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**NEW LEGISLATIVE FRAMEWORK (NLF) ALIGNMENT PACKAGE
(Implementation of the Goods Package)**

**COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN
PARLIAMENT AND THE COUNCIL**

**Alignment of ten technical harmonisation directives to Decision No 768/2008/EC of the
European Parliament and of the Council of 9 July 2008 on a common framework for the
marketing of products**

(Text with EEA relevance)

{SEC(2011) 1375 final}
{SEC(2011) 1376 final}

1. POLITICAL CONTEXT

Europe needs a strategy to help it emerge stronger from the economic crisis and turn the EU into a smart, sustainable and inclusive economy delivering high levels of employment, productivity and social cohesion. **Europe 2020** sets out a vision of Europe's social market economy for the 21st century.

Although the single market is not itself one of the seven flagship policies identified as essential to achieve the headline targets of the EU 2020 strategy, the Communication on EU 2020 states that EU-level instruments, notably the single market, financial levers and external policy tools, will be fully mobilised to tackle bottlenecks and deliver the Europe 2020 goals. Operational proposals to ensure the full contribution of these instruments to the strategy are an integral part of the Europe 2020.

The Communication goes on to assert that a stronger, deeper, extended single market is vital for growth and job creation. With a view to re-launching the single market, in late 2009 President Barroso invited Prof. Mario Monti to prepare a report setting out recommendations and solutions. Prof Monti presented his report in 2010, observing that the single market is instrumental in several other areas of EU policy making which attract great political interest and risk not delivering what they are intended to deliver, if they cannot fully stand on a robust single market.

In relation to goods in particular, Prof. Monti stated that maintaining a dynamic and expanding single market for goods required building on the full implementation of the goods package, approved in 2008, particularly with regard to the mutual recognition principle and market surveillance.

The present 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.

In the presence of the world economic crisis, this remains particularly important today because an effectively functioning internal market is crucial to fostering competitiveness, growth and employment in the European Union – major political priorities of the European Commission, as demonstrated in the proposal for a Single Market Act¹.

2. THE GOODS PACKAGE AND ITS CONTRIBUTION TO THE INTERNAL MARKET

The free movement of goods is a major foundation stone of the internal market, as enshrined in the Treaty, and is at the very heart of the development of the European Union.

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

¹ COM(2011) 206 final of 13.4.2011.

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.

Technical harmonisation legislation has proved a success. The internal market for goods is a reality and has simultaneously ensured a high degree of safety of goods and facilitated their free movement throughout the European Union.

However, the implementation and enforcement of this legislation has revealed a number of weaknesses that undermine its effectiveness, illustrated by continued presence on the market of non-compliant and potentially dangerous goods. This damages confidence in the whole system and creates an uneven playing field for economic operators. It is due partly to the unsatisfactory performance of certain notified bodies and inconsistencies throughout the legislation making its application unnecessarily complicated for manufacturers and authorities.

Non-compliance can be potentially harmful to users of goods. It also reduces the competitiveness of compliant firms as non-compliant rivals take unfair advantage (e.g. by avoiding costly conformity assessment procedures).

One major difficulty for national market surveillance authorities is that non-compliant goods and the operators who supplied them are very often not traceable, particularly when the goods originate in third countries. Moreover, market surveillance is not always carried out in the Member States as consistently or rigorously as it should be, allowing potentially dangerous goods to circulate. As market surveillance is primarily carried out at national level, there is an urgent need for better monitoring, coordination and exchange of information at EU level in order to ensure a more uniform level of safety throughout the EU.

Legislative requirements for goods have become increasingly complicated for economic operators. Modern goods have become technologically more complex and present more diverse risks than before to both the health and safety of persons and the environment. This has meant that manufacturers and other economic operators now have to contend with a large and growing number of different pieces of legislation which apply simultaneously to a single product. In addition, inconsistencies have gradually arisen in product legislation - different terminology is used to describe concepts that are in fact common to all harmonising legislation (e.g. conformity assessment procedures and safeguard clauses). This last problem is more important than at first appears.

Even minor divergences can make it difficult for economic operators to understand how to comply with EU legislative requirements. This can lead honest operators to invest heavily in areas which are in fact unnecessary, in the belief that this will make absolutely sure of compliance. At the same time, legislative inconsistencies and ambiguities provide unscrupulous operators with ways to circumvent public authority controls. Often, it is unclear to national authorities what checks must be done, or how. This leads to Member States (or even regions within those States) adopting different approaches, with the result that market surveillance is not performed with uniform regularity, operating criteria and rigour across the

EU. This in turn allows an uneven playing field to develop for economic operators, be they manufacturers or importers.

On the basis of these considerations, in 2003 the Commission presented a Communication to the Parliament and the Council on the implementation of the New Approach, adopted in 1985². This concluded that the New Approach legislative technique needed to be reviewed and complemented by legislative requirements for the accreditation of conformity assessment bodies and a general policy on market surveillance for goods.

3. THE NEW LEGISLATIVE FRAMEWORK AND ITS IMPLEMENTATION

In response to this review process, the Commission presented a collection of measures which came to be known as the “Goods package”. 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). These texts go far beyond a mere review of the New Approach and in fact set up a new legislative environment for the harmonised area.

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 a real and effective market surveillance policy for all goods placed on the market, whether they originate in the EU or in third countries.

The objective of the NLF texts is to reinforce the effectiveness of legislation protecting health and safety (and other public interests) by:

- filling in the missing elements of EU policy, e.g. accreditation and market surveillance including the control of goods from third countries;
- addressing the shortcomings of the existing situation in the light of twenty years of implementation of the New Approach alongside more traditional legislation;
- bringing coherence to legislation which now cuts across more and more sectors.

The two texts contribute in their different ways to answering these needs and complete the legislative quality chain: (essential) requirements relating to health and safety and other public interest protection, quality requirements for manufacturers and conformity assessment bodies, an accreditation system to ensure the quality of conformity assessment bodies, transparent conformity assessment procedures, strong market surveillance and controls of goods from third countries. A weak or missing link in this chain can allow unsafe goods to reach the market and the end user, whether private or professional. The NLF texts are complementary documents, inextricably linked the one to the other, and both relate very closely to sectoral legislation, which they support and complement.

² Communication from the Commission to the European Parliament and the Council: Enhancing the Implementation of the New Approach Directives, COM(2003) 240 final of 7.5.2003.

The Regulation introduces principles, rules, rights and obligations. Its provisions have been directly applicable since 1st January 2010 and are being implemented by national authorities, with the Commission helping to ensure a coordinated approach.

The Decision contains model provisions based on those in many existing pieces of Union harmonisation legislation but does not itself have any legal effect. As a *sui generis* decision, it constitutes a commitment on the part of the EU legislator to apply its contents as systematically as possible to all product legislation, past, present and future, and hence facilitate implementation by all involved.

The full effects of the Regulation depend to some extent on the process of integrating the provisions of the Decision into the sectoral legislation.

The NLF texts apply in conjunction with Union harmonisation legislation in the following manner:

- sectoral legislation sets levels of health and safety and other public interest protection, imposes requirements on economic operators and national authorities, chooses the appropriate conformity assessment procedures and includes safeguard mechanisms;
- Regulation (EC) No 765/2008 sets out rules for the accreditation of conformity assessment bodies which provide conformity assessment services under sectoral legislation and imposes obligations on market surveillance authorities relating to the enforcement of obligations set out in sectoral legislation and to the control of goods from third countries.

Through the alignment process, the provisions of Decision No 768/2008/EC on definitions, obligations of economic operators, traceability requirements, consolidated criteria and procedures for the notification of conformity assessment bodies and consolidated conformity assessment procedures are all integrated into sectoral legislation, thus allowing the market surveillance provisions set out in Regulation (EC) No 765/2008 to have full effect.

4. THE ALIGNMENT PROCESS AND THE PRESENT PACKAGE

For future legislation, the Commission will systematically examine whether it is feasible to integrate the provisions of the Decision into sectoral legislation, aligning as often and as fully as possible. Where it decides not to align, the unsuitability of the provisions of the Decision must be fully explained. This process will take place as and when sectoral legislation is modified.

Since the adoption of the Decision, a number of pieces of legislation have come up for review. The toys directive was revised by directive 2009/48/EC of 18 June 2009³, and is the first directive to be fully aligned with Decision No 768/2008/EC. Others are in the pipeline.

The question is what to do where no review/revision of legislation is envisaged in the near future. Clearly, the more coherent product legislation is, the easier it is to comprehend and

³ OJ L 170, 30.6.2009, p. 1.

therefore to comply with and to enforce. Horizontal, non-sectoral harmonised solutions certainly contribute to better coherence, as in the cases of conformity assessment procedures, rules for notified bodies, etc.

There is therefore a real need to review a number of directives which would not ordinarily be revised in the near future, in order to enable market surveillance-related provisions to be quickly put into operation in the sectors concerned.

Therefore it is proposed to align with the Decision a package of directives which were not due for revision but in relation to which provisions on market surveillance and other cross-sectoral issues would be beneficial, without calling into question purely sectoral considerations.

The objective of this package is therefore to amend selected directives solely to integrate horizontal provisions of the Decision in a one-off, simplified process without reviewing sectoral matters, in order to produce the immediate benefits of the NLF in as many sectors as possible.

In order to maximise legal clarity, the Commission has opted for the recast legislative technique. This and the Interinstitutional Agreement between the European Parliament, the Council and the Commission should help focus discussion in the co-decision procedure on the horizontal alignment of the texts with Decision No 768/2008/EC and avoid reopening discussions on sector-specific aspects.

The directives should also be aligned with the terminology and provisions of the Lisbon Treaty. In particular the new provisions on comitology must be introduced as a number of the directives concerned established committees.

5. THE SELECTION OF THE DIRECTIVES CONCERNED

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.). Most existing legislation required updating for sector-specific reasons and these individual revisions appear in the Commission Work Programme. Alignment will take place in the context of these revisions.

The Commission also looked for legislation which largely 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 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.

Basic data for some of these sectors can be summarised as follows:

The low voltage and EMC directives cover in general all domestic and professional electrical appliances which answer to an output of some € 235.59 billion for equipment covered by LVD and € 200.12 billion for equipment covered by EMC. The trade balance is negative

(LVD: €103.93 billion of imports and €83.09 billion of exports. The internal consumption is estimated at €256.42 billion. EMC: €100.78 billion of imports and €76.07 billion of exports. The internal consumption is estimated at €224.83 billion).

The ATEX equipment directive covers any product likely to be used in an explosive atmosphere, whether electrical, mechanical or pressure driven (mines, petrochemical plants, mills, filling stations. etc). The output is to the order of some € 2.2 billion, and its trade balance is positive: imports amount to €400 million, whereas internal consumption estimated at €1.9 billion, 86% of internal production.

The sector of measuring instruments (including non-automatic weighing instruments) which covers all measuring meters for water, gas, electricity, petrol and all other liquids and includes all weighing instruments in retail commerce has an output of some € 5.75 billion. Most instruments are manufactured in the EU, imports representing less than a quarter of EU production.

Pyrotechnics, which cover not only fireworks but also the technology for automobile air-bags, has an output of €4.2 billion (€2.8 billion for airbags). The fact that 95% of fireworks are produced outside the EU underlines the need for strong traceability requirements.

Pressure equipment (including simple pressure vessels) may fall under several different sectors as it is mostly used as a component in a larger end product. Goods including pressure equipment range from consumer goods (e.g. pressure cookers, domestic air conditioning systems, fire extinguishers, etc.) to industrial goods (e.g. pressure vessels and piping in chemical plants, various types of machinery, etc.).

This clearly shows the importance of the sectors concerned and underlines that enhancing legislative coherence and enabling effective market surveillance, in particular in relation to goods originating in third countries, will have very positive effects.

6. THE CONTENTS OF THE PROPOSALS

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 language used in the provisions of the Decision has been retained as far as possible, but in certain circumstances it has been adapted to enable correct and meaningful integration into the directives. Thus, terminology may differ from one directive to another but the meaning and legal obligations will be the same.

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).

7. CONCLUSIONS

The Commission attaches great importance to these proposals, which make an important contribution to the political goal of a properly functioning internal market for consumers, professionals and economic operators in general. The aligned directives will help strengthen the competitiveness of European enterprises, guaranteeing a level playing field for all where law-abiding operators will be protected against those less scrupulous.

This initiative is also very much in line with the Commission's objective of Better Regulation and Simplification, as it brings coherence and legislative uniformity across many different industrial sectors, helping to make EU legislation easier to understand, implement, obey and enforce.

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 involved⁴. 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.

⁴ An exception is made for the pyrotechnic articles directive. The Commission proposes a small correction to Annex I point (4) in order to avoid an unintended ban of airbags and certain other pyrotechnic articles after 4 July 2013. The amendment is relatively minor in terms of changes made to the existing text. Hence it is considered more appropriate and efficient to keep the directive inside the package instead of carrying out an independent revision process.