Procedure file

Basic information

2011/0357(COD) COD - Ordinary legislative procedure (ex-codecision

procedure) Directive

Electrical equipment designed for use within certain voltage limits: making available on the market. Recast. 'Goods package'

Repealing Directive 2006/95/EC 2003/0094(COD)

See also 2007/0029(COD) See also 2007/0030(COD)

Amended by 2017/0353(COD)

Subject

2.10.03 Standardisation, EC/EU standards and trade mark, certification,

3.40.06 Electronics, electrotechnical industries, ICT, robotics

Procedure completed

Key players

| European Parliament | Committee responsible | Rapporteur | Appointed |
|---------------------|---|------------|------------|
| | Internal Market and Consumer Protection | | 29/11/2011 |

PPE ROITHOVÁ Zuzana

Shadow rapporteur

S&D SCHALDEMOSE Christel

20/02/2014

ALDE MANDERS Toine

Verts/ALE RÜHLE Heide

ECR FOX Ashley

EFD SALVINI Matteo

Committee for opinion Rapporteur for opinion Appointed

ITRE Industry, Research and Energy The committee decided not to

give an opinion.

JURI Legal Affairs

Council of the European Union Council configuration Meeting Date

Competitiveness (Internal Market, Industry, Research 3295

and Space)

Commission DG Commissioner **European Commission**

Internal Market, Industry, Entrepreneurship and SMEs TAJANI Antonio

European Economic and

Social Committee

| Key | event | S |
|-----|-------|---|
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| Key events | | | |
|------------|--|---------------|---------|
| 21/11/2011 | Legislative proposal published | COM(2011)0773 | Summary |
| 30/11/2011 | Committee referral announced in Parliament, 1st reading/single reading | | |
| 10/07/2012 | Vote in committee, 1st reading/single reading | | |
| 28/11/2012 | Committee report tabled for plenary, 1st reading/single reading | A7-0259/2012 | Summary |
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| 04/02/2014 | Debate in Parliament | T | |
|------------|---|---------------------|---------|
| 05/02/2014 | Results of vote in Parliament | | |
| 05/02/2014 | Decision by Parliament, 1st reading/single reading | <u>T7-0088/2014</u> | Summary |
| 20/02/2014 | Act adopted by Council after Parliament's 1st reading | | |
| 26/02/2014 | Final act signed | | |
| 26/02/2014 | End of procedure in Parliament | | |
| 29/03/2014 | Final act published in Official Journal | | |

| Technical information | |
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| Procedure reference | 2011/0357(COD) |
| Procedure type | COD - Ordinary legislative procedure (ex-codecision procedure) |
| Procedure subtype | Recast |
| Legislative instrument | Directive |
| | Repealing Directive 2006/95/EC 2003/0094(COD) See also 2007/0029(COD) See also 2007/0030(COD) Amended by 2017/0353(COD) |
| Legal basis | Treaty on the Functioning of the EU TFEU 114-p1 |
| Modified legal basis | Rules of Procedure EP 150 |
| Mandatory consultation of other institutions | European Economic and Social Committee |
| Stage reached in procedure | Procedure completed |
| Committee dossier | IMCO/7/07955 |

| Documentation gateway | | | | |
|---|---------------------|------------|----|---------|
| Legislative proposal | COM(2011)0773 | 21/11/2011 | EC | Summary |
| Committee draft report | PE488.068 | 07/05/2012 | EP | |
| Amendments tabled in committee | PE491.154 | 07/06/2012 | EP | |
| Committee report tabled for plenary, 1st reading/single reading | A7-0259/2012 | 28/11/2012 | EP | Summary |
| Text adopted by Parliament, 1st reading/single reading | <u>T7-0088/2014</u> | 05/02/2014 | EP | Summary |
| Commission response to text adopted in plenary | SP(2014)446 | 20/05/2014 | | |

| Additional information | |
|------------------------|-------------|
| National parliaments | <u>IPEX</u> |
| European Commission | EUR-Lex |

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2011/0357(COD) - 21/11/2011 Legislative proposal

PURPOSE: to align Directive 2006/95/EC on the harmonisation of the laws of Member States relating to electrical equipment designed for use within certain voltage limits with the new legislative framework, in particular to Decision No 768/2008/EC establishing a common framework for the marketing of products (Goods Package).

PROPOSED ACT: Directive of the European Parliament and of the Council.

BACKGROUND: 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.

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.

This proposal on the harmonisation of the laws of Member States relating to electrical equipment designed for use within certain voltage limits 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.

