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

COMMISSION STAFF WORKING PAPER

IMPACT ASSESSMENT

Accompanying document to the

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

Disclaimer: This report commits only the Commission's services involved in its preparation and does not prejudge the final form of any decision to be taken by the Commission.

{COM(2011) 763 final}
{SEC(2011) 1375 final}

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1. PROCEDURAL ISSUES AND CONSULTATION OF INTERESTED PARTIES

1.1. Identification

Lead DG: DG ENTR

Agenda Planning/WP Reference: 2010/ENTR/002

1.2. Organisation and timing

Work on the present Impact Assessment started in spring 2009. DG ENV, EMPL, EUROSTAT, INFSO, MARKT, LS, SANCO, TAXUD, TREN, TRADE and the SG were invited to join the IASG. The group met four times, on 1 December 2009, 7 April 2010, 2 February 2011 and 1 March 2011 and representatives of DG SANCO, DG ENTR and the LS participated in these meetings.

1.3. Consultation and expertise

External expertise was used to obtain some basic data on the measuring instruments sector.[1] Furthermore, findings from studies concerning lifts (2004[2] and 2007[3]), and equipment used in potentially explosive atmospheres (ATEX)[4] have been used to underpin this report[5].

National authorities have been consulted through the Senior Officials Group for Standardisation and Conformity Assessment Policy and the sector specific working groups established under the ten directives concerned (see section 11.1 in Annex 3). Some bilateral meetings with national experts took place.

From June to October 2010 a public consultation was carried out which was published on the Your Voice in Europe website. It consisted of four targeted questionnaires for economic operators, authorities, notified bodies and users and we received 300 replies.[6] In view of the high number of SME active in the sectors

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1 *Interim Evaluation of the Measuring Instruments Directive*, Final report by CSES Centre for Strategies and Evaluation Services (UK), July 2010: http://ec.europa.eu/enterprise/sectors/legal-metrology-and-prepack/public-consultation/public-consultation-files/evaluation_report_by_cses_en.pdf

2 *Evaluation of the Application of the Lift Directive (95/16/EC)*. Final Report to the European Commission (DG ENTR) submitted by: The European Evaluation Consortium,The Evaluation Partnership Limited (UK); Economisti Associati (Italy); Particip GmbH (Germany);navreme knowledge development (Austria); Authorised Representative The Evaluation Partnership Limited, 21 June 2004. The study examined the functioning of the Lifts Directive in 7 Member States: Belgium, Finland, Germany, Italy, Portugal, Spain and the United Kingdom.

3 Study on the *Technical Assessment of Means of Preventing the Crushing Risk on Lifts subject to Directive 95/16/EC*, Report Number ME/07/07, Science Group: Hazard Reduction Group Health and Safety Laboratory; Project Leader: Jonathan Statham; Crown copyright (2007). The study aim was the examination whether the solutions available, other than free space or refuges, to prevent the crushing risk can provide an equivalent level of safety.

4 See "Market description, competitiveness analysis in the field of products and protective systems intended for use in potentially explosive atmospheres" (1999); available on http://ec.europa.eu/enterprise/sectors/mechanical/files/atex/atexcomp_finalreport_en.pdf

5 A glossary and a list of acronyms can be found in Annex 1.

6 A summary of the results is available at http://ec.europa.eu/enterprise/policies/single-market-goods/regulatory-policies-common-rules-for-products/new-legislative-framework/index_en.htm

concerned, a specific SME consultation was carried out in addition to the general consultation. 603 SME were consulted through the Enterprise Europe Network in May/June 2010. More information on stakeholders who participated in the consultation can be found in the annex (see section 11.2 in Annex 3). Several bilateral meetings also took place with industry associations from the electro-technical sector, the measuring instruments sector, the pressure equipment sector and the lifts sector. The Commission's minimum consultation standards were fully met.

In general all stakeholders expressed wide-spread support for the initiative. There is unanimity on the need to improve market surveillance and the system for assessing and monitoring Notified Bodies. Authorities fully support the exercise because it will strengthen the existing system and improve cooperation at EU level. Industry also expects a simplification effect from the alignment of legislation. Certain concerns were expressed on very specific aspects, mainly relating to translation obligations and certain aspects of traceability requirements. While a number of these concerns can be addressed by appropriate guidance, some could not be taken into account because these measures are indispensable to increasing the efficiency of market surveillance. They do not entail unreasonable costs for industry and the benefits resulting from improved market surveillance should outweigh the costs. More details of stakeholders' views can be found in section 11.

1.4. Scrutiny by the Commission Impact Assessment Board

The Impact Assessment Board of the European Commission assessed a draft version of the present impact assessment and issued its opinion on 12/04/2011. The Board made several recommendations and, in the light of these, the final impact assessment report:

Clarifies the considerations on the basis of which the ten directives have been selected to be part of this initative;

Describes in more detail the measures intended to address all the aspects raised in the problem description;

Presents in a clearer manner a comparison of the costs and benefits of this initiative;

Clarifies the monitoring and evaluation arrangements for this initative.

2. CONTEXT

2.1. The New Legislative Framework

This initiative is a further step in the implementation of the **"goods package"** adopted in August 2008. The goods package is a set of horizontal measures aimed at improving the functioning of the internal market for goods. It consists of three instruments:

– **Regulation 764/2008**[7], which is intended to improve the free movement of goods in the "**non-harmonised area**" (free movement is ensured by Articles 34, 35 and 36 of the TFEU) by reinforcing the application of the principle of the mutual recognition.

– **Regulation 765/2008**[8] and **Decision 768/2008**[9], which together form the **"New Legislative Framework"**, and which have the aim of improving the free movement of goods in the "**harmonised area**" (free movement is ensured by EU harmonisation legislation on the marketing of products).

In the harmonised area the goods package was preceded by a stocktaking exercise on the experience gained with the existing legislation in that area, and in particular with the New Approach. 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 a twofold objective: On the one hand it ensures that products available in Europe meet a high level of protection of public interests like health and safety, consumer protection or environmental protection. 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.[10]

The overall conclusion of the 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 unveiled a number of shortcomings observed across various sectors, namely a significant number of non-compliant products that reach the market, the unsatisfactory performance of certain notified bodies[11], and inconsistencies throughout the legislation making its application unnecessarily complicated for manufacturers and authorities.

To remedy these shortcomings the "**New Legislative Framework" (NLF)** was adopted as part of the goods package. It consists of two complementary instruments, **Regulation 765/2008 on accreditation and market surveillance** (NLF Regulation) and **Decision 768/2008 establishing a common framework for the marketing of**

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7 Regulation (EC) No 764/2008 of the European Parliament and of the Council of 9 July 2008 laying down procedures relating to the application of certain national technical rules to products lawfully marketed in another Member State and repealing Decision No 3052/95/EC, OJ L218 of 13.08.2008. For more information see http://ec.europa.eu/enterprise/policies/single-market-goods/free-movement-non-harmonised-sectors/mutual-recognition/index_en.htm

8 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

9 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

10 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

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

products (NLF Decision). The NLF was accompanied by an impact assessment[12]. Its objective is to strengthen and complete the existing rules and to improve the way in which the requirements are actually applied and enforced in practice by business and authorities.

The **NLF Regulation** has introduced rules on **accreditation**[13] 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 **NLF Decision** sets out a **common framework** for EU legislation that lays down requirements for the marketing of products. It contains the **provisions** which are **commonly used** in EU product legislation (e.g. definitions, obligations of economic operators, notified bodies, safeguard mechanisms, etc). These common provisions have been reinforced to ensure that the directives work more effectively in practice. New elements, such as obligations on importers, have been introduced, which are crucial for improving the safety of products on the market.

The NLF Decision **complements the NLF Regulation**. While the latter basically contains the obligations on Member States and their authorities to ensure that products on their market are safe and comply with the legal requirements, the NLF Decision contains the corresponding obligations imposed on economic operators such as manufacturers, importers and distributors, as well as the bodies testing and certifying products. These obligations provide the means for authorities to effectively carry out their obligations under the Regulation. Hence, the two instruments are **inextricably linked** and can only fully deliver their results in interplay with each other.

However, unlike the NLF Regulation, the NLF 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 NLF Decision the three EU institutions involved in the legislative process, Council, Parliament and Commission have committed themselves to use its provisions as much as possible in future legislation on products in order to further the utmost coherence of the regulatory framework[14]. To give practical effect to the NLF Decision's provisions, they need to be integrated into the existing product legislation.

