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.
- **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.