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;
- Option 2 Alignment to the NLF Decision by non-legislative measures;
- 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 for the following reasons: (i) it will improve the competitiveness of companies and notified bodies taking their obligations seriously, as opposed to those cheating on the system; (ii) 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; (iii) it does not entail significant costs for economic operators and notified bodies; (iv) 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.

LEGAL BASIS: Article 114 of the Treaty on the Functioning of the European Union (TFEU).

CONTENT: 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. 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 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.

The main elements of the proposal are as follows:

- 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.
- Obligations of economic operators and traceability requirements: the proposal clarifies the obligations of manufacturers 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 materials are correctly marked and accompanied by instructions and safety information. 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 the 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.
- 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 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.
- Conformity assessment and CE marking: Directive 2006/95/EC on the placing on the market of electrical equipment has selected the appropriate conformity assessment procedures which manufacturers have to apply in order to demonstrate that their electrical material

- complies with the essential safety requirements. The proposal aligns these procedures to their updated versions set out in the NLF Decision
- 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 notified bodies is revised. The competence of a notified body must be demonstrated by an accreditation certificate.
- 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
 non-compliant electrical equipment is found.

BUDGETARY IMPLICATIONS: this proposal does not have any implications for the EU budget.

2011/0357(COD) - 28/11/2012 Committee report tabled for plenary, 1st reading/single reading

The Committee on the Internal Market and Consumer Protection adopted the report by Zuzana ROITHOVÁ (EPP, CZ) on the 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).

The committee recommends that the European Parliaments position adopted at first reading, following the ordinary legislative procedure, should amend the Commission proposal as follows:

Definitions: the term 'making available on the market' shall mean the 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.

Consumer protection: Members consider it necessary to ensure consumer protection, including a high level of protection of vulnerable consumers in those cases where the electrical equipment is not intended for professional use (the safety of children, elderly and the persons with disabilities).

Where applicable, electrical equipment not intended for professional use may be made available on the market only if it is constructed in such way that it can be easily used and accessed by persons with disabilities.

Manufacturers shall indicate, on the electrical equipment, their name, registered trade name or registered trade mark and the postal, or, if available, the website address at which they can be contacted or, where that is not reasonably possible, those details shall be provided on the packaging or in a document accompanying the electrical equipment. The contact details shall be in a language easily understood by end-users and market surveillance authorities. Such instructions and safety information as well as any labelling shall be clear, understandable and intelligible.

In addition, economic operators should ensure that all required relevant information is also displayed in the case of distance selling.

Products in stock: Members consider it 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. Economic operators should be able to sell stocks of electrical equipment designed for use within some certain voltage limits that are already in the distribution chain on the date of application of national measures transposing this Directive. Member States shall ensure that the obligations of economic operators concerning the products in stock are applied.

EU Declaration of conformity (DoC): upon the request of the market surveillance authorities, the economic operator shall provide a copy of the EU declaration of conformity in paper form or by electronic means. It is also proposed to add an exception to the rule on 'one single DoC' for cases where the providing a single document creates specific problems due to its complexity or extent. In this case, it should be possible to replace that single EU declaration by individual EU declarations of conformity relevant for the particular electrical equipment.

Identification of economic operators: economic operators shall present the information 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. Economic operators shall not be required to update that information after supply is finalised.

Market surveillance: Members suggest that Member States shall, on an annual basis, provide the Commission with details of the activities of their market surveillance authorities and of any plans for and increase of market surveillance, including the allocation of more resources, the increase of efficiency and the building of the necessary capacity for achieving those goals. Member States shall provide adequate funding to their market surveillance authorities.

Member States shall ensure that appropriate restrictive measures are taken in respect of the electrical equipment concerned, such as withdrawal of the electrical equipment from their market, without delay.

Compliant electrical equipment presenting a health or safety risk: where a Member State finds that although electrical equipment is in compliance with this Directive, it presents a risk to the health or safety of persons and safety of domestic animals and property, 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.

Penalties: Members propose that the Member States shall build upon existing mechanisms to ensure correct application of the regime governing the CE marking and shall take appropriate action in the event of improper use of the marking. Rules on penalties applicable to infringements by economic operators of the national provisions may include criminal penalties for serious infringements. The penalties shall be proportionate to the seriousness of the offence.

Non-retroactive nature of EU legislation: Member States shall ensure that electrical equipment which was lawfully placed on the market before may be made available on the market by distributors without further product requirements.

Transposition: Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive. The Commission shall make those texts publicly available by publishing them on the internet.

