The Member States shall communicate to the Commission the texts of the main provisions of national laws which they adopt in the field covered by this Directive.

# *Article* <u>1426</u>

## 🗵 Repeal 🖾

Directive  $\frac{73/23/EEC}{2006/95/EC}$  is hereby repealed  $\boxtimes$  with effect from [the date set out in the second subparagraph of Article 25(1) of this Directive],  $\bigotimes$  without prejudice to the obligations of the Member States relating to the time-limits for transposition into national law and application of the Directives set out in <u>Annex V</u>, Part B <u>of Annex V to Directive</u> 2006/95/EC.

References made to the repealed Directive shall be construed as  $\boxtimes$  references  $\bigotimes$  being made to this Directive and should  $\boxtimes$  shall  $\bigotimes$  be read in accordance with the correlation table in <u>Annex V<del>Annex VI</del></u>.

# Article <u>27<del>15</del></u>

# $\boxtimes$ Entry into force $\bigotimes$

♦ 2006/95

 $\mathbf{1}$ 

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

Articles 1, 3(2), 4, 5, 13(2) and 13(3) and Annexes I, II and V shall apply from [the date set out in the second subparagraph of Article 25(1)].

↓ 2006/95 (adapted)

Article <u>28<del>16</del></u>

# 🖾 Addressees 🖾

♦ 2006/95

This Directive is addressed to the Member States.

Done at [...],

For the European Parliament The President For the Council The President

**↓** 2006/95 (adapted)

# ANNEX I

#### PRINCIPAL ELEMENTS OF THE SAFETY OBJECTIVES FOR ELECTRICAL EQUIPMENT DESIGNED FOR USE WITHIN CERTAIN VOLTAGE LIMITS

### 1. General conditions

(a)  $\underline{\pm}$  the essential characteristics, the recognition and observance of which will ensure that electrical equipment will be used safely and in applications for which it was made, shall be marked on the equipment, or, if this is not possible, on an accompanying notice  $\underline{z}$ :

(b) The brand name or the trade mark should be clearly printed on the electrical equipment or, where that is not possible, on the packaging.

 $(\underline{e})(\underline{b}) \underline{\pm} t$  he electrical equipment, together with its component parts, <u>shall<del>should</del></u> be made in such a way as to ensure that it can be safely and properly assembled and connected  $\underline{\underline{s}}$ .

 $\underline{(d)(c)} \underline{\pm}t$  he electrical equipment <u>shallshould</u> be so designed and manufactured as to ensure that protection against the hazards set out in points 2 and 3 of this Annex is assured, providing that the equipment is used in applications for which it was made and is adequately maintained.

2. Protection against hazards arising from the electrical equipment

Measures of a technical nature <u>shall<del>should</del></u> be prescribed in accordance with point 1, in order to ensure:

(a) that persons and domestic animals are adequately protected against the danger of physical injury or other harm which might be caused by direct or indirect contact;

(b) that temperatures, arcs or radiation which would cause a danger, are not produced;

(c) that persons, domestic animals and property are adequately protected against nonelectrical dangers caused by the electrical equipment which are revealed by experience;

(d) that the insulation must be suitable for foreseeable conditions.

3. Protection against hazards which may be caused by external influences on the electrical equipment

Technical measures are to be laid down in accordance with point 1, in order to ensure:

(a) that the electrical equipment meets the expected mechanical requirements in such a way that persons, domestic animals and property are not endangered;

(b) that the electrical equipment shall be resistant to non-mechanical influences in expected environmental conditions, in such a way that persons, domestic animals and property are not endangered;

(c) that the electrical equipment shall not endanger persons, domestic animals and property in foreseeable conditions of overload.

# ANNEX II

## EQUIPMENT AND PHENOMENA OUTSIDE THE SCOPE OF THIS DIRECTIVE

Electrical equipment for use in an explosive atmosphere

Electrical equipment for radiology and medical purposes

Electrical parts for goods and passenger lifts

Electricity meters

Plugs and socket outlets for domestic use

Electric fence controllers

Radio-electrical interference

Specialised electrical equipment, for use on ships, aircraft or railways, which complies with the safety provisions drawn up by international bodies in which the Member States participate.

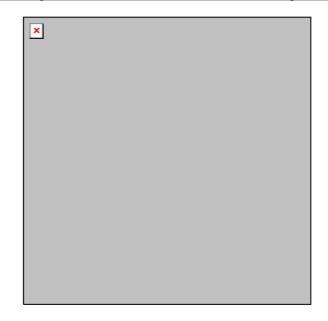
♦ 2006/95

## ANNEX III

#### CE CONFORMITY MARKING AND EC DECLARATION OF CONFORMITY

#### A. CE CONFORMITY MARKING

The CE conformity marking shall consist of the initials 'CE' taking the following form:



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

The various components of the CE marking must have substantially the same vertical dimension, which may not be less than 5 mm.

#### B. EC DECLARATION OF CONFORMITY

The EC declaration of conformity must contain the following elements:

 name and address of the manufacturer or his authorised representative established within the Community,

a description of the electrical equipment,

reference to the harmonised standards,

where appropriate, references to the specifications with which conformity is declared,

identification of the signatory who has been empowered to enter into commitments on behalf of the manufacturer or his authorised representative established within the Community,

₽ new

# ANNEX III [Annex II, Module A, of Decision No 768/2008/EC]

# Module A

# Internal production control

1. Internal production control is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2, 3 and 4, and ensures and declares on his sole responsibility that the electrical equipment concerned satisfy the requirements of this Directive.

## 2. Technical documentation

The manufacturer shall establish the technical documentation. The documentation shall make it possible to assess the electrical equipment's 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 electrical equipment. The technical documentation shall, wherever applicable, contain at least the following elements:

- a general description of the electrical equipment,

- conceptual design and manufacturing drawings and schemes of components, subassemblies, circuits, etc.,

- descriptions and explanations necessary for the understanding of those drawings and schemes and the operation of the electrical equipment,

- 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 safety objectives 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 electrical equipment with the technical documentation referred to in point 2 and with the requirements of this Directive.

# 4. CE marking and EU declaration of conformity

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

4.2. The manufacturer shall draw up a written EU declaration of conformity for a product model and keep it together with the technical documentation at the disposal of the national authorities for ten years after the electrical equipment has been placed on the market. The EU declaration of conformity shall identify the electrical equipment 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.

↓ 2006/95

### ANNEX IV

#### INTERNAL PRODUCTION CONTROL

1. Internal production control is the procedure whereby the manufacturer or his authorised representative established within the Community, who carries out the obligations laid down in point 2, ensures and declares that the electrical equipment satisfies the requirements of this Directive that apply to it. The manufacturer or his authorised representative established within the Community must affix the CE marking to each product and draw up a written declaration of conformity.

2. The manufacturer must establish the technical documentation described in point 3 and he or his-authorised representative established within the Community must keep it on Community territory at the disposal of the relevant national authorities for inspection purposes for a period ending at least 10 years after the last product has been manufactured.

Where neither the manufacturer nor his authorised representative is established within the Community, this obligation is the responsibility of the person who places the electrical equipment on the Community market.

3. Technical documentation must enable the conformity of the electrical equipment to the requirements of this Directive to be assessed. It must, as far as relevant for such assessment, cover the design, manufacture and operation of the electrical equipment. It must include:

a general description of the electrical equipment,

 conceptual design and manufacturing drawings and schemes of components, subassemblies, circuits, etc.,

 descriptions and explanations necessary for the understanding of said drawings and schemes and the operation of the electrical equipment,

 a list of the standards applied in full or in part, and descriptions of the solutions adopted to satisfy the safety aspects of this Directive where standards have not been applied,

results of design calculations made, examinations carried out, etc.,

test reports.

 The manufacturer or his authorised representative must keep a copy of the declaration of conformity with the technical documentation.

5. The manufacturer must take all measures necessary in order that the manufacturing process shall ensure compliance of the manufactured products with the technical documentation referred to in point 2 and with the requirements of this Directive that apply to them.

<sup>₽</sup> new

# ANNEX IV [Annex III of Decision No 768/2008/EC]

### EU DECLARATION OF CONFORMITY

- 1. No xxxxxx (unique identification of the electric equipment):
- 2. Name and address of the manufacturer or his authorised representative:
- 3. This EU declaration of conformity is issued under the sole responsibility of the manufacturer:
- 4. Object of the declaration (identification of electrical equipment allowing traceability. It shall include a colour image of sufficient clarity to enable the identification of the electric equipment).
- 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, or references to the specifications in relation to which conformity is declared:
- 7. Additional information:

Signed for and on behalf of:....

(place and date of issue)

(name, function)(signature)

**↓** 2006/95 (adapted)

## ANNEX V

#### PART A

#### **Repealed Directive with its amendment**

Council Directive 73/23/EEC	<del>(OJ L 77, 26.3.1973, p. 29)</del>
Council Directive 93/68/EEC Article 1	<del>(OJ L 220, 30.8.1993, p. 1)</del>
point 12 and Article 13 only	

#### PART B

#### List of time-limits for transposition into national law and application

#### (referred to in Article 14)

Directive	Time-limit for transposition	Date of application
<del>73/23/EEC</del>	<del>21 August 1974<sup>11</sup></del>	E.
<del>93/68/EEC</del>	<del>1 July 1994</del>	<del>1 January 1995<sup>12</sup></del>

<sup>&</sup>lt;sup>11</sup> (1)In the case of Denmark the time-limit was extended to five years, i.e. 21 February 1978. See Article 13(1) of Directive 73/23/EEC.

<sup>&</sup>lt;sup>12</sup> (2)Until 1 January 1997 Member States had to allow the placing on the market and the bringing into service of products which complied with the marking arrangements in force before 1 January 1995. See Article 14(2) of Directive 93/68/EEC.

**↓** 2006/95 (adapted)

# ANNEX VI

# **Correlation Table**

Directive <del>73/23/EEC</del> ≥ 2006/95/EC ≤	This Directive
Articles 1 — 7	Articles 1 — 7
Article 8(1)	Article 8(1)
Article 8(2)	Article 8(2)
Article 8(3)(a)	Article 8(3), first subparagraph
Article 8(3)(b)	Article 8(3), second subparagraph
Article 9(1), first indent	Article 9(1) (a)
Article 9(1), second indent	Article 9(1) (b)
Article 9(2) to (5)	Article 9(2) to (5)
Article 10	Article 10
Article 11, first indent	Article 11(a)
Article 11, second indent	Article 11(b)
Article 11, third indent	Article 11(c)
Article 12	Article 12
Article 13(1)	—
Article 13(2)	Article 13
_	Article 14
<b>—</b>	Article 15
Article 14	Article 16
Annexes I to IV	Annexes I to IV
<b>—</b>	Annex V
—	Annex VI
⊠ Article 1	I → Article 1

Article 2	Article 3
Article 3	Article 4
Article 4	Article 5
Article 5	Article 12
Article 6	Article 13
Article 7	Article 14
Article 8 (1)	Article 16
Article 8 (2)	-
Article 8 (3)	-
Article 9	Articles 18 to 20
Article 10	Articles 16 and 17
Article 11	-
Article 12	-
Article 13	Article 25 (2)
Article 14	Article 26
Article 15	Article 27
Annex I	Annex I
Annex II	Annex II
Annex III	Articles 15 and 16 and Annex
Annex IV	Annex III
Annex V	- 🖾

IV