Basic information

2011/0356(COD) COD - Ordinary legislative procedure (ex-codecision procedure) Directive	Procedure completed
Equipment and protective systems intended for use in potentially explosive atmospheres. Recast. 'Goods package' See also 2007/0029(COD) See also 2007/0030(COD) Amended by 2017/0353(COD) Amended by 2022/0280(COD) **Subject** 2.10.03 Standardisation, EC/EU standards and trade mark, certification, compliance 3.40.08 Mechanical engineering, machine-tool industry	

Key players

European Parliament

Committee responsible	Rapporteur	Appointed
IMCO Internal Market and Consumer Protection	ROITHOVÁ Zuzana (PPE)	29/11/2011
	Shadow rapporteur SCHALDEMOSE Christel (S&D) MANDERS Antonius (ALDE) RÜHLE Heide (Verts/ALE) FOX Ashley (ECR) SALVINI Matteo (EFD)	

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	Meetings	Date
Competitiveness (Internal Market, Industry, Research and Space)	3295	2014-02-20

European

Commission DG	Commissioner

Commission	Internal Market, Industry, Entrepreneurship and SMEs	TAJANI Antonio
European Economic and Social Committee		

Key events

Date	Event	Reference	Summary
21/11/2011	Legislative proposal published	COM(2011)0772	Summary
30/11/2011	Committee referral announced in Parliament, 1st reading		
10/07/2012	Vote in committee, 1st reading		
25/07/2012	Committee report tabled for plenary, 1st reading	A7-0255/2012	Summary
04/02/2014	Debate in Parliament		
05/02/2014	Decision by Parliament, 1st reading	T7-0084/2014	Summary
05/02/2014	Results of vote in Parliament		
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

Procedure reference	2011/0356(COD)
Procedure type	COD - Ordinary legislative procedure (ex-codecision procedure)
Procedure subtype	Recast
Legislative instrument	Directive
Amendments and repeals	See also 2007/0029(COD) See also 2007/0030(COD) Amended by 2017/0353(COD) Amended by 2022/0280(COD)
Legal basis	Treaty on the Functioning of the European Union TFEU 114-p1
Other legal basis	Rules of Procedure EP 165
Mandatory consultation of other institutions	European Economic and Social Committee
Stage reached in procedure	Procedure completed
Committee dossier	IMCO/7/07952

Documentation gateway

European Parliament

Document type	Committee	Reference	Date	Summary

Committee draft report		PE488.067	08/05/2012	
Amendments tabled in committee		PE491.130	12/06/2012	
Committee report tabled for plenary, 1st reading/single reading		A7-0255/2012	25/07/2012	Summary
Text adopted by Parliament, 1st reading/single reading		T7-0084/2014	05/02/2014	Summary

Council of the EU

Document type	Reference	Date	Summary
Draft final act	00053/2013/LEX	26/02/2014	

European Commission

Document type	Reference	Date	Summary
Legislative proposal	COM(2011)0772	21/11/2011	Summary
Commission response to text adopted in plenary	SP(2014)446	20/05/2014	

National parliaments

Document type	Parliament /Chamber	Reference	Date	Summary
Contribution	PT_PARLIAMENT	COM(2011)0772	16/01/2012	
Contribution	IT_SENATE	COM(2011)0772	20/02/2012	

Additional information

Source	Document	Date
National parliaments	IPEX	
European Commission	EUR-Lex	
European Commission	EUR-Lex	

Final act

Directive 2014/0034
OJ L 096 29.03.2014, p. 0309 Summary

Equipment and protective systems intended for use in potentially explosive atmospheres. Recast. 'Goods package'

2011/0356(COD) - 21/11/2011 - Legislative proposal

PURPOSE: to align Directive 94/9/EC on the harmonisation of the laws of the Member States relating to equipment and protective systems intended for use in potentially explosive atmospheres 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 the Member States relating to equipment and protective systems intended for use in potentially explosive atmospheres 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 94/9/EC. To ensure the readability of the amended text, the technique of **recasting** has been chosen. The proposal does not change the scope of Directive and the essential health and safety requirements.