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12 See SEC 2007(173) http://ec.europa.eu/governance/impact/ia_carried_out/docs/ia_2007/sec_2007_0173_en.pdf

13 Accreditation is a tool for the control of the competence of laboratories and certification/inspection bodies delivering certificates in the EU

14 Article 2 of Decision 768/2008 reads: "***Subject matter and scope***: 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".

2.2. Political background

In the wake of large-scale product recalls, **product safety** has gained a lot of **political attention** lately. In the summer of 2007, when the NLF was actually under negotiation between Parliament and Council, a major recall of toys pushed the item up the political agenda. The events not only exposed deficiencies in the way that market surveillance currently operates in Europe (market surveillance to effectively deal with dangerous products), they also put into question the credibility of EU legislation and its capacity to adequately protect the health and safety of consumers. This added considerable momentum to the NLF negotiation process. There was consensus amongst all actors on the need to improve the situation on market surveillance and to strengthen the obligations on economic operators. The negotiations on the goods package were finalised in record time.

In response to these concerns, the Commission immediately presented a proposal for a revised Directive on the Safety of Toys in 2008. It fully took on board the new framework set by the NLF Decision and became the first directive to be aligned to the NLF.[15]

Improving the safety of products, in particular as regards imported products, still remains an important issue for the European Parliament[16] and there are high expectations to upgrade the remaining product safety legislation to the new standards set by the NLF Decision.

2.3. Implementation of NLF

Right after the adoption of the NLF in summer 2008 the Commission examined ways to bring the **existing legislation** into line with the enhanced provisions of the NLF Decision. The Decision itself provides that its provisions are to be used when legislation is drafted or revised. An internal survey showed that for a majority of the existing directives there was a need to address technical, sector-specific elements (e.g. need to clarify or expand the scope, need to update safety requirements to technical progress) in addition to the problems observed at horizontal cross-sector level. Hence a full revision of these directives had been planned within a time-frame of 5 years. Examples are the Recreational Craft Directive, the Directive on Personal Protective Equipment or the R&TTE Directive. In line with Article 2 of the NLF Decision such a revision will also include an alignment to the NLF.

For a number of other directives no particular problems with their sector-specific elements were identified which would have required a full revision of these directives including the sector-specific elements. The only deficiencies perceived in these sectors were those of a horizontal nature identified in the 2004 stocktaking exercise which led to the adoption of the NLF.

While no full revisions were thus planned for these directives - neither within the 5 year framework nor beyond that period - it was nevertheless considered that the

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15 See http://ec.europa.eu/enterprise/sectors/toys/documents/directives/index_en.htm

16 See for example the own initiative Report on the revision of the General Product Safety Directive and market surveillance (2010/2085(INI)) http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//NONSGML+REPORT+A7-2011-0033+0+DOC+PDF+V0//EN&language=EN

cross-cutting horizontal problems of non-compliance and incoherence need to be addressed and that these sectors should also fully benefit from the improvements of the NLF. Given the strong link between the NLF Regulation and the NLF Decision, and the objective of ensuring more consistency throughout the regulatory framework for products, it appeared desirable to also align these directives to the NLF Decision within the same timeframe. In order to stress the fact that this exercise exclusively concerns the horizontal elements of these directives which will be aligned to the NLF Decision - as the follow-up to the commitments undertaken in the context of the goods package - and to achieve a result which is as coherent as possible, it has been decided to deal with these directives in a package.

The ten directives concerned are the following:

(1) **Low Voltage Directive:** Directive 2006/95/EEC on the harmonisation of the laws of Member States relating to electrical equipment designed for use within certain voltage limits

(2) **Electromagnetic Compatibility Directive:** Directive 2004/108/EC on the approximation of the laws of the Member States relating to electromagnetic compatibility and repealing Directive 89/336/EEC

(3) **ATEX Directive:** Directive 94/9/EC of the European Parliament and the Council on the approximation of the laws of the Member States concerning equipment and protective systems intended for use in potentially explosive atmospheres

(4) **Lifts Directive**: European Parliament and Council Directive 95/16/EC on the approximation of the laws of the Member States relating to lifts

(5) **Pressure Equipment Directive:** 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

(6) **Simple Pressure Vessels Directive**: Council Directive 2009/105/EC on the harmonisation of the laws of the Member States relating to simple pressure vessels

(7) **Measuring Instruments Directive:** Directive 2004/22/EC of the European Parliament and of the Council on measuring instruments

(8) **Non-automatic Weighing Instruments Directive:** Council Directive 2009/23/EEC on the harmonisation of the laws of the Member States relating to non-automatic weighing instruments

(9) **Civil Explosives Directive:** Council Directive 93/15/EEC on the harmonisation of the provisions relating to the placing on the market and supervision of explosives for civil use

(10) **Pyrotechnic Articles Directive:** Directive 2007/23/EC on the placing on the market of pyrotechnic articles

2.4. Specificities of this impact assessment and its link to the impact assessment on the New Legislative Framework

Against this background the objective of this impact assessment is to examine whether an alignment of the aforementioned directives to the new framework set by the NLF Decision would be beneficial for the sectors concerned and preferable to waiting for a full review of these directives. The objective of the horizontal review, which resulted in the adoption of the NLF, was to address problems perceived globally throughout the various sectors - including those of the ten directives discussed in this document - and to provide solutions that can work across all sectors. In that context a number of possible solutions and their impacts have already been analysed[17]. To avoid unnecessary duplications, this report will draw to a large extent on the impact assessment carried out on the revision of the horizontal framework. This impact assessment will revisit the problems already analysed in the impact assessment for the NLF with a more sector-specific focus. In view of the political commitment laid down in Article 2 of the NLF Decision[18] to use the solutions offered by the Decision as consistently as possible, the number of options will be limited to different ways to give effect to the NLF Decision. Consequently the analysis of the impacts will also focus on the impacts resulting from the measures set out by the NLF Decision and examine whether they are suitable solutions for the sectors concerned, and have a positive impact.

This specific context also explains why the analysis will exclusively focus on **horizontal elements of the directives** and their possible alignment to the NLF Decision. No other changes in terms of content will be made to the Directives. This means that reflections on purely sector-specific aspects like the products covered by the directives, the adequacy of the essential health and safety requirements or the choice of the applicable conformity assessment procedures will be left aside.

2.5. Description of directives and sectors

This section provides a summary of the ten directives and the key data characterising the sectors concerned by this initiative. A more detailed description is contained in sections 10.1 to 10.8 in Annex 2.

2.5.1. Objective and content of the directives

Most of the directives aim to ensure a high level of safety of the products they cover. The directive on electromagnetic compatibility protects against electromagnetic disturbance and the metrology directives guarantee the accuracy of measurements performed by measuring instruments. In addition, all the directives simultaneously ensure the free movement of the products they cover throughout the EU.

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17 See SEC 2007(173) http://ec.europa.eu/governance/impact/ia_carried_out/docs/ia_2007/sec_2007_0173_en.pdf

18 See footnote 14

The directives are all so-called New Approach directives, using the same legislative technique[19] to achieve their policy objectives. They contain essential (health and safety) requirements[20] which the products must meet in order to be placed on the EU market. They also set out the procedures that manufacturers must carry out to demonstrate that their products fulfil those requirements (conformity assessment procedures). Eight of the ten directives require the intervention of an independent third party, the notified body[21] in that procedure. As a visible sign that the products comply with the essential requirements, the CE marking must be affixed to them. The directives also contain a safeguard clause, whereby Member States must inform the Commission of any restrictive measure that they take against non-compliant products which present a risk. The Commission then has to deliver an opinion as to whether the measure is justified.

Some provisions are specific to the sectors and products covered by the directive (scope, sector-specific definitions, essential requirements, choice of applicable conformity assessment procedures and specificities of procedure). Others are common to all directives (horizontal) and are basically the same (general definitions, manufacturers' obligations, basic conformity assessment procedures, requirement for notified bodies, CE marking, safeguard clause). However, certain – unnecessary – discrepancies have gradually made their way into the directives. See chapter 3.3.

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19 The legislative technique of the New Approach is explained in detail in sections 1.2 and 1.3 of the impact assessment on the NLF. http://ec.europa.eu/governance/impact/ia_carried_out/docs/ia_2007/sec_2007_0173_en.pdf

20 The terminology varies from directive to directive, some use "essential safety requirements", others "essential requirements" and the Low Voltage Directive uses the term "safety objectives".

21 Notified bodies are conformity assessment bodies testing, inspecting and certifying a product. They are notified to the Commission by the Member States in which they are established.

