

# Procedure file

Basic information	
COD - Ordinary legislative procedure (ex-codecision procedure) Directive	2013/0221(COD) Procedure completed
Making available on the market of pressure equipment. Recast Repealing Directive 97/23/EC <a href="#">1993/0462(COD)</a> Amended by <a href="#">2017/0353(COD)</a>	
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
	<b>IMCO</b> Internal Market and Consumer Protection		09/07/2013
		PPE <a href="#">ROITHOVÁ Zuzana</a>	
		Shadow rapporteur	
		S&D <a href="#">WESTPHAL Kerstin</a>	
		ALDE <a href="#">MANDERS Antonius</a>	
	ECR <a href="#">FOX Ashley</a>		
	EFD <a href="#">SALVINI Matteo</a>		
	Committee for opinion	Rapporteur for opinion	Appointed
	<b>ITRE</b> Industry, Research and Energy	The committee decided not to give an opinion.	
	<b>JURI</b> Legal Affairs		02/12/2013
		EFD <a href="#">SPERONI Francesco Enrico</a>	
Council of the European Union	Council configuration	Meeting	Date
	<a href="#">General Affairs</a>	<a href="#">3313</a>	13/05/2014
European Commission	Commission DG	Commissioner	
	<a href="#">Internal Market, Industry, Entrepreneurship and SMEs</a>	TAJANI Antonio	
European Economic and Social Committee			

Key events			
28/06/2013	Legislative proposal published	<a href="#">COM(2013)0471</a>	Summary
04/07/2013	Committee referral announced in Parliament, 1st reading		

17/12/2013	Vote in committee, 1st reading		
07/01/2014	Committee report tabled for plenary, 1st reading	<a href="#">A7-0008/2014</a>	Summary
15/04/2014	Results of vote in Parliament		
15/04/2014	Decision by Parliament, 1st reading	<a href="#">T7-0390/2014</a>	Summary
13/05/2014	Act adopted by Council after Parliament's 1st reading		
15/05/2014	Final act signed		
15/05/2014	End of procedure in Parliament		
27/06/2014	Final act published in Official Journal		

### Technical information

Procedure reference	2013/0221(COD)
Procedure type	COD - Ordinary legislative procedure (ex-codecision procedure)
Procedure subtype	Recast
Legislative instrument	Directive
	Repealing Directive 97/23/EC <a href="#">1993/0462(COD)</a> Amended by <a href="#">2017/0353(COD)</a>
Legal basis	Treaty on the Functioning of the EU TFEU 114
Other legal basis	Rules of Procedure EP 159
Mandatory consultation of other institutions	<a href="#">European Economic and Social Committee</a>
Stage reached in procedure	Procedure completed
Committee dossier	IMCO/7/13231

### Documentation gateway

Legislative proposal	<a href="#">COM(2013)0471</a>	28/06/2013	EC	Summary
Committee draft report	<a href="#">PE519.690</a>	11/10/2013	EP	
Economic and Social Committee: opinion, report	<a href="#">CES5475/2013</a>	16/10/2013	ESC	
Committee report tabled for plenary, 1st reading/single reading	<a href="#">A7-0008/2014</a>	07/01/2014	EP	Summary
Text adopted by Parliament, 1st reading/single reading	<a href="#">T7-0390/2014</a>	15/04/2014	EP	Summary
Draft final act	<a href="#">00038/2014/LEX</a>	15/05/2014	CSL	
Commission response to text adopted in plenary	<a href="#">SP(2014)471</a>	09/07/2014	EC	
Follow-up document	<a href="#">COM(2020)0675</a>	29/10/2020	EC	

### Additional information

National parliaments	<a href="#">IPEX</a>
European Commission	<a href="#">EUR-Lex</a>

[Directive 2014/68](#)

[OJ L 189 27.06.2014, p. 0164](#) Summary

[Corrigendum to final act 32014L0068R\(04\)](#)

[OJ L 157 23.06.2015, p. 0112](#) Summary

Final legislative act with provisions for delegated acts

## Making available on the market of pressure equipment. Recast

**PURPOSE:** to recast Directive 97/23/EC of the European Parliament and of the Council on the approximation of the laws of the Member States concerning pressure equipment.

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

**ROLE OF THE EUROPEAN PARLIAMENT:** the European Parliament decides in accordance with the ordinary legislative procedure and on an equal footing with the Council.