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 products 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 products bear the CE marking, the name of the manufacturer and of the importer, if relevant, and that it is accompanied by the required documentation and instructions.
- **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 94/9/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 94/9/EC on the placing on the market of products has selected the appropriate conformity assessment procedures which manufacturers have to apply in order to demonstrate that their products comply 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.
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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 article is found.

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

DELEGATED ACTS: the proposal contains provisions empowering the Commission to adopt delegated acts in accordance with Article 290 of the Treaty on the Functioning of the European Union.

Equipment and protective systems intended for use in potentially explosive atmospheres. Recast. 'Goods package'

2011/0356(COD) - 05/02/2014 - Text adopted by Parliament, 1st reading/single reading

The European Parliament adopted by 646 votes to 13, with 12 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 the Member States relating to equipment and protective systems intended for use in potentially explosive atmospheres (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 that products on the market fulfil the requirements providing for a high level of protection of health and safety of persons, especially workers, and, where appropriate, protection of **domestic animals and property**.

This Directive covers products which are **new to the Union market** when they are placed on the market; that is to say they are either new products made by a manufacturer established in the Union or products, whether new or second-hand, imported from a third country. It should apply to **components** intended to be incorporated into equipment and protective systems intended for use in potentially explosive atmospheres.

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

Obligations of economic operators: manufacturers should ensure that each product is accompanied by a copy of the EU declaration of conformity or of the attestation of conformity, as appropriate. However, where a large number of products is delivered to a single user, the batch or consignment concerned may be accompanied by a single copy. They should also ensure that products, other than components, which they have placed on the market bear the **specific marking of explosion protection**.

In order to protect the health and safety of end-users, manufacturers and importers should:

- carry out sample testing of products made available on the market,
- investigate non-conforming products and product recalls,
- if necessary, keep a register of complaints, of non-conforming products and product recalls, and keep distributors informed of any such monitoring;
- **indicate, on the product, their name, registered trade name or registered trade mark and the postal address** at which they can be contacted or, where that is not possible, on its packaging or in a document accompanying the product.

Distributors who consider or have reason to believe that a product which they have made available on the market is not in conformity with this Directive should make sure that the **corrective measures necessary** to bring that product into conformity, to withdraw it or recall it, if appropriate, are taken.

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.

Before making a product available on the market, **distributors** shall verify that it bears the CE marking, that it is accompanied by the EU declaration of conformity, by the required documents and by the instructions and safety information.

CE marking: Parliament enhanced the rules as regards the CE marking. **Specific, clear marking of equipment** and protective systems, stating their use in a potentially explosive atmosphere, has also been introduced. 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 products that have 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.

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.

Equipment and protective systems intended for use in potentially explosive atmospheres. Recast. 'Goods package'

2011/0356(COD) - 26/02/2014 - Final act

PURPOSE: to align Directive 94/9/EC on the harmonisation of the laws of the Member States relating to equipment and protective systems intended for use in potentially explosive atmospheres with the new legislative framework, which established a common framework for the marketing of products (Goods Package).

LEGISLATIVE ACT: Directive 2014/34/EU of the European Parliament and of the Council on the harmonisation of the laws of the Member States relating to equipment and protective systems intended for use in potentially explosive atmospheres (recast).

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 Union’s 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:

Scope and application: this Directive aims to ensure that **equipment and protective systems intended for use in potentially explosive atmospheres** on the market fulfil the requirements providing for a high level of protection of health and safety of persons, especially workers, and, where appropriate, protection of domestic animals and property, while guaranteeing the functioning of the internal market.