2.5.2. Key data of sectors concerned

Table 1: Key data of sectors concerned

	Products	Size of the industry (market output)	Trade balance (share of imports)	Industry structure, SME presence	Number of NB in the EU[22]
Electro-technical sector (Low Voltage Directive (LVD) and electro magnetic compatibility directive (EMC))	**Electric welding and soldering tools, electric domestic appliances, computers and other information processing equipment, electric motors, generators and transformers. electricity distribution and control apparatus, insulated wire and cable (LVD only), lighting equipment and electric lamps (LVD only), other electrical equipment, electronic valves and tubes and other electronic components (LVD only), television and radio receivers, sound or video recording or video recording or reproducing apparatus and associated goods.**	**€ 235.59 billion (equipment covered by LVD)** **€ 200.12 billion (equipment covered by EMC)**	**Negative trade balance:** **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** **Most imports come from China, followed at a considerable distance by the USA, Japan and South Korea.**	**The structure of the industry is characterised by a few large corporations producing a wide range of electrical equipment, and many small companies specialised in niche markets.**	**148 (LVD)** **131 (EMC)**
ATEX	**Mechanical, electrical and telecommunication equipment, protective systems and devices, to**	**€ 2.2 billion**	**Positive trade balance: Imports amount to € 400 million. Internal consumption estimated**	**The ATEX sector is characterised by a large number of SME and micro enterprises,**	**55**

[22] NANDO database on 3 January 2011 http://ec.europa.eu/enterprise/newapproach/nando/

	be used in potentially explosive atmospheres (in underground mines, petrochemical plants, oil refineries, filling stations and other places where flammable gases may be present, and also premises like flour mills and agricultural warehouses where airborne dust can present an hazard): mechanical gears, brakes and seals; gas and steam turbines; electrical motors, pumps, fans; electrical tools and instrumentation; fork lift trucks; filter units and vented silo bins; switches, control and detection systems and components; torches; plugs and sockets outlets; heating cables; computers, phones and other similar equipment; vent panels; enclosures; sparks arrestors; temperature protective devices; etc.		**at € 1.9 billion, 86% of internal production.**	**around 90%, mainly based in France, Germany, Italy and the United Kingdom, but also with significant presences and market shares in Denmark, the Netherlands, Norway, Poland, Spain, Sweden as well as in Switzerland.**	
Pressure Equipment (incl simple pressure vessels)	**Pressure vessels, piping, boilers, steam generator, safety accessories and pressure accessories, etc…**	**No data available (see Annex 10.2)**	**Manufacturing of pressure equipment is gradually shifting to low cost countries.**	**A substantial number of SME is involved in production**	**237[23]** **95 (simple pressure vessels)**
NAWI	**Non-automatic weighing instruments, i.e. measuring**	**€ 2.5 billion**	**Not available**	**Small companies (< 50 employees) clearly dominate**	**270**

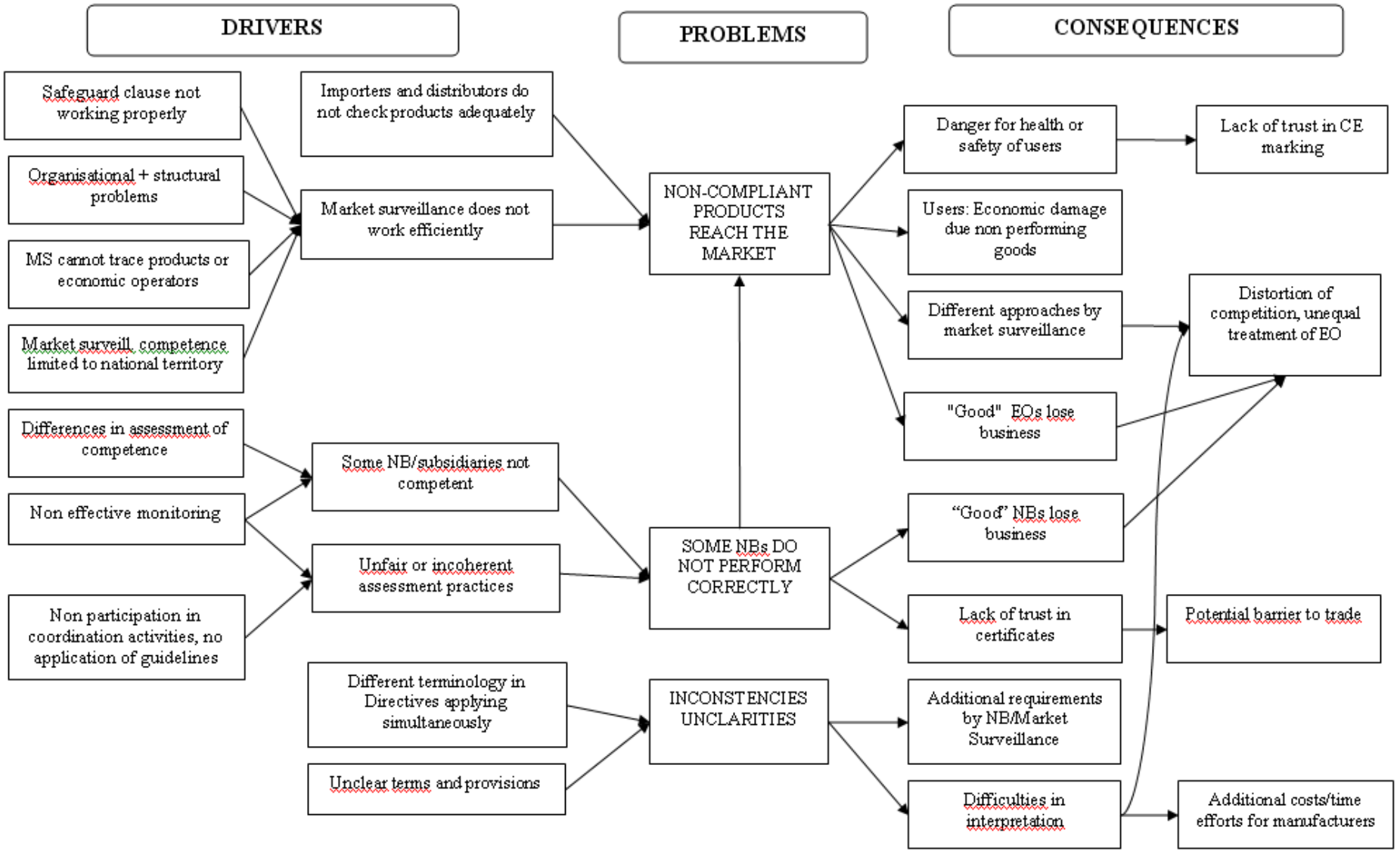
[23] This figure includes recognised third party organisations and user inspectorates.

	instruments serving to determine the mass of a body and requiring the intervention of an operator during weighing			**with 60%. 35% are medium sized enterprises with 50-250 employees and 4% are large companies with more than 250 employees-**	
Measuring Instruments	**Water meters, gas meters, electricity meters, heat meters, meters for liquids other than water, weighing machines, taximeters, material measures to measure length, dimensional measuring instruments and exhaust gas analysers.**	**€ 3.25 billion**	**Around 20-25% of measuring instruments in the EU27 are imported**	**There are around 900 manufacturers active in the 10 sectors covered by the MID not including the large number of SMEs operating as distributors, importers or providers of repair services.**	**140**
Lifts	**Lifts permanently serving buildings and constructions intended for the transport of persons, persons and goods or goods alone if the car is accessible as well as safety components for use in such lifts**	**€ 3.17 billion**	**Very positive trade balance: € 36 million of imports and € 693 million of exports.** **Internal consumption: € 2.51 billion**	**The structure of the industry is characterised by four multinational lifts companies and many small companies specialised. designing and installing new lifts and producing safety components for this lifts**	**192**
Civil Explosives	**Explosive substances and articles which are not used by the armed forces or the police, but commercially. The main end-users of civil explosives are the mining industry, the quarrying industry, and the construction and civil engineering industry (primarily for demolition, land clearance and tunnelling)**	**€ 1.35 billion.**	**Trade with third countries is limited. Imports play a significant role only in niche markets like explosives used for offshore drilling operations. Important trading partners are Norway, Switzerland and the USA. Importers in the EU are generally large companies with specific demands, for example**	**20 manufacturers of explosives and approximately 500 distributors are active in the EU. At manufacturers' level, there are no SME: Around 4 000 people are directly employed by these companies. Nearly all of the distributors, on the other hand, are SME employing around 5 000 people. Thus, a**	**13**

			in the oil drilling industry.	**total of 9 000 people are employed by the civil explosives industry.**	
Pyrotechnic articles	**Fireworks, theatrical pyrotechnic articles, pyrotechnic articles for technical purposes and automotive pyrotechnic articles (automotive restraint systems, i.e. most importantly gas generators used in airbags and seatbelt tensioners).**	**€ 1.4 billion (fireworks)** **€ 2.8 billion (automotive)**	**95% of all consumer fireworks are manufactured overseas.**	**Fireworks industry: mainly SME; altogether employing in total an estimated 15 000 to 20 000 people.** **Automotive pyrotechnic articles: big international automotive supplier companies, around 40 000 employees.**	**10**

3. PROBLEM DESCRIPTION

The consultations have identified three main problems with regard to the functioning of the current legislation: (1) non-compliance of significant number of products that reach the market, (2) unsatisfactory performance of certain Notified bodies and (3) complexity of the current legislation. Those have been analysed in a more horizontal context in the impact assessment for the New Legislative Framework. The problem tree below illustrates the drivers and the consequences of the abovementioned problems, which are discussed in more detail further in this chapter.