**BACKGROUND:** Directive 97/23/EC is an example of that Union harmonisation legislation, ensuring the free movement of pressure equipment. It sets out essential safety requirements that pressure equipment and assemblies must comply with in order to be made available on the EU market.

(1) 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.

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. 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 (NLF Decision).

In view of ensuring consistency across Union harmonisation legislation for industrial products, it is necessary to align Directive 97/23/EC to the provisions of the NLF Decision. The Commission has already proposed the alignment of nine other Directives to the NLF Decision within an NLF implementation package adopted on 21 November 2011.

(2) Directive 97/23/EC provides for a classification of pressure equipment in categories, according to the ascending level of risk due to pressure. This includes the classification of the fluid contained in the pressure equipment as dangerous or not, according to Council Directive 67/548/EEC on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances.

On 1 June 2015 Directive, 67/548/EEC is to be repealed and replaced by [Regulation \(EC\) No 1272/2008](#) of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures, which implements in the Union the Globally Harmonised System of Classification and Labelling of Chemicals that has been adopted at international level, within the United Nations (UN) structure.

Regulation (EC) No 1272/2008 introduces new hazard classes and categories only partially corresponding to those provided for by Directive 67/548/EEC. Directive 97/23/EC should therefore be aligned to Regulation (EC) No 1272/2008 while maintaining the existing levels of protection of that Directive.

**IMPACT ASSESSMENT:**

Alignment to the New Legislative Framework Decision: three options were examined and compared:

- Option 1 - no changes to the current situation;
- Option 2 - alignment to the NLF Decision by non-legislative measures;
- Option 3 - alignment to the NLF Decision by legislative measures. This option consists in integrating the provisions of the NLF Decision into Directive 97/23/EC. Option 3 was found to be the preferred option.

Alignment to the CLP Regulation: the impact assessment study concluded that the impact of the proposed alignment would be limited and in particular that the overall economic impact will be low.

Based on the number of substances that would be subject to a different classification and the proportion of manufacturers that would be affected, the impact assessment study estimates the overall costs of aligning Directive 97/23/EC to the CLP Regulation to be of the order of EUR 8.5 million per year. The cost is due to the changes in the alignment for the health hazard classes.

However, looking at the current compliance costs, and according to the impact assessment study, the total average cost of the conformity assessment for the pressure equipment covered by Directive 97/23/EC is estimated at EUR 236.3 million per year. Therefore, the incremental cost due to the alignment of Directive 97/23/EC to the CLP Regulation is low compared to the total cost for conformity assessment. However, the implementation of the CLP Regulation in the Union is mandatory and the cost cannot be avoided.

**LEGAL BASIS:** Article 114 of the Treaty on the Functioning of the European Union.

**CONTENT:** this proposal intends to align Directive 97/23/EC on pressure equipment to:

the goods package adopted in 2008 and in particular to Decision No 768/2008/EC establishing a common framework for the marketing of products;

Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures.

The changes made to the provisions of Directive 97/23/EC concern: the definitions, the obligations of economic operators, the presumption of conformity provided by harmonised standards, the declaration of conformity, CE marking, conformity assessment bodies, the safeguard clause procedure, the conformity assessment procedures and the classification of the fluids.

The proposal includes:

- measures to address the problem of non-compliance by clarifying the obligations of economic operators and requiring enhanced traceability requirements;
- measures intended to ensure the quality of work done by conformity assessment bodies by reinforcing the notification requirements, revised notification process, specifying requirements for notifying authorities and more stringent information obligations;
- measures intended to ensure greater consistency amongst Directives by aligning commonly used definitions and terminology and aligning the conformity assessment procedures.

**BUDGETARY IMPLICATION:** the proposal has no implication for the EU budget.

**DELEGATED ACTS:** this 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 (TFEU).

## Making available on the market of pressure equipment. Recast

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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 making available on the market of pressure equipment (recast).

The committee recommended that Parliaments position in first reading following the ordinary legislative procedure should amend the Commission proposal.

It should be recalled that the commission presented this recast of Directive 97/23/EC on the approximation of the laws of the Member States concerning pressure equipment in June 2013 in the framework of the implementation of the New Legislative Framework (NLF) adopted in 2008 (the Goods Package).

This Directive was separated from the alignment package presented in November 2011 because, unlike the other 9 Directives, this recast also contained an alignment with another EU legislative act, namely Regulation (EC) No 1272/2008 (CLP Regulation) on classification, labelling and packaging of substances and mixtures.

