

Making available on the market of pressure equipment. Recast

2013/0221(COD) - 28/06/2013 - Legislative proposal

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On 1 June 2015 Directive, 67/548/EEC is to be repealed and replaced by [Regulation \(EC\) No 1272/2008](#) of the European Parliament and of the Council on classification, labelling and packaging of substances and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).