DRIVERS
PROBLEMS
CONSEQUENCES
Safeguard clause not working properly
Organisational + structural problems
MS cannot trace products or economic operators
Market surveill. competence limited to national territory
Importers and distributors do not check products adequately
Market surveillance does not work efficiently
Differences in assessment of competence
Non effective monitoring
Non participation in coordination activities, no application of guidelines
Some NB/subsidiaries not competent
Unfair or incoherent assessment practices
Different terminology in Directives applying simultaneously
Unclear terms and provisions
NON-COMPLIANT PRODUCTS REACH THE MARKET
SOME NBs DO NOT PERFORM CORRECTLY
INCONSTENCIES UNCLARITIES
Danger for health or safety of users
Users: Economic damage due non performing goods
Different approaches by market surveillance
"Good" EOs lose business
"Good" NBs lose business
Lack of trust in certificates
Additional requirements by NB/Market Surveillance
Difficulties in interpretation
Lack of trust in CE marking
Distortion of competition, unequal treatment of EO
Potential barrier to trade
Additional costs/time efforts for manufacturers

3.1. Products which do not comply with the requirements

3.1.1. The problem that requires action and its underlying drivers

The directives concerned by this initiative have set up strict 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). These requirements apply to all products placed on the EU market, i.e. to products manufactured inside the EU as well as products imported into the EU.

Nevertheless not all products on the market comply with these requirements. Non-compliance can take different forms ranging from simple formal non-compliance to substantial non-compliance with essential health and safety requirements. Examples of non-compliance with formal requirements are missing documents, missing or wrongly affixed markings or missing labelling as well as non-compliance with procedural requirements (e.g. application of wrong conformity assessment procedure) while the product itself nevertheless complies with the requirements relating to its design and production. Substantial non-compliance means that there is a deficiency in the design or construction of the product itself. The product does not attain the performance level laid down in the relevant essential requirement.

If the product fails to meet an essential health and safety requirement it can be potentially dangerous for its users. The risks relating to substantial non-compliance vary in accordance with the nature of the product.

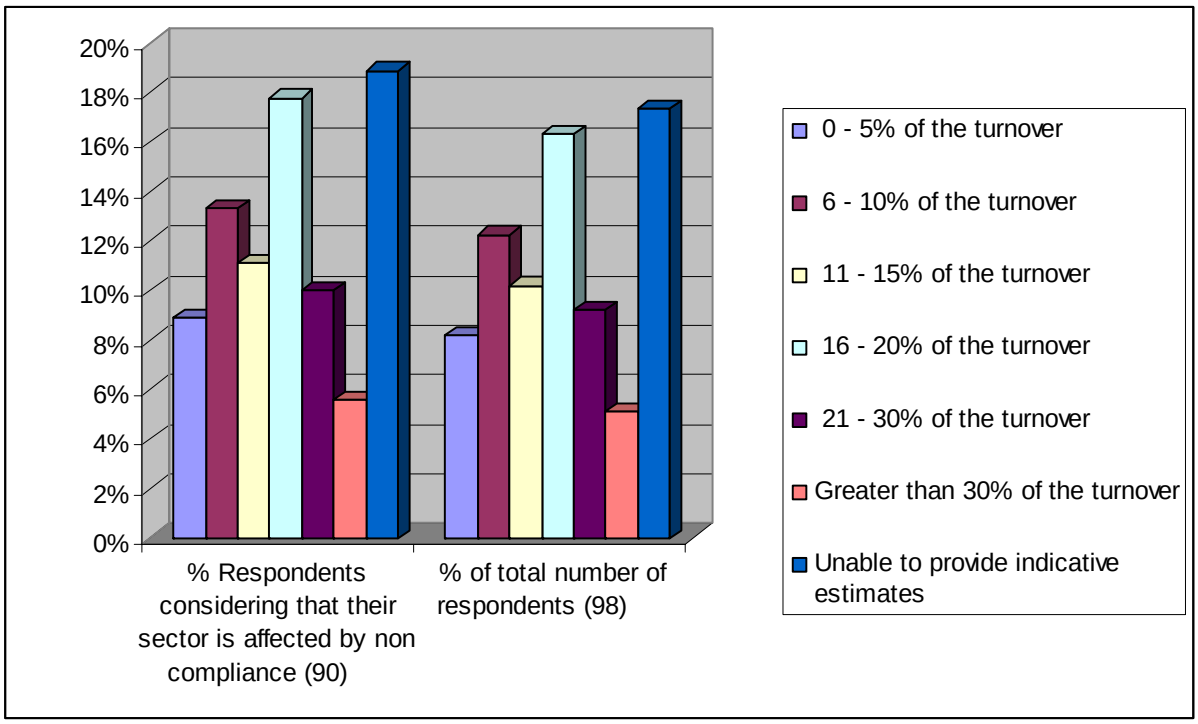
Defective electronic products can present a risk of electric shock or burns. Defective fireworks, e.g. fireworks which ignite prematurely, can lead to ear damage caused by excessive sound levels, severe burns and eye injuries, and in some cases even death. Non-compliance of equipment used in potentially explosive atmospheres or pressure can have even catastrophic effects. Consequences of this kind of explosion include severe or deadly injuries to persons, serious damage to installations and surrounding civil and industrial infrastructures. Non compliance of measuring instruments can lead to wrong measuring results which can cause economic damage for end-users (e.g. electricity or water meters). Further details on the risks associated with the products covered by the directives are provided in Annex 2 (see detailed sector descriptions in section 10).

According to available data the number of accidents is however relatively low in relation to the number of products on the market. On a general note it has to be mentioned that it is often difficult to determine on the basis of the information available whether accidents are due to the malfunctioning of a product or to misuse by the user. There is no Europe-wide database on accidents involving products and knowledge depends on national statistics, information collected from hospitals etc;

Apart from posing risks to users, non-compliance (both formal and substantial) has important economic consequences: It leads to unfair competition. Operators not adhering to the rules can make significant savings on compliance costs by, for

example, avoiding costly conformity assessment procedures. They can consequently offer their products at lower prices than their competitors who respect the law.[24] In sectors where there is tough competition from imported low-price products, European industry is disadvantaged. The situation "punishes" the law-abiding manufacturer, as compliance becomes a "competitive disadvantage". 87% of economic operators responding to the public consultation consider that they suffer from unfair competition due to this situation. Economic operators have also provided estimates of the size of their losses in terms of their annual turnover, reproduced below:

Figure 1: Perceived losses in % of annual turnover



Since much non-compliance often passes unnoticed, the share of non-compliant products on the market cannot be quantified. It is also impossible to provide a solid estimate, in particular as regards heterogeneous sectors like electrical equipment, pressure equipment or measuring instruments. Data availability also varies from sector to sector.[25] The figures reported hereafter illustrate the problem, but they do not allow conclusions to be drawn on the actual share of non-compliant products on the market per sector.

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[24] Quote from reply obtained in the 2006 public consultation on the NLF: "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."

[25] Data availability depends to an important extent on the level of activity of market surveillance authorities. Market surveillance is carried out on a risk based approach and hence focuses on sensitive product categories (e.g. consumer products). In some sectors industry associations are very active in that area and sometimes even carry out their own investigations. This explains why in certain sectors there is more information available than in others.

The problem of non-compliance is generally perceived in all sectors concerned. 92% of economic operators reacting to the public consultation consider that their sector is affected by non compliance. General findings across all sectors are that many non-compliant products are imported[26] and that many non-compliant products are counterfeit.