This Directive covers products which are **new to the Union market when they are placed on the market**; that is to say they are either new products made by a manufacturer established in the Union or products, 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 products on the market or using them for their own purposes, **manufacturers** shall ensure that they have been designed and manufactured in accordance with the essential health and safety requirements set out in Annex II of the Directive. They shall ensure that products which they have placed on the market bear a type, batch or serial number or other element allowing their identification, or, where the size or nature of the product does not allow it, that the required information is provided on the packaging or in a document accompanying the product. They shall ensure that products, other than components, which they have placed on the market bear the **specific marking of explosion protection.**

Before placing a product on the market, **importers** shall ensure that the appropriate conformity assessment procedure has been carried out by the manufacturer. They should ensure that the manufacturer has drawn up the technical documentation, that the product bears the CE marking.

Distributors shall verify that the product bears the CE marking, where applicable, that it is accompanied by the EU declaration of conformity or the attestation of conformity and the required documents and by instructions and safety information.

Manufacturers and distributors shall indicate, on the product, their **name, registered trade name or registered trade mark and the postal address** at which they can be contacted. The contact details shall be in a **language easily understood by end-users** and market surveillance authorities. Such instructions and information, as well as any labelling, shall be **clear, understandable and intelligible**.

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

EU declaration of conformity: the EU declaration of conformity shall have the model structure set out in Annex X of the Directive. By drawing up the EU declaration of conformity, the manufacturer shall assume responsibility for the compliance of the product with the requirements laid down in this 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 and the inscriptions shall be **affixed visibly, legibly and indelibly** to the product or to its data plate. It shall be affixed before the product is placed on the market. **Parliament enhanced the rules as regards the CE marking**. Specific, clear marking of equipment and protective systems, stating their use in a potentially explosive atmosphere, has also been introduced. Member States should 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 product 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 products 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 product** 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 products that have 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.

Equipment and protective systems intended for use in potentially explosive atmospheres. Recast. 'Goods package'

2011/0356(COD) - 25/07/2012 - 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 the Member States relating to equipment and protective systems intended for use in potentially explosive atmospheres (recast).

The committee recommends that the European Parliament's position adopted at first reading, under the ordinary legislative procedure, should amend the Commission proposal as follows:

Further align the Directive with the new legislative framework and ensure legal certainty: Members consider it important to bring a number of changes to the proposed Directive in order to reach a higher level of consistency with the terms used by the Decision No 768/2008/EC and eliminate the possible inconsistencies in the text which could otherwise create legal uncertainty.

They also consider it important to **clarify the legal situation for products which have been legally placed on the market in compliance with the current Directive** before the new Directive applies, but which are still in stock. They propose that economic operators should be able to sell stocks of non-automatic weighing instruments that are already in the distribution chain on the date of application of national measures transposing this Directive.

Obligations imposed on economic operators: an amendment stipulates that manufacturers shall indicate, on the instrument (or on the label if this is not possible), their name, registered trade name or registered trade mark the postal, or, if available, the **website address** at which they can be contacted. The contact details shall be in a **language easily understood** by end-users and market surveillance authorities. With a view to enhancing **consumer protection**, Members state that such instructions and safety information as well as **any labelling shall be clear, understandable and intelligible**. Moreover, they consider that all obligations imposed on economic operators by this Directive should also apply in the case of **distance selling**.

EU declaration of conformity: upon request of the market surveillance authority, the economic operator shall provide a copy of the EU declaration of conformity in **paper form or by electronic means** and shall ensure that it is **translated** into the language or languages required by the Member State in which market the non-automatic weighing instruments is placed or made available.

To cut red tape, Members state that when issuing a single EU declaration of conformity could cause specific problems due to the complexity or scope of that single EU declaration, it should be possible to replace that single EU declaration by individual EU declarations of conformity.

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

Improve market surveillance: Members propose that the Member States: (i) provide, on an annual basis, the Commission with details of the activities of their market surveillance authorities; (ii) provide adequate funding to their market surveillance authorities in order to ensure that their activities are coherent and effective across the Union.

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

Transparency: the Commission should have the obligation to **publish on the Internet** the national provisions of transposed Directive and relevant sanctions.