The committee supported the Commissions general intention of a simple alignment and therefore limited its amendments to the proposal to changes reflecting the agreement obtained between Council and Parliament on the nine other Directives and which had been omitted in the proposal.

**Scope:** the Directive covered pressure equipment which is new to the Union market when it was placed on the market; that is to say it was either new pressure equipment made by a manufacturer established in the Union or pressure equipment, whether new or second-hand, imported from a third country.

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

**Economic operators:** the latter should be responsible for the compliance of pressure equipment with the requirements of the Directive, so as to ensure a high level of protection of public interests, such as the health and safety of persons, and the protection of domestic animals and of property.

Manufacturers should indicate, on the pressure equipment, their name, registered trade name or registered trademark and the postal address at which they can be contacted or, where that is not possible, on their packaging or in a document accompanying the equipment. The address should indicate a single point at which the manufacturer can be contacted. The contact details should be in a language easily understood by consumers, other users and market surveillance authorities.

Every importer should indicate on the pressure equipment his name, registered trade name or registered trade mark and the postal address at which he can be contacted.

**Lightening the administrative burden:** 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 mark:** 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.

**Reasonable transitional period:** Members proposed clarification related to the legal situation for products which had been legally placed on the market in compliance with the current Directive before the new Directive applied, but which were still in stock. These products might still be made available on the market after the date of application of the new Directive.

## Making available on the market of pressure equipment. Recast

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The European Parliament adopted by 608 votes to 16, against 10 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 making available on the market of pressure equipment (recast).

The committee recommended that Parliaments position in first reading following the ordinary legislative procedure should amend the Commission proposal.

It should be recalled that the commission presented this recast of Directive 97/23/EC on the approximation of the laws of the Member States

concerning pressure equipment in June 2013 in the framework of the implementation of the New Legislative Framework (NLF) adopted in 2008 (the Goods Package).

This Directive was separated from the alignment package presented in November 2011 because, unlike the other 9 Directives, this recast also contained an alignment with another EU legislative act, namely Regulation (EC) No 1272/2008 (CLP Regulation) on classification, labelling and packaging of substances and mixtures.

The committee supported the Commissions general intention of a simple alignment and therefore limited its amendments to the proposal to changes reflecting the agreement obtained between Council and Parliament on the nine other Directives and which had been omitted in the proposal.

Scope: the Directive covered pressure equipment which is new to the Union market when it was placed on the market; that is to say it was either new pressure equipment made by a manufacturer established in the Union or pressure equipment, whether new or second-hand, imported from a third country.

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

Economic operators: the latter should be responsible for the compliance of pressure equipment with the requirements of the Directive, so as to ensure a high level of protection of public interests, such as the health and safety of persons, and the protection of domestic animals and of property.

Manufacturers should indicate, on the pressure equipment, their name, registered trade name or registered trademark and the postal address at which they can be contacted or, where that is not possible, on their packaging or in a document accompanying the equipment. The address should indicate a single point at which the manufacturer can be contacted. The contact details should be in a language easily understood by consumers, other users and market surveillance authorities.

Every importer should indicate on the pressure equipment his name, registered trade name or registered trade mark and the postal address at which he can be contacted.

Lightening the administrative burden: 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: this shall be affixed visibly, legibly and indelibly to each item of pressure equipment or its dataplate. 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.

Reasonable transitional period: Parliament and the Council clarified the legal situation of products which have been placed legally on the market in conformity with the Directive in force, i.a. before the new Directive applies, but which are still in stock in the distribution chain.

Market surveillance and control of pressure equipment and assemblies entering the Union market: a procedure for dealing with pressure equipment or assemblies presenting a risk at national level has been introduced as well as a Union safeguard measure.

In case of formal non-compliance of equipment, Member States shall require the relevant economic operator to put an end to the non-compliance concerned. Where the non-compliance persists, the Member State concerned shall take all appropriate measures to restrict or prohibit the equipment or assembly being made available on the market or ensure that it is recalled or withdrawn from the market.

The Commission should adopt immediately applicable implementing acts where, in duly justified cases relating to compliant pressure equipment or assemblies which present a risk to the health or safety of persons, to domestic animals or to property, imperative grounds of urgency so require.

In order to take into account emerging very serious safety reasons, the power to adopt acts should be delegated to the Commission in respect of amendments to classification of pressure equipment or assemblies.