Most data on non-compliance is available in the electro-technical sector. It is also the sector in which stakeholders and in particular industry associations have been most active in pointing to the problem.[27] The LVD market surveillance authorities have undertaken three cross border actions, on portable household lights[28], cord extension sets[29] and Christmas lighting[30]. Only 5% of the household lights tested showed no shortcomings (either administrative or technical). Whilst not causing immediate danger to consumers, the shortcomings were considered serious enough to require remedies. Only one in six cord extension sets fully complied with the requirements. 58% of the cord extension sets tested were considered sufficiently unsafe by the authorities to justify a sales ban. Similar findings were obtained in three market surveillance campaigns carried out by the EMC Administrative Cooperation group (ADCO) recently, which focused on Energy Saving Lamps[31], Power Tools[32] and Consumer Entertainment Electronic Products[33]. The results of these campaigns showed that the level of technical non-compliance was 23% for the Energy Saving Lamps, 20% for the Power Tools and 50% for the Consumer Entertainment Electronic Products. Further general conclusions drawn from the campaigns were that the share of non-compliant imported products was generally higher than the share of non-compliant products originating from EU countries, and that for a considerable part of non-compliant products the origin could not be determined.

In other sectors, in particular for products for professional use, information on cases of non-compliance is based on feedback from stakeholders and authorities, reports from ADCO groups and notified body groups.[34] It appears that the problem is less felt in specialised sectors like ATEX or civil explosives sector, although a few cases of non-compliance have been reported.

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26 This is also confirmed by the number of RAPEX notifications. 73% of all notifications in 2009 concerned imported products, as opposed to 20% of products originating from EU Member States. See "Keeping European Consumers Safe", 2009 Annual Report on the operation of RAPEX, p.21 available at http://ec.europa.eu/consumers/safety/rapex/docs/2009_rapex_report_en.pdf.

27 See e.g. ORGALIME position paper Call for an effective pan-European market surveillance system http://www.orgalime.org/Pdf/PP_Orgalime-ANEC_on%20market%20surveillance_apr09.pdf

28 See http://europa.eu/rapid/pressReleasesAction.do?reference=IP/08/615&format=HTML&aged=0&language=EN

29 See http://ec.europa.eu/enterprise/sectors/electrical/files/lvd-adco/20080903_lvd_adco_-_final_report_-_extension_leads_-_2007_project_en.pdf

30 See http://ec.europa.eu/enterprise/sectors/electrical/files/lv/report_luminaires_en.pdf

31 See Report on campaign concerning Energy Saving Lamps available at http://ec.europa.eu/enterprise/sectors/electrical/files/emc/ms-campaign-first_en.pdf

32 See Report on campaign concerning power tools http://ec.europa.eu/enterprise/sectors/electrical/files/emc/ms-campaign-second_en.pdf

33 Report on campaign concerning Consumer Entertainment Products available at http://ec.europa.eu/enterprise/sectors/electrical/files/emc/ms-campaign-third_en.pdf

34 Products for professional users (ATEX products, civil explosives and the majority of pressure equipment) as well as measuring instruments and lifts have only started being recorded in RAPEX since 1 January 2010.

Table 2: Percentage of respondents to the public consultation considering that their sector is affected by non-compliance

	Electro-technical	ATEX	Civil explosives	Pyrotechnic articles	Lifts	Measuring instruments	Pressure equipment	Total
Economic Operators	96%	75%	-	0% (100% don't know)	88%	94%	83%	92%
Authorities	86%	64%	0% (50% don't know or No)	78%	55%	52%	80%	66%
Notified B	94%	44%	25%	50% (50% don't know)	44% (55% No)	31% (40% don't know)	65%	60%
Users	100%	25% (75% don't know)	-	0% (50% don't know or No)	100%	67%	82%	64%
SMEs	53%	44%	12,5%	0% (50% don't know or No)	35% (40% No)	41%	49%	48%

A major reason for the considerable number of non compliant products on the market is that market surveillance does not operate effectively in the European Union. There is a widely shared perception amongst stakeholders that market surveillance is not sufficiently active and rigorous. This view corresponds to the findings of the studies concerning the measuring instruments directive and the lifts directive:

"For measuring instruments under Directive 2004/22/EC, the poor quality of market surveillance is one of the important concerns of industry and it is an area where most authorities recognise that their effort until recently has been partial. Most authorities concentrate on checking whether the CE+M mark is properly affixed and that the necessary paperwork is conducted while in some countries even these typical tests are not properly conducted on a periodical basis. Only in few countries have there been actual tests of the conformity of the products placed in the market usually on the basis of annual surveillance programmes focusing on specific categories of measuring instruments. The absence of proper surveillance appears to be the main reason for almost all occasions of unfair competition reported." [35]

The study "Evaluation of the Application of the Lift Directive (95/16/EC)"[36] concluded that market surveillance in the lifts sector was often limited to reactive

[35] See CSES evaluation, p. 47 http://ec.europa.eu/enterprise/sectors/legal-metrology-and-prepack/public-consultation/public-consultation-files/evaluation_report_by_cses_en.pdf

[36] See footnote 2.

surveillance, and many stakeholders were uninformed and even unaware of market surveillance activities in their countries. It was recommended that market surveillance be improved.

The organisational and structural reasons for the deficiencies in market surveillance were highlighted in section 2.2.1 of the impact assessment on the NLF. The ineffectiveness of market surveillance is however also rooted in certain practical obstacles.

One major difficulty for the authorities is the lack of traceability of non-compliant products and the operators who have supplied them, in particular when the products originate in third countries. When authorities have doubts about the conformity of a product they need specific information allowing them to evaluate its compliance with the legislation. This information is usually in the hands of the manufacturer. While most of the directives require that the name of the manufacturer appear on the product, it often proves difficult to identify and contact manufacturers based in third countries (delays in time, no contact details, no voluntary cooperation, competence of authorities limited to the EU, etc)[37] In many instances the origin of the product cannot be identified at all. For these reasons, the authorities need to be able to get back to the person who placed the product on the EU market, i.e. the importer. However there is currently no obligation to identify the importer on a product. There is also no requirement which would allow the authorities to track a product throughout the distribution chain, identify the actors involved and stop further supplies of potentially dangerous products.[38] Only for civil explosives has a particular traceability regime been set up by Commission Directive 2008/43[39], ensuring the traceability of every individual product. It will become applicable on 5 April 2012.

A further reason for the presence of non-compliant products on the market is that operators further down the supply and distribution chain, namely importers and distributors are not carrying 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 latter has actually carried out this task properly. Some of them are also not aware of the applicable legislation and, as regards importers, fail to verify whether a product is actually intended to be sold on the EU market. The directives only contain obligations for the manufacturers but do not address the other economic operators. [40]

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37 A foreign manufacturer has the possibility to establish an authorised representative in the EU who inter alia acts as the contact point with EU authorities. This is however not obligatory. In practice mainly big companies with well known brand names have appointed an authorised representative.

38 The problem of traceability and the high share of imported products was one of the main conclusions drawn from the market surveillance campaigns carried out by the LVD and EMC ADCOs. See footnotes 28 and 30.

39 See http://ec.europa.eu/enterprise/sectors/chemicals/documents/specific-chemicals/explosives/index_en.htm

40 The pyrotechnic articles directive is an exception, as it contains certain obligations for importers and distributors. . As regards consumer products the General Product Safety Directive has imposed a number of general obligations which also apply to consumer products covered by the directives in question. Furthermore the Blue Guide contains a section that gives some general guidance to importers and distributors which can be seen as best practice recommendations.

The absence of specific obligations for importers and distributors hampers the efficiency of market surveillance actions, in particular as regards imported products. The competence of market surveillance authorities is limited to the territories of the EU Member States. If a manufacturer established outside the EU does not cooperate with the European authorities by e.g. providing the necessary documentation or taking corrective action, the authorities have no legal means to enforce these measures upon the foreign manufacturer directly. In such a case they can only take effective action against the non-compliant products by addressing the importer or the distributor of these products.

Apart from that the absence of EU wide obligations for importers and distributors has led to Member States imposing differing obligations on importers and distributors in their national laws. This contributes to market surveillance authorities in different Member States having different approaches to cases of non-compliance.Measures taken against the product concerned (withdrawal, marketing ban, etc..) have different levels of severity, and different measures in relation to demonstrating compliance are requested from importers and distributors. One example is the approach towards product information (declaration of conformity, safety information, user instructions, etc). First, not all of these documents are required by all directives and second, it is not always specified in the legislation which language has to be used. There have been a number of cases where national market surveillance authorities have requested translations into their national language. Economic operators and authorities reacting to the public consultation have confirmed the existence of different practices (see section 12.1.1 in Annex 4). Sometimes non-compliant products are withdrawn in one Member State but still circulate in the territory of another Member State. In principle the safeguard clause procedures provided for in all directives should avoid such differences in treatment. These procedures do however not work effectively[41].