2011/0357(COD) - 05/02/2014 Text adopted by Parliament, 1st reading/single reading

The European Parliament adopted by 651 votes to 12, with 11 abstentions, a legislative resolution on the 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).

Parliament adopted its position at first reading following the ordinary legislative procedure. The amendments adopted in plenary are the result of an agreement reached between the European Parliament and the Council. They amended the proposal as follows:

Further align the Directive to the new legislative framework and ensure legal certainty: the amendments made by the Parliament seek to ensure that the proposed Directive is more consistent with the terms used by Decision No 768/2008/EC and to eliminate any inconsistencies in the text which could otherwise create legal uncertainty.

Purpose and scope: the objective of this Directive is to ensure the electrical equipment on the market fulfils the safety objectives providing for a high level of protection of health and safety of persons, and of domestic animals and property, while guaranteeing the functioning of the internal market.

This Directive covers electrical equipment designed for use within certain voltage limits which is new to the Union market when it is placed on the market; that is to say it is either new electrical equipment made by a manufacturer established in the Union or electrical equipment, whether new or second-hand, imported from a third country.

This Directive should apply to all forms of supply, including distance selling.

The harmonised standards relevant to this Directive should also take into account the United Nations Convention on the Rights of Persons with Disabilities.

Obligations of economic operators: When placing their electrical equipment on the market, manufacturers should ensure that it has been designed and manufactured in accordance with the safety objectives referred to in the Directive and set out in Annex I. Manfacturers and importers should indicate on the electrical equipment his name, registered trade name or registered trade mark and the postal address at which he can be contacted.

The contact details shall be in a language easily understood by end-users and market surveillance authorities.

In order to increase consumer protection, manufacturers should ensure that the product is accompanied by instructions and safety information in a language which can be easily understood by end-users, as determined by the Member State concerned.

Such instructions and safety information, as well as any labelling, shall be clear, understandable and intelligible.

In order to facilitate communication between economic operators, market surveillance authorities and end-users, Member States should encourage economic operators to include a website address in addition to the postal address.

EU declaration of conformity: the EU declaration of conformity should be translated into the language or languages required by the Member State in which the electrical equipment is placed or made available on the market.

In order to reduce the administrative burden on economic operators, that single EU declaration of conformity may be a dossier made up of relevant individual declarations of conformity.

CE marking: Parliament called on the Member States to build upon existing mechanisms to ensure correct application of the regime governing the CE marking and shall take appropriate action in the event of improper use of that marking.

Notified bodies: a conformity assessment body 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. The impartiality of the conformity assessment bodies, their top level management and of the personnel responsible for carrying out the conformity assessment tasks shall be guaranteed.

Market surveillance: Member States should take all appropriate measures to ensure that products covered by this Directive may be placed on the market only if, when properly stored and used for their intended purpose, or under conditions of use which can be reasonably foreseen, they do not endanger the health and safety of persons.

Restrictive measures in case of non-compliance: Member States should ensure that appropriate restrictive measures, such as withdrawal of the product concerned, are taken in respect of the measuring instrument concerned without delay.

Rules on penalties applicable to infringements by economic operators may include criminal penalties for serious infringements. These penalties should be effective, proportionate and dissuasive.

Stock: distributors should therefore be able to supply electrical equipment that has been placed on the market, namely stock that is already in the distribution chain, before the date of application of national measures transposing this Directive.

Implementing measures: in order to ensure uniform conditions for the implementation of this Directive, implementing powers should be conferred on the Commission.

On duly justified imperative grounds of urgency relating to the protection of health and safety of persons, the Commission should adopt immediately applicable implementing acts.

The Commission shall be assisted by the Committee on Electrical Equipment.

When matters relating to this Directive, other than its implementation or infringements, are being examined, i.e. in a Commission expert group, the European Parliament should receive full information and documentation and, where appropriate, an invitation to attend such meetings.

PURPOSE: to align Directive 2006/95/EC on the harmonisation of the laws of Member States relating to electrical equipment designed for use within certain voltage limits with the new legislative framework, which established a common framework for the marketing of products (Goods Package).

LEGISLATIVE ACT: Directive 2014/35/EU of the European Parliament and of the Council on the harmonisation of the laws of the Member States relating to the making available on the market of electrical equipment designed for use within certain voltage limits.

CONTENT: the Directive is part of a package aiming to recast eight directives in order to adapt them to the EU's new legislative framework on sectoral product harmonisation.