Lastly, 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 in line with existing practice receive full information and documentation and, where appropriate, an invitation to attend such meetings.

## Making available on the market of pressure equipment. Recast

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Corrigendum to Directive 2014/68/EU of the European Parliament and of the Council of 15 May 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of pressure equipment ([\(Official Journal of the European Union L 189 of 27 June 2014\)](#))

Article 14(7) (Conformity assessment procedures):

- instead of: 7. By way of derogation from paragraphs 1 and 2 of this Article, the competent authorities may, where justified in respect of which the procedures referred to in paragraphs 1 and 2 of this Article have not been applied and the use of which is in the interests of experimentation.
- read: 7. By way of derogation from paragraphs 1 to 6 of this Article, the competent authorities may, where justified in respect of which the procedures referred to in paragraphs 1 to 6 of this Article have not been applied and the use of which is in the interests of experimentation;

Article 48(2) (Transitional provisions):

- instead of: 2. Member States shall not impede the making available on the market and/or the putting into service of pressure equipment or assemblies covered by Directive 97/23/EC which are in conformity with that Directive and which were placed on the market before 1 June 2015.
- read: 2. Member States shall not impede the making available on the market and/or the putting into service of pressure equipment or assemblies covered by Directive 97/23/EC which are in conformity with that Directive and which were placed on the market before 19 July 2016.

## Making available on the market of pressure equipment. Recast

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**PURPOSE:** to recast Directive 97/23/EC of the European Parliament and of the Council on the approximation of the laws of the Member States concerning pressure equipment.

**LEGISLATIVE ACT:** Directive 2014/68/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 pressure equipment.

**CONTENT:** Directive 97/23/EC is an example of Union harmonisation legislation, which ensures the free movement of pressure equipment. It sets out essential safety requirements that pressure equipment and assemblies must comply with in order to be made available on the EU market.

In order to remedy the shortcomings of the current legislation, this Directive aims to align Directive 97/23/ EC: i) on the new legislative framework comprising of [Council Regulation \(EC\) No 765/2008](#) on accreditation and market surveillance and [Decision No 768/2008/EC](#) on a common framework for the marketing of products and ii) to [Regulation \(EC\) No 1272/2008](#) of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures.

The Directive shall apply to the design, manufacture and conformity assessment of pressure equipment (eg, boilers, pressure cookers, fire extinguishers, heat exchangers, steam generators, process heating) with a maximum allowable pressure PS greater than 0.5 bar.

This Directive covers pressure equipment and assemblies which are new to the Union market when they are placed on the market; that is to say they are either new pressure equipment or assemblies made by a manufacturer established in the Union or pressure equipment or assemblies, whether new or second-hand, imported from a third country.

The changes introduced by this Directive relate to the definitions, obligations of economic operators (including the EU declaration of conformity), the presumption of conformity, the conformity assessment procedures, Union safeguard procedure, the classification of pressure equipment, comitology and delegated acts.

Economic operators should be responsible for the compliance of pressure equipment and assemblies with the requirements of this Directive, 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 of persons, and the protection of domestic animals and of property, and to guarantee fair competition on the Union market.

Manufacturers should indicate, on the pressure equipment, their name, registered trade name or registered trademark and the postal address at which they can be contacted or, where that is not possible, on their packaging or in a document accompanying the equipment. The address should indicate a single point at which the manufacturer can be contacted. The contact details should be in a language easily understood by consumers, other users and market surveillance authorities. Every importer should indicate on the pressure equipment or assembly his name, registered trade name or registered trade mark and the postal address at which he can be contacted.

Non-compliance: Member States shall require the relevant economic operator to put an end to the non-compliance concerned. Where the non-compliance persists, the Member State concerned shall take all appropriate measures to restrict or prohibit the equipment or assembly being made available on the market or ensure that it is recalled or withdrawn from the market.

**ENTRY INTO FORCE:** 17.07.2014.

**TRANSPOSITION:** 28.02.2015 and 18.07.2014 depending on the provisions. The Directive shall apply from 01.06.2015 and from 19.07.2015 depending on the provisions.

**DELEGATED ACTS:** the Commission shall be empowered to adopt delegated acts in order to take into account emerging serious safety reasons. The power to adopt delegated acts shall be conferred on the Commission for a period of five years from 1 June 2015. The European Parliament or the Council may raise objections to a delegated act within a period of two months from the date of notification (this may be extended by two months). If the European Parliament or Council express objections, the delegated act will not enter into force.