To some extent the problem of non-compliance is also due to the fact that some notified bodies do not carry out proper conformity assessment. This is outlined in more detail as a separate problem in section 3.2.[42]

3.1.2. Who is affected and to what extent

Final users of the products: consumers, workers and professional users

– Risk of accidents and injury from products not meeting safety requirements

– Economic damage from non-performing products and the need to replace defective goods

41 For more details see section 2.24 of the impact assessment on the NLF.

42 For the sake of completeness it is also mentioned that certain weaknesses in the standardisation process sometimes lead to insufficient standards and consequently to non-compliant products As the standardisation system is currently undergoing a review which inter alia takes account of these weaknesses the issue is not further examined in this context. See http://ec.europa.eu/enterprise/policies/european-standards/standardisation-policy/policy-review/index_en.htm

Manufacturers, importers and distributors who abide to the law

– Losses in turnover and market share due to unfair competition from competitors not complying with the rules

– Different approaches by market surveillance authorities

National market surveillance authorities

– Inefficiencies, ineffective testing and investigation costs if operator cannot be found

SME

The results of the SME consultation show that non-compliance is also a problem for SME, although the number of SME considering themselves affected is lower than the number of respondents to the public consultation considering themselves affected by the problem. 54% of SME indicated that they suffer from unfair competition due to non-compliance (compared to 87% of economic operators reacting to the public consultation).

With regard to the economic damage suffered from this unfair competition, most SME (22%) could not give an estimate. 11% considered that their losses range between 6 to 10% of their annual turnover, 10% put their losses between 0 to 5% of their turnover as regards the product category most concerned by non compliance.

3.1.3. Predicted evolution of the problem

The NLF Regulation, which became applicable on 1 January 2010, should lead to a certain improvement of the current situation. It strengthened the obligations of Member States on market surveillance and provides for reinforced cooperation and information exchange on non compliant products. It also requires controls of imported products. Market surveillance should hence become more effective and more visible and deter those operators who have been encouraged by a perceived absence of market surveillance activities to cheat the system. However, even under the best functioning market surveillance system, authorities can only control a relatively limited amount of products on the market. Certain operators will still try their luck, given the economic savings they can achieve.

Regarding the lack of traceability, the situation will improve in the civil explosive sector due to introduction of the traceability regime of Commission Directive 2008/43[43]. In the other sectors the situation will remain the same. The NLF Regulation will also not improve the situation or the issue of unclear, missing or differing obligations for importers and distributors. Furthermore, although the NLF Regulation obliges market surveillance authorities to take restrictive action against non-compliant products and to inform the market surveillance authorities of other Member States about this action, it does not oblige them to take a uniform approach towards non-compliant products found.

[43] See http://ec.europa.eu/enterprise/sectors/chemicals/documents/specific-chemicals/explosives/index_en.htm

Currently the Commission is carrying out an information campaign on the CE marking which is specifically targeted at professionals.[44] It aims to improve the knowledge of importers and distributors in particular about the system behind the CE marking and their respective obligations. The campaign might lead to increased awareness among a certain number of economic operators who will subsequently pay more attention to checking the conformity of products which they are supplying. However it must be taken into the consideration that the campaign will most probably not reach all importers and distributors. Moreover, the campaign will not change the behaviour of economic operators who are consciously disregarding the rules behind the CE marking.

While the NLF Regulation and the CE marking campaign might lead to a certain improvement of the current situation, at the same time certain trends suggest a worsening of the problem. The continuous delocalisation of production towards third countries which is currently observed in many of the sectors concerned will make the tasks of market surveillance authorities more complex and difficult. This is also underpinned by the fact that the share of RAPEX notifications concerning imported products has been consistently growing since 2004.[45] The problems that market surveillance authorities are encountering with imported non-compliant products will therefore be likely to increase. Consequently they will need to rely increasingly on the information provided by importers and distributors. The lack of traceability in the supply and distribution chain will then become an even bigger problem. One exception is the civil explosives sector, where the new traceability regime applicable from April 2012 should lead to a significant improvement of the current situation.

3.2. Low quality of services delivered by certain Notified Bodies

3.2.1. The problem that requires action

Eight of the ten directives concerned require the certification of products by **"notified bodies"**[46] before they can be placed on the market.[47] Notified bodies hence play an important role in guaranteeing the safety of products on the market. Therefore, they must have the necessary competence and capacity to carry out their tasks correctly. Most notified bodies work in a thorough and responsible manner. However there have been problems with the quality of services delivered by some of them.[48] In the lifts sector for example, five complaints were introduced against notified bodies between 2009 and 2010. Some cases of incorrect issuing of certificates (e.g. for Category 3 equipment), leading to some market distortions, have

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44 For more information see http://ec.europa.eu/enterprise/policies/single-market-goods/cemarking/

45 See Annual reports on the operation of RAPEX, available at http://ec.europa.eu/consumers/safety/rapex/stats_reports_en.htm#annual.

46 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.

47 In the electro-technical sector the role of notified bodies is different. Under the Low Voltage Directive notified bodies are not involved in the conformity assessment, but only get involved if there is a challenge to the conformity of products. Under EMC Directive recourse to notified bodies in the conformity assessment procedure is voluntary and the purpose of the Body is to help the manufacturer by reviewing the technical documentation for apparatus.

48 68% of the notified bodies reacting to the public consultation confirmed that they are aware of problems with the quality of services provided in their sector. This assessment was shared by a high number of economic operators using notified bodies (84%) and by the majority of public authorities (53%).

been recorded by some Member States and the ATEX Notified Bodies Group (ExNBG). The ADCO group on pressure equipment has also raised a number of concerns relating to the work of certain notified bodies, in particular as regards activities carried out by subsidiaries or subcontractors based in third countries.

68% of notified bodies replying to the public consultation stated that there are problems with the quality of services of notified bodies. This view was shared by 84% of economic operators which use the services of notified bodies and 53% of public authorities.

There are basically two reasons behind the poor quality of work delivered by certain notified bodies: Some do not have the necessary competence to carry out assessments properly. This problem has in particular been observed with subsidiaries or subcontractors of European notified bodies located outside the EU. Others are laxer in their assessment or in the application of procedures which allows them to issue their certificates at significantly lower rates. For example, the elimination or reduction of on site controls or relaxed requirements as to the frequency of periodic audits/inspections can reduce the costs of assessments quite considerably.[49]

The study on the measuring instruments directive also identified concerns about the operation of notified bodies in the assessment of conformity and the overall certification procedure. On the one hand, important parts of the industry and the national authorities claim that notified bodies tend to use guidance documents as if they are regulations providing the only possible means of establishing conformity. Industry representatives referred to occasions when alternative approaches were rejected or considered unfavourably. This is seen as having a negative effect on the development of technological innovation although only a few specific examples were provided. On the other hand, notified bodies appear rather inconsistent in their operation with important variations in their capacity to carry out the necessary tests, especially those in the new Member States. They are also inconsistent in terms of the content of certificates issued and the use of evaluation certificates.[50]

Improper conformity assessment not only creates a risk of unsafe products reaching the market, but also distorts competition within the manufacturing industry and among notified bodies. Less rigorous assessment of product conformity means that the manufacturer can make savings on compliance and certification costs. Notified bodies performing diligent assessments frequently lose projects or clients to competitors taking less stringent approaches and/or offering their services at lower prices due to unfair practices.

