EUROPEAN COMMISSION

21.11.2011
SEC(2011) 1375 final

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

COMMISSION STAFF WORKING PAPER

Accompanying document to

10 PROPOSALS TO ALIGN PRODUCT HARMONISATION DIRECTIVES TO DECISION No 768/2008/EC

EXECUTIVE SUMMARY OF THE IMPACT ASSESSMENT

{COM(2011) 763 final}
{SEC(2011) 1376 final}

1. PROBLEM DEFINITION

General problems with product harmonisation directives …

Over a period of more than 30 years the EU has set up requirements in its "technical harmonisation" directives for a vast range of products such as machinery, automobiles, toys, electrical products, lifts, etc. This legislation has two objectives: On the one hand it ensures that products available in Europe safeguard public interests like health and safety, consumer protection or environmental protection at a high level. On the other hand it ensures the free movement of products by replacing national rules with a single harmonised set of conditions for the marketing of the products concerned that apply in all EU Member States[1].

A stocktaking exercise on experience gained with existing legislation in the harmonised area, and in particular with the New Approach was launched in 2004. The overall conclusion of this stocktaking was that the legislation has largely succeeded in liberalising trade in goods and in setting robust requirements ensuring the safety of products. However, it also revealed a number of shortcomings, namely a significant number of **non-compliant products** still reaching the market, the unsatisfactory performance of certain **notified bodies**[2], and **inconsistencies** throughout the legislation making its application unnecessarily complicated for manufacturers and authorities.

… and general solution identified

To remedy these shortcomings, the "New Legislative Framework" (NLF) was adopted as part of the goods package. It consists of two complementary instruments:

- Regulation (EC) No 765/2008 on accreditation and market surveillance (NLF Regulation)[3]
- Decision No 768/2008/EC establishing a common framework for the marketing of products (NLF Decision)[4].

Both instruments strengthen and complete the existing rules and improve the way they are applied and enforced in practice by business and authorities.

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1 The evolution of the EU's policy on technical harmonisation is outlined in detail in the impact assessment that accompanied the New Legislative Framework. SEC(2007) 173, http://ec.europa.eu/governance/impact/ia_carried_out/docs/ia_2007/sec_2007_0173_en.pdf

2 Laboratories and certification or inspection bodies delivering certificates which are notified to the Commission by Member States.

3 Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93, OJ L218 of 13.08.2008.

4 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, and repealing Council Decision 93/465/EEC, OJ L218 of 13.08.2008.

The Regulation introduced rules on accreditation and requirements for the organisation and performance of market surveillance and controls of products from third countries. The Regulation became applicable on 1 January 2010.

The Decision contains model text that is meant to reinforce various provisions commonly used in EU product legislation (for example concerning definitions, obligations of economic operators, notified bodies, safeguard mechanisms, etc) so that the legislation works more effectively in practice. It also introduces new aspects, such as obligations of importers, which are crucial to improving the safety of products on the market.

However, unlike the Regulation, the Decision does not have immediate legal effects on economic operators, individuals or Member States. It is conceived as a **"toolbox" for future legislation**. By adopting the Decision, the Parliament, the Council and the Commission have committed themselves to using its provisions as much as possible in future product legislation in order to maximise the coherence of the regulatory framework[5]. To give practical effect to the provisions of the Decision, they need to be integrated into existing and new product legislation.

A specific set of harmonisation directives

Against this background, the Commission has identified a specific set of product harmonisation directives for which alignment with the NLF Decision could be dealt with as a 'package' (i.e. as opposed to individual alignments carried out at the same time as broader revisions[6]). The ten directives concerned are the following:

- **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

- **ATEX Directive:** 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 of 29 June 1995 on the approximation of the laws of the Member States relating to lifts

- **Pressure Equipment Directive (PED):** Directive 97/23/EC on the approximation of the laws of the Member States concerning pressure equipment

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5 Article 2 (Subject matter and scope) of Decision No 768/2008/EC reads: "This Decision sets out the common framework of general principles and reference provisions for the drawing up of Community legislation harmonising the conditions for the marketing of products (Community harmonisation legislation. Community harmonisation legislation shall have recourse to the general principles set out in this Decision and to the relevant reference provisions of Annexes I, II and III. However, Community legislation may depart from those general principles and reference provisions if that is appropriate on account of the specificities of the sector concerned, especially if comprehensive legal systems are already in place."

6 Examples of individual alignments that are being carried out together with the revision of sector-specific elements (e.g. product requirements or testing methods) are the Recreational Craft Directive, the Directive on Personal Protective Equipment or the R&TTE Directive.

– **Measuring Instruments Directive (MID):** 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 and repealing Directive 89/336/EEC

– **Low Voltage Directive (LVD):** Directive 2006/95/EEC 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 (NAWI):** Directive 2009/23/EC on non-automatic weighing instruments

– **Simple Pressure Vessels Directive (SPVD)**: Directive 2009/105/EC relating to simple pressure vessels

The directives concerned by this initiative set out requirements which ensure that products are designed and manufactured in such a way that they do not pose a risk to the health and safety of consumers or other users, that they produce accurate measuring results (measuring instruments) or that they do not cause electromagnetic disturbances (electromagnetic compatibility directive).

The economic sectors to which the directives apply are electric and electronic goods (LVD and/or EMC), equipment for use in potentially explosive atmospheres (ATEX), pressure equipment (SPVD or PED), measuring instruments (MID or NAWI), civil explosives, lifts and pyrotechnic articles.

General problems also affect this specific set of directives

This impact assessment examines to what extent the general problems identified with product harmonisation legislation also affect these 10 directives and whether their alignment with the new framework established by the NLF Decision would be beneficial for the sectors concerned.

The **problem of non-compliance** with the requirements of directives is generally perceived throughout all sectors concerned, whereas certain sectors (and product categories) are more affected than others. Overall 92% of economic operators answering the public consultation consider that their sector is affected by non compliance.

Non-compliance can be potentially harmful for product users, although the risks vary according to the nature of the product. For instance defective electronic products falling under the scope of the LVD can present a risk of electric shock or burns. Electrical equipment that does not comply with the essential requirements of the EMC could produce electromagnetic disturbances that affect the correct functioning of other apparatus (TVs, radio and telecommunications networks) and may not work as intended. The explosion of industrial pressure equipment such as a boiler or a reactor vessel in a chemical plant is likely to lead to serious injuries and may cause

significant damage to surrounding infrastructures. Non compliance of measuring instruments can lead to wrong measuring results linked with economic damage for end-users.

In addition, non-compliance hampers the competitiveness of compliant firms. Non-compliant economic operators can gain significant cost advantages (e.g. by avoiding costly conformity assessment procedures) by comparison with those who follow the rules[7]. In sectors where there is tough competition from imported low-price products, European industry is disadvantaged. 87% of economic operators responding to the public consultation consider that they suffer from unfair competition due to this situation.

A major reason for non compliance is that market surveillance does not operate effectively in the EU. This perception is widely shared amongst stakeholders. A specific difficulty for the authorities is the traceability of non-compliant products and the operators who supplied them, in particular when the products originate in third countries.

A further reason is that existing obligations in product directives focus on manufacturers, while importers and distributors do not carry out the necessary checks to ensure that they are not supplying non-compliant products. They rely on the fact that it is the task of the manufacturer to ensure the compliance of the product and do not check whether the manufacturer has actually carried out this task properly. To remedy this, Member States have introduced obligations on importers and distributors in their national laws, which however differ from country to country and lead to different approaches when dealing with non-compliant products.

Eight of the ten directives concerned require the certification of products by "**notified bodies**"[8] before they can be placed on the market[9]. Notified bodies hence play an important role in ensuring the safety and compliance of products on the market. However there have been problems with the **quality of services** delivered by some of them. This assessment was shared by 68% of notified bodies, 84% of economic operators using notified bodies and 53% of public authorities that participated in the public consultation.

