

Common framework for the marketing of products

2007/0030(COD) - 21/11/2011 - Follow-up document

The Commission presents a Communication on the alignment of ten technical harmonisation directives to Decision No 768/2008/EC on a common framework for the marketing of products. It recalls that, since the 1970s, a large variety of goods have come to be regulated by EU legislation designed to ensure the protection of the consumer, the worker in the workplace, the environment, energy resources and so on in a uniform manner, thereby ensuring free movement throughout the Union. The adoption of the **New Approach legislative technique** in 1985, restricting legislative requirements to those that are essential and addressing detailed technical issues in harmonised European Standards, has contributed to the acceleration of the harmonisation process, enabling whole industrial sectors to benefit from free movement.

This initiative is an important step in the implementation of the legislative framework adopted as part of the **“goods package”** on 9 July 2008. The objective of the 2008 package was to boost the free movement of safe goods by reinforcing the effectiveness of EU product safety legislation, strengthening consumer protection and levelling the playing field for economic operators.

The **New Legislative Framework (NLF) texts** - Regulation (EC) No 765/2008 and Decision No 768/2008/EC - were adopted as part of the package (which also included a Communication on car registration and a proposal for a regulation on mutual recognition).

The two NLF texts constitute a major political breakthrough for the functioning of the internal market for goods, in that they not only establish an overarching and coherent approach to technical harmonisation policy in relation to product safety but also open the door to an effective market surveillance policy for all goods placed on the market, whether they originate in the EU or in third countries.

Following adoption of the NLF in July 2008, the Commission services screened product legislation to identify instruments due to be revised within the next 3-5 years (i.e. up to 2013) for sector-specific reasons (e.g. to clarify or expand their scope, to update safety requirements etc.). The Commission also looked for legislation that shared the structure and approach of the provisions of Decision No 768/2008/EC to form part of an exercise devoted solely to alignment with the Decision. This automatically limited the choice of directives to those adopted under the New Approach technique, as other legislation (in particular old or traditional approach directives) would require more in depth adaptation going beyond mere “alignment”. This process led the Commission to identify **the following ten new approach directives for inclusion in this alignment package:**

- Civil Explosives Directive: Directive 93/15/EEC on the harmonisation of the provisions relating to the placing on the market and supervision of explosives for civil use;
- Directive on equipment for use in explosive atmospheres (ATEX): Directive 94/9/EC on the approximation of the laws of the Member States concerning equipment and protective systems intended for use in potentially explosive atmospheres;
- Lifts Directive: Directive 95/16/EC on the approximation of the laws of the Member States relating to lifts;

- Pressure Equipment Directive: Directive 97/23/EC on the approximation of the laws of the Member States concerning pressure equipment;
- Measuring Instruments Directive: Directive 2004/22/EC on measuring instruments;
- Electromagnetic Compatibility Directive (EMC): Directive 2004/108/EC on the approximation of the laws of the Member States relating to electromagnetic compatibility;
- Low Voltage Directive (LVD): Directive 2006/95/EC on the harmonisation of the laws of Member States relating to electrical equipment designed for use within certain voltage limits;
- Pyrotechnic Articles Directive: Directive 2007/23/EC on the placing on the market of pyrotechnic articles;
- Non-automatic Weighing Instruments Directive: Directive 2009/23/EC on non- automatic weighing instruments;
- Simple Pressure Vessels Directive: Directive 2009/105/EC relating to simple pressure vessels.

The Commission notes the following:

- the **major common characteristic of these directives is that they have a similar structure:** definitions, essential health and safety requirements, references to harmonised European standards, requirements for manufacturers, traceability requirements and conformity assessment requirements (all have conformity assessment procedures, eight require the intervention of notified bodies) and safeguard mechanisms;
- **some of the directives have cross sectoral relevance** (in particular, low voltage, EMC, measuring instruments, equipment for use in explosive atmospheres and pressure equipment) thus reinforcing the expected benefits of alignment for economic operators and national authorities responsible for the surveillance of these markets;
- the sectors concerned are very important industrial sectors which are faced with **severe international competition and will therefore benefit from simplification** and the guarantee of a level playing field in the EU market. The report sets out the basic data for some of these sectors, including the figures on output and trade balance regarding equipment covered by the directives in question. These underline that enhancing legislative coherence and enabling effective market surveillance, in particular in relation to goods originating in third countries, will have very positive effects.

The main provisions: the proposals covered by this initiative are strictly limited in content to alignment with Decision No 768/2008/EC and the new terminology of the Lisbon Treaty (including the new provisions on comitology). More specifically, they will **align definitions, traceability requirements, obligations of economic operators, criteria and procedures for the selection of conformity assessment bodies (notified bodies) and conformity assessment requirements.**

The substance of the alignment of the ten directives can be summarised as follows:

(1) Measures intended to address the problem of non-compliance:

- **obligations of importers and distributors** to check that goods bear the CE marking are accompanied by the required documents and carry traceability information. Additional obligations are imposed on importers;
- **obligations of manufacturers** to provide instructions and safety information in a language easily understood by consumers and end-users, and to carry out sample testing and product monitoring;
- **traceability requirements** throughout the whole distribution chain: manufacturers and importers must put their names and addresses on products; every economic operator must be able to inform the authorities from whom he purchased a product and to whom he supplied it;
- reorganisation of **safeguard clause** procedure (market surveillance) to clarify how the relevant enforcement authorities are informed about dangerous goods and ensure that the same action is taken in relation to that product in all Member States.

(2) Measures intended to ensure the quality of work done by notified bodies:

- reinforcement of the **notification requirements** for notified bodies (including subcontractors and subsidiaries) such as impartiality, competence in carrying out their activity and the application of guidance developed by coordination groups;
- **revised notification process**: Member States notifying a body must include information on the evaluation of the competence of that body. Other Member States can object to the notification within a certain period;
- requirements for notifying authorities (i.e. the national authorities responsible for the assessment, notification and monitoring of notified bodies) such as objectivity and impartiality in carrying out their activity;
- **information obligations**: notified bodies must inform notifying authorities of refusals, restrictions, suspensions and withdrawals of certificates.

(3) Measures intended to ensure greater consistency among directives:

- alignment of commonly used definitions and terminology.
- alignment of the texts of the conformity assessment procedures.

It should be underlined that issues relating to the implementation of EU standardisation policy, which could have knock-on effects on the implementation of the directives covered here, are being dealt with in a separate initiative (the standardisation package).

The Commission has selected instruments for this package on the basis that the only amendments made to them relate to alignment with the provisions of the NLF. **No changes are made to the substantive technical aspects of the particular sectoral legislation involved.** Accordingly, the Commission calls upon the European Parliament and Council **to treat the package as such in order to ensure the overall coherence** implicit in the recast technique and to avoid splitting up debates into a collection of sectoral discussions.