3.2.2. Underlying drivers

The competence and performance of notified bodies is assessed by the Member State which notified them. The approach, rigour and regularity of such assessments however differs from one Member State to another. The directives set out basic criteria which bodies must meet in order to be notified (e.g. impartiality, technical know-how, objectivity etc). Some Member States apply these criteria more

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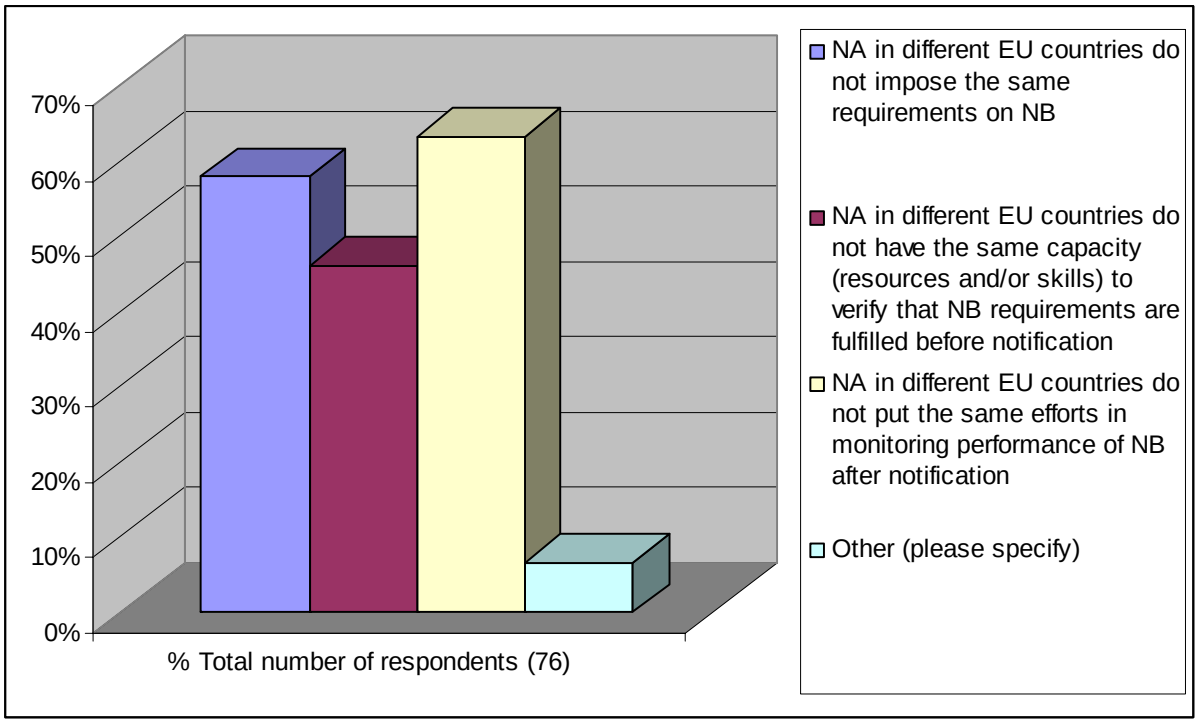
[49] For a more detailed analysis of this problem see Chapter 2.1.1 of the impact assessment on the NLF http://ec.europa.eu/governance/impact/ia_carried_out/docs/ia_2007/sec_2007_0173_en.pdf page 13

[50] CSES evaluation, p48

stringently than others which results in an uneven playing field for notified bodies. Some base their assessments on the relevant standards[51] in that area, while others do not. Some Member States organise designation, assessment and monitoring of notified bodies directly through their public administration, others use national accreditation[52]. Chapter 2.1.2 of the NLF impact assessment provides details of the divergent approaches of Member States.[53]

Notified bodies responding to the public consultation confirmed that there are marked differences in the assessment and monitoring of notified bodies.

Figure 2: Differences in the assessment and monitoring of notified bodies



Due to these differences, the way in which the competence of notified bodies has been assessed and how they are monitored is not transparent. The lifts sector is a good example of deficiencies in this context. In certain Member States a strikingly high number of notified bodies[54] does not correspond to the reality of the market in

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51 The application of the standards is voluntary. Where they are used, they give a presumption of conformity with the requirements laid down in the directives. It has to be noted here that only the more recent directives like the measuring instruments directive or the directive on pyrotechnic articles contain a set of requirements for notified bodies which corresponds to the state of the art. In the older directives the requirements are often rudimentary. The standards therefore go beyond what is strictly required by the directives.

52 Accreditation is a formal system which provides an independent and authoritative attestation of the competence, impartiality and integrity of conformity assessment bodies, thereby supporting the value and credibility of the work done and certificates issued.

53 SEC 2007(173) http://ec.europa.eu/governance/impact/ia_carried_out/docs/ia_2007/sec_2007_0173_en.pdf page 15

54 The number of notified bodies and their origin are available in the NANDO database : http://ec.europa.eu/enterprise/newapproach/nando/index.cfm?fuseaction=directive.notifiedbody&dir_id=16&type_dir=NO%20CPD&pro_id=99999&prc_id=99999&ann_id=99999&prc_anx=99999

conformity assessment services in that sector. It can be assumed that many of these bodies do not actually perform any conformity assessment activity under the lifts directive and therefore do not have the necessary competence to be notified.[55]

The situation is particularly problematic with regard to subsidiaries or subcontractors located outside the EU which carry out conformity assessment activities on behalf of a European notified body, as it is totally unclear how the competence of such bodies has been assessed.[56]

Apart from divergences in the assessment and monitoring of notified bodies, the different quality of conformity assessments is also due to insufficient coordination. In principle notified bodies should coordinate their work in the Notified Bodies groups set up under the directives. However not all notified bodies follow the work of these groups and implement their decisions. In the pressure equipment sector for instance, only 50 out of the 237 notified bodies participate in the regular meetings of the Conformity Assessment Bodies Forum PED/SPVD.[57] Some notified bodies never participate and do not have any national representation. It is questionable whether and how these notified bodies keep up to date with the PED Guidance documents and the the Conformity Assessment Bodies Forum Recommendations.

3.2.3. Who is affected and to what extent

Consumers or professional users of products:

– Conformity assessment that is improperly carried out entails the risk that unsafe products get to the market. See also chapter 3.1.

Manufacturing industry:

– Distortion of competition in the manufacturing industry. Less rigorous implementation of the procedures means that certificates can be issued at significantly lower rates. Less rigorous assessment of conformity with the legal requirements also allows manufacturers to make savings on compliance costs.

Notified bodies:

– Notified bodies performing properly rigorous conformity assessment services suffer from unfair competition.

– Different treatment due to different assessment and monitoring practices applied by Member States.

SME

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55 The issue was also raised in the 2004 study on the application of the lifts directive. It was furthermore subject of discussions in the lifts committee and in the Notified Bodies Group for lifts (NB-L).

56 This problem has been intensely discussed in the pressure equipment ADCO group and was also raised in other Working groups or Notified Bodies groups, e.g. in the ATEX sector.

57 Some Member States make notification conditional on participation in the meetings. For those Member States there is a good representation with national mirror groups.

According to the SME consultation 36% of SME using Notified Body services are aware of problems in that area while 44% are not. The most frequently indicated problems were mistakes in assessment, lack of competence, conflict of interests and poor quality of subcontractors.

3.2.4. Predicted evolution of the problem

A certain improvement of the situation can be expected from the NLF Regulation. It has introduced EU wide rules on the operation of accreditation and a peer evaluation system that should lead to an even quality of accreditation activities. It does not render accreditation obligatory; however it obliges Member States which do not use accreditation to demonstrate the competence of a body to provide the necessary evidence that the body has been assessed in an equivalent manner.

The NLF Regulation should lead to harmonisation of accreditation practices. Bodies which are accredited should hence have undergone a more or less similarly rigorous assessment of their competence. Consequently a certain improvement may be expected in relation to accredited notified bodies. Regarding notified bodies which are assessed according to different regimes, the problem will largely persist.

3.3. Complexity of the regulatory environment

3.3.1. The problem that requires action and its underlying drivers

The third problem to be tackled is the complexity and inconsistency of the existing regulatory environment for products. Today, products are often regulated by several legal instruments with different objectives (protection of health and safety, environmental protection, energy efficiency, etc)[58] Manufacturers must comply with all of their requirements. Multiple directives may apply simultaneously: For example, many measuring instruments must also comply with the Electromagnetic Compatibility directive. Certain pyrotechnic articles must also comply with the Low Voltage Directive or the Electromagnetic Compatibility Directive. Another example concerns lifts which must also to comply with requirements of the Machinery Directive.

Inconsistencies among the directives create additional costs for enterprises, partly due to increased effort spent analysing complex legislation, be this additional staff or working hours or the cost of external legal consultants. More important, however, are costs resulting from different procedures or different formal requirements, e.g. concerning the content of the Declaration of conformity. They must all be complied with and thus lead to additional compliance and conformity assessment costs.

The ten directives concerned by this initiative are based on the principles of the "New Approach" and use common elements like CE marking, conformity assessment procedures, notified bodies, certain definitions or safeguard clauses. However, the drafting of these common principles varies - sometimes significantly - from one directive to another.

[58] Concrete examples have been presented in the impact assessment for the NLF in chapter 2.4.1

The directives have evolved over time and gradually certain inconsistencies have crept in. They do not use the same terminology for concepts common to all of them. Procedures for demonstrating conformity also differ from one directive to another. Sometimes definitions or legal provisions are not sufficiently precise and allow divergent interpretations, leading to incompatibility, legal uncertainty and confusion.