One reason is that certain notified bodies lack the necessary competence to carry out conformity assessments properly. Another reason is that, in order to issue their certificates at significantly lower rates, certain bodies do not put the required level of effort into their assessment or into the application of procedures. For example, the elimination or reduction of on site controls or relaxed requirements regarding the frequency of periodic audits/inspections can reduce the costs of assessments quite considerably.

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7 Quote from questionnaire reply: "Expert estimations say that fulfilling the safety and administrative provisions required by our regulations can add up to a fifth of total manufacturing costs. In the absence of efficient enforcement mechanisms some manufacturers might be tempted to "take the easy way" and to market non-compliant products."

8 These bodies are conformity assessment bodies, which test, inspect and certify products. They are called "notified bodies", because they are notified by the Member States to the Commission.

9 In the electro-technical sector the role of notified bodies is different. For instance under EMC Directive recourse to notified bodies in the conformity assessment procedure is voluntary.

The third problem to be tackled is the inconsistency gradually built up in the existing product legislation due to the fact that the directives have evolved over time. For example different terminology is used for concepts that are common to all of them (conformity assessment procedures, definitions or safeguard clauses). Sometimes definitions or legal provisions leave room for divergent interpretations and this leads to legal uncertainty and confusion, in particular when two or more directives apply simultaneously. For example, a considerable number of measuring instruments also have to comply with the EMC. Certain pyrotechnic articles also have to comply with the LVD or EMC.

2. ANALYSIS OF SUBSIDIARITY

This initiative concerns the proper functioning of the internal market in goods. EU action in this area is based on Article 114 of the TFEU. The aspects addressed in this context are already regulated by the ten directives concerned, although they do not effectively address the weaknesses identified or, as regards inconsistency, may even be the source of the problem. Action taken at national level to address these problems has led to divergent national approaches in the treatment of economic operators and risks creating obstacles to the free movement of goods. Hence it is appropriate to take action at EU level.

3. OBJECTIVES

This initiative has 3 main objectives. The first is to ensure that products on the EU market are safe and fulfil all the requirements ensuring a high level of protection of public interests (health and safety, electromagnetic compatibility, correct measurements). The main specific goal is to reduce the number of non-compliant products on the market by providing authorities with more effective tools to carry out market surveillance controls and to monitor the activities of notified bodies.

The second objective is to improve the functioning of the internal market, by ensuring that non-compliant products and economic operators are equally treated and that notified bodies are equally assessed throughout the EU market.

Finally, this initiative aims to simplify the regulatory environment for products.

4. POLICY OPTIONS

Due to the specific context of this initiative as explained in section 1, this impact assessment explores a limited set of options. The objective is to ascertain whether the directives concerned should make use of the measures of the NLF Decision and, if so, to assess whether alignment with the Decision should be carried out by legislative or non legislative means. The resulting options are:

– Option 1: **No policy change**. This option consists of not introducing any changes to the existing situation.

– Option 2: **Alignment with the NLF Decision by non legislative measures**. Option 2 consists of a set of non-regulatory instruments that encourage the

voluntary application of all or part of the solutions contained in the NLF Decision. The latter could also be presented as “best practice” in guidance documents and the parties concerned would be encouraged to apply them. In practice, this option would be a “voluntary” alignment with the NLF Decision.

– Option 3: **Alignment with the NLF Decision by legislative measures**. Option 3 consists of the modification of the directives concerned that would then make use of the measures set out in the NLF Decision.

Under option 2 and option 3 the measures provided by the NLF Decision can be summarised as follow:

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

- *Obligations for importers and distributors* to check that products bear the CE marking, are accompanied by the required documents and carry traceability information. Additional obligations are imposed on importers.

- *Manufacturer obligations* to provide instructions and safety information in a language easily understood by consumers and end-users, to carry out sample testing and product monitoring.

- *Traceability requirements* throughout the whole distribution chain: manufacturers and importers must put their name and address on the product; 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 products and ensure that equivalent action is taken against that product in all Member States.

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

- *Reinforcement of the notification requirements* for notified bodies (including subcontractors and subsidiaries) such as impartiality and competence in carrying out their activity and 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 in charge of 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 more consistency among the directives:

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

5. ASSESSMENT OF IMPACTS

The impact assessment report examines the economic impacts of the options in terms of internal market, competitiveness, costs and administrative burdens for economic operators or notified bodies and the impacts on public authorities and consumers/users. The report also looks at the social impact on public health and safety and on the simplification of the regulatory environment.

Although no additional policy initiative is taken, the no policy change option is expected to have some positive impact in the sectors concerned already, due to the progressive implementation of the NLF Regulation, which strengthens the powers of market surveillance authorities. This plays a positive role in relation to the goal of reducing non-compliance and delivers benefits both to compliant-firms (competitiveness) and users (economic and safety impact). The NLF Regulation also facilitates the task of public authorities in their activities relating to the notification and monitoring of some conformity assessment bodies (i.e. those using accreditation). However, the option has no real impact on the internal market or on the simplification of the regulatory environment.

The option of alignment with the NLF Decision by non-legislative measures has the potential for positive impacts on all stakeholders. For instance, clarifying the responsibilities of importers and distributors and introducing specific traceability requirements would facilitate the equal treatment of the parties involved (positive impact on internal market); it would also provide authorities with more effective tools to address non-compliance and so reduce the scope for unfair competition (competitiveness) and risks taken by users (economic and safety impact). However, under option 2 the provisions of the NLF Decision would only be non binding 'best practice' and so their implementation would entirely depend on the voluntary commitment of the different stakeholders. This casts serious doubt on whether the positive impacts identified will actually materialise and provide real added value with respect to the no- change option[10].

Under the option of alignment with the NLF Decision by legislative measures the provisions of the NLF Decision would be part of applicable sector legislation. The provisions of the NLF Decision would be binding obligations enforceable by Commission and by national authorities. This would give a stronger guarantee that the positive impacts of the alignment would actually occur.

This analysis of positive impacts is largely supported by stakeholders. For instance 73-76% of general economic operators and small and medium enterprises

[10] It this respect, it is important to note that existing guidance contained in the so-called "Blue Guide" (*Guide to the implementation of directives based on the New Approach and the Global Approach*, European Commission, September 1999), already points to the responsibilities of the economic operators that are then clarified by Decision No 768/2008/EC. However as the Blue Guide is not binding, it has not been sufficient to address the issues identified.

participating in the public consultation believe that clarification of obligations relating to them and market surveillance procedures will help defend the competiveness of EU businesses. Similarly most stakeholders[11] agree that this policy action will help protect public health and safety.

Alignment by legislative measures is not expected to have a significant impact on the costs of firms and notified bodies. Most obligations of economic operators complement existing obligations or codify what would be normal practice for a responsible/compliant firm according to the spirit of existing legislation. Similarly, the requirements for notified bodies are fully in line with standards defining the relevant benchmark for the assessment of conformity assessment bodies[12]. Overall an impact on costs is possible, in relation to obligations of importers/distributors and traceability, but is considered moderate. Indeed 55% of general economic operators and 30-33% of small and medium enterprises having participated in the consultations believe that the alignment of these obligations will bring about moderate cost increases, while a further 12% and 27% respectively consider that there will be no or no significant cost increases. Due to the large variety of products concerned by this exercise, it is not possible to provide quantitative estimates.

At the end of the impact assessment there was no indication that the selected option might result in a disproportionate burden for SME.

Some implementation costs for public authorities have been identified, in particular as regards the need to re-notify conformity assessment bodies in accordance with the requirements in the NLF Decision. However, the number of re-notifications to be handled by each competent authority is very limited (with the exception of the authorities dealing with non-automatic weighing instruments, in only 2 countries). In any case, the Commission will introduce a specific transitional provision that allows time for re-notifications before the general date of applicability of the directives.

6. COMPARISON OF OPTIONS

The no policy change option is only partly effective in relation to the objectives of this policy intervention. Furthermore, it is not coherent with the policy commitment underpinning the NLF Decision.

The option of aligning by non-legislative measures might be more effective than option 1 as, in principle, it addresses all the objectives, except simplification. However, it does not guarantee positive impacts due to its poor enforceability. In terms of efficiency the non-legislative measure is the option with the lowest score since, on the one hand it does not guarantee significant benefits by comparison with

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11 58-78% of economic operators, 72-78% of notified bodies 58-62% of authorities and about 72-79% of users participating in the consultation (excluding the measuring instrument sector).

12 These are 1) EN 45011:1998, General requirements for bodies operating product certification systems; 2) EN ISO/IEC 17020:2004, General criteria for the operation of various types of bodies performing inspection; 3) EN ISO/IEC 17021:2006, Conformity assessment – Requirements for bodies providing audit and certification of management systems; 4) EN ISO/IEC 17024:2003, Conformity assessment – General requirements for bodies operating certification of persons; 5) EN ISO/IEC 17025:2005, Conformity assessment – General requirements for the competence of testing and calibration laboratories.

the no policy change scenario, and on the other hand it brings about some (moderate) increase in compliance costs for economic operators and notified bodies that voluntarily commit to the best practice proposed.

The option of aligning by legislative measures addresses all the objectives and is more effective than both option 1 and option 2. This option will bring about moderate costs that are more than offset by its positive impacts. This option is then considered efficient. Furthermore, this option is fully consistent with the policy commitment underpinning the NLF Decision.

In the light of its effectiveness, efficiency and coherence, option 3 stands out as the preferred option.

Table 1: Comparison of the listed options

	Effectiveness	Efficiency	Coherence
Option 1: No change	Neutral **[It addresses to some extent the objectives of reducing the number of non-compliant products and scope for unfair competition.** **It addresses the objective of increasing reliability of NB, but only when accredited.** **It does not meet the objectives of equal treatment of EO and of consistency of legislation / simplification of product regulatory framework]**	Neutral **[No additional resources needed, however objectives only partially met.]**	Neutral **[Incoherent with other NLF instrument and policy commitment underpinning NLF Decision]**
Option 2: Non-legislative measures	Low **does not provide tangible improvement with respect to Option 1 due to poor enforceability. It will increase the compliance gap between responsible and unscrupulous EO/NB. It does not address simplification.**	Low **less efficient than Option 1, same effectiveness vs higher costs for responsible stakeholders**	Neutral **[Incoherent with other NLF instrument and policy commitment underpinning NLF Decision]**
Option 3: Alignment	High **addresses all objectives. More effective than option 1 and option 2 in relation to the objectives of reducing the number of**	High **important benefits for all stakeholders vs small or moderate additional costs**	Coherent **with other NLF instrument and policy commitment underpinning NLF Decision**

	non-compliant products and scope for unfair competition. Effective as to simplification.		

7. MONITORING AND EVALUATION

The evaluation of the effectiveness of the legislation will be based on the feedback received through the various cooperation mechanisms already established under the directives themselves to facilitate their implementation (experts groups, administrative cooperation groups (ADCOs), notified body groups).

In 2018 the Commission will produce a comprehensive report on the functioning of market surveillance,[13] which will also allow conclusions to be drawn for the evaluation of this initiative.

Indicators allowing to monitor the reduction of non-compliant products on the market and the improvement of the quality of conformity assessment services delivered by notified bodies will be based on information obtained via the RAPEX system, the market surveillance database established under Article 23 of the NLF Regulation, data provided by authorities responsible for the controls at external borders, the National Market Surveillance Programmes established under Article 18 of the NLF Regulation, the market surveillance and safeguard clause notification procedures established under every directive and the NANDO[14] database.

[13] See Article 40 of Regulation (EC) No 765/2008.

[14] http://ec.europa.eu/enterprise/newapproach/nando/