The recast seeks to further harmonise and simplify national laws applicable to:

- · explosives for civil uses
- · simple pressure vessels
- electromagnetic compatibility
- non-automatic weighing instruments
- measuring instruments
- · lifts and safety components for lifts
- equipment for use in potentially explosive atmospheres
- · electrical equipment designed for use within certain voltage limits.

The EU's "new legislative framework", which was adopted in 2008, is a general measure of the internal market with the objective of strengthening the effectiveness of the Unions legislation on product safety and its implementation mechanisms. It aims to strengthen the safety of products available on the market, and ensures a better functioning internal market for instance through equal treatment of economic operators on the market.

It is made up of two complementary texts: regulation 765/2008 outlining the requirements concerning accreditation and surveillance for the marketing of products, and decision 768/2008/EC relating to a common framework for the marketing of products.

The main elements of the new Directive are as follows:

Purpose and scope: the purpose of this Directive is to ensure that electrical equipment on the market fulfils the requirements providing for a high level of protection of health and safety of persons, and of domestic animals and property, while guaranteeing the functioning of the internal market. This Directive shall apply to electrical equipment designed for use with a voltage rating of between 50 and 1 000 V for alternating current and between 75 and 1 500 V for direct current, other than the equipment and phenomena listed in Annex II.

This Directive covers electrical equipment designed for use within certain voltage limits which is new to the Union market when it is placed on the market; that is to say it is either new electrical equipment made by a manufacturer established in the Union or electrical equipment, whether new or second-hand, imported from a third country. This Directive should apply to all forms of supply, including distance selling.

Obligations of economic operators and traceability requirements: the Directive clarifies the obligations of manufacturers and introduces obligations for importers and distributors:

- When placing their electrical equipment on the market, manufacturers shall ensure that they have been designed and manufactured in accordance with the essential safety requirements set out in Annex I. Equipment which they have placed on the market must bear a type and serial or batch identification allowing their identification. Where the size or nature of the electrical equipment does not allow it, the required information shall be placed on the packaging or in a document accompanying the instrument.
- Before placing a product 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 instrument bears the CE marking and that it is accompanied by the required documents and by instructions and safety information.
- Manufacturers and importers shall indicate on the equipment their name, registered trade name or registered trade mark and the postal address at which they can be contacted. The address shall indicate a single point at which the manufacturer can be contacted. The contact details shall be in a language easily understood by end-users and market surveillance authorities. The instructions and safety information should be in a language which can be easily understood by end-users, as determined by the Member State concerned.

Economic operators who consider or have reason to believe that equipment which they have placed on the market is not in conformity with this Directive shall immediately take the corrective measures necessary to bring it into conformity, to withdraw or recall it, if appropriate.

EU declaration of conformity: the EU declaration of conformity shall have the model structure set out in Annex IV of the Directive. In order to reduce the administrative burden on economic operators, that single EU declaration of conformity may be a dossier made up of relevant individual declarations of conformity.

CE marking: the Directive states that the CE marking shall be affixed visibly, legibly and indelibly to the electrical equipment or to its data plate. It shall be affixed before the equipment is placed on the market. As requested by the European Parliament, Member States shall build upon existing mechanisms to ensure correct application of the regime governing the CE marking and shall take appropriate action in the event of improper use of that marking.

Notified bodies: the Directive 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 notified bodies is revised. The competence of a notified body must be demonstrated by an accreditation certificate. A conformity assessment body shall be a third-party body independent of the organisation or the electrical equipment it assesses. The impartiality of the conformity assessment bodies, their top level management and of the personnel responsible for carrying out the conformity assessment tasks shall be guaranteed.

Market surveillance and the safeguard clause procedure: the Directive 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 article is found. Member States should take all appropriate measures to ensure that equipment may be placed on the market only if, when properly stored and used for their intended purpose, or under conditions of use which can be reasonably foreseen, they do not endanger the health and safety of persons.

Restrictive measures in case of non-compliance: appropriate restrictive measures, such as withdrawal of the equipment concerned from the market should be taken in respect of the instrument concerned without delay.

Rules on penalties applicable to infringements by economic operators could include criminal penalties for serious infringements. The penalties provided for should be effective, proportionate and dissuasive.

Transitional provisions/products in stock: distributors should therefore be able to supply electrical equipment that has been placed on the market, namely stock that is already in the distribution chain, before the 20 April 2016.

ENTRY INTO FORCE: 18/04/2014.

TRANSPOSITION: 19/04/2016. Measures shall apply from 20.04.2016.