Good examples of such inconsistencies are the terms "placing on the market" and "manufacturer" which are frequently used in all the directives concerned. Most of the directives do not define these terms. Where they do, the definitions vary, as can be seen in the table below:

Table 3: Examples of inconsistencies in definitions

•	"Placing on the market"	"Manufacturer"
Measuring instruments	**'Placing on the market' means making available for the first time in the Community an instrument intended for an end user, whether for reward or free of charge**	**'Manufacturer' means a natural or legal person responsible for the conformity of the measuring instrument with this Directive with a view to either placing it on the market under his own name and/or putting it into use for his own purposes**
Lifts	**Placing on the market of the lift shall occur when the installer first makes the lift available to the user**	**The 'manufacturer of the safety components' shall mean the natural or legal person who takes responsibility for the design and manufacture of the safety components and who affixes the CE marking and draws up the EC declaration of conformity**
Pyrotechnic articles	**'Placing on the market' means the first making available on the Community market of an individual product, with a view to its distribution and/or use, whether for payment or free of charge. Fireworks built by a manufacturer for his own use and which have been approved by a Member State for use on its territory are not to be considered as having been placed on the market.**	**'Manufacturer' means a natural or legal person who designs and/or manufactures a pyrotechnic article, or who causes such an article to be designed and manufactured, with a view to placing it on the market under his own name or trademark.**
Civil explosives	**'Placing on the market' shall mean any first disposal against payment or free of charge of explosives covered by this Directive with a view to their distribution and/or use on the**	**No definition**

Inconsistencies are not limited to the use of certain terms - they also concern entire provisions e.g. on the safeguard clause procedure. In the measuring instruments directive, the procedure can only be launched if non-compliance is of a systematic nature[59], i.e. when it affects a whole series of products. Under the low voltage directive[60] and the directive on pyrotechnic articles[61] the Commission only issues an opinion on the legitimacy of a national measure when other Member States have raised objections against that measure. Hence, different procedural steps must be followed, making it more difficult for national authorities to apply them.

Inconsistencies also affect conformity assessment procedures. In principle, conformity assessment in the directives is based on the set of standardised conformity assessment procedures ("modules") in Decision 93/465/EC[62]. However the directives have slightly modified these standard procedures. To some extent, sector-specific aspects (e.g. test methods) have been added to tailor the procedure to the sector. However, unnecessary differences in wording have given rise to interpretation questions.

3.3.2. Who is affected, how and to what extent?

- **Industry, business – manufacturers, importers and distributors**

– Difficulties in interpreting and correctly applying the legislation, additional effort in terms of time or additional costs for legal advice

- **National authorities implementing and enforcing the legislation**

– Difficulties in interpretation, extra work

- **Notified bodies and other conformity assessment bodies**

– Difficulties in interpretation, in particular as regards conformity assessment, additional procedural requirements

SME

The results of the SME consultation show that differences in the legislation are also a problem for SME: 67% of respondents must apply some of the directives concerned by this initiative simultaneously. For 40% this means that they have to apply different conformity assessment procedures and 18% said that this causes significant additional burdens for them. 13% consider the extra-burden insignificant. Compared to the results of the public consultation (21% significant burden, 43% some extra

59 See Article 19 of the Measuring instruments directive http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:2004L0022:20091201:en:PDF

60 See Article 9 of the Low Voltage Directive. http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2006:374:0010:0019:en:PDF

61 See Article 16 of the Directive o Pyrotechnic Articles http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2007:154:0001:0021:en:PDF

62 Decision 93/465 was the predecessor of Decision 768/2008 and contained a number of elements common to the New Approach. See section 1.2 of the impact assessment on the NLF.

burden) the figures are lower. This could be because SME often operate in specialised areas and on components and might be less affected than bigger manufacturers assembling complex products.

3.3.3. Predicted evolution of the problem

Given that legislation on products is growing rather than decreasing to reflect new societal concerns (environmental aspects, energy efficiency aspects) it is expected that the situation will either remain the same or (more probably) worsen.

3.4. EU right to act

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. This legislation does however not address the identified problems effectively or, as regards the inconsistency problem, is even at the source of the problem. National divergent national approaches to deal with the problems have led to a different treatment of economic operators. If actions are taken at national level to address the problems, this risks creating obstacles to the free movement of goods ensured by the directives concerned. Hence it is more appropriate to take action at EU level.

As regards the problem of inconsistencies throughout the directives, this is a problem which can only be solved by the EU legislator.

4. OBJECTIVES

4.1. General policy 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 guaranteeing a high level of protection. The second is to improve the functioning of the internal market. Thirdly, the initiative aims to simplify the regulatory environment for products.

4.2. Specific and operational policy objectives

GENERAL	SPECIFIC	OPERATIONAL
Ensure a high level of protection of public interests, in particular public health and safety and consumer protection	**Reduce the number of non-compliant products, in particular unsafe products**	**Ensure traceability of products**
	Improve market surveillance mechanisms and tools	**Ensure controls on product conformity throughout the whole supply and distribution chain**
	Ensure the reliability and high quality of conformity assessment activities carried out by notified bodies	**Provide market surveillance authorities with an effective cooperation mechanism to ensure a common approach to non compliant products**
		Specify common criteria for the assessment, monitoring and control of NB to be applied equally throughout the EU
Ensure the proper functioning of the internal market in the sectors concerned	**Ensure equal treatment of non-compliant products throughout the EU market and equal treatment of economic operators in the enforcement process**	**Provide market surveillance authorities with an effective cooperation mechanism to ensure a common approach to non compliant products**
	Ensure equal conditions regarding the assessment and monitoring of notified bodies	**Specify common criteria for the assessment, monitoring and control of NBs to be applied equally throughout the EU**
	Ensure consistency of conformity assessment services carried out by notified bodies	**Ensure coordinated approach of notified bodies to conformity assessment**
Simplify the regulatory environment	**Facilitate interpretation and implementation**	**Clarify unclear terms and provisions in the directives**
	Ensure more consistency of terminology and procedural requirements throughout the directives	**Eliminate unnecessary differences in terminology**

4.3. Consistency with other policies and objectives

This initiative is in line with the Commission's policy on the Single Market (Single Market Act)[63] and Better Regulation policy.

5. OPTIONS

Due to the specific context of this initiative, explained in section 2, this impact assessment explores a limited set of options. The impact assessment for the NLF identified and analysed a number of policy options to address the problems set out in chapter 3 across various sectors. As a result of this analysis, the NLF Decision was adopted, providing a set of policy measures considered to be the most adequate cross-sector solutions. Since the objective of this impact assessment is to ascertain whether the directives concerned should make use of these measures, the options examine whether to align them with the NLF Decision and, if so, how.

5.1. No policy change

Option 1 is to leave the existing situation unchanged. The horizontal elements of the directives would not be amended. Alignment with the new framework would only be contemplated when there was also a need to update sector-specific aspects of the directives (which is not envisaged for any of the directive concerned).

5.2. Alignment with the NLF Decision via non legislative measures

Option 2 consists of a set of non-regulatory instruments that encourage the voluntary application of all or part of the measures in the NLF Decision. Those measures could become the content of voluntary agreements which economic operators, national authorities and notified bodies agree to apply. The measures could also be presented as "best practice" in guidance documents. This could for example be done by developing current general guidance sections in the Blue Guide on economic operators or on notified bodies. The parties concerned would be encouraged to apply them. The measures in the NLF Decision are explained in detail under option 3.

In practice, this option would be a "voluntary" alignment to the NLF Decision.

5.3. Alignment with the NLF Decision via legislative measures

Under Option 3 the directives concerned take on board the solutions set out in the NLF Decision to address problems relating to non-compliance, quality of notified bodies and inconsistency in the legal framework. The measures in the Decision designed to resolve these problems are as follows:[64]

Measures intended to address the problem of non-compliance:

- Introduction of **obligations for importers and distributors:** Both must check that products bear the CE marking, are accompanied by the required documents

[63] See http://ec.europa.eu/internal_market/strategy/index_en.htm

[64] The description provides a complete list of all the measures foreseen in the Decision.

and carry the name of the manufacturer and the importer (if relevant). **Importers** must furthermore check that the manufacturer outside the EU has applied the correct conformity assessment procedure and establish a link to the manufacturer that allows the technical documentation to be obtained when it is requested by authorities. They must carry out sample tests on products which they have supplied, when this is appropriate in the light of the risks presented by a product to the health and safety of consumers. If necessary, they must also keep a register of complaints, non-conforming products and product recalls and keep distributors informed about such monitoring (Articles R4 and R5 in Annex 1 of the NLF Decision).

- Additional **manufacturer obligations**: In addition to the obligations that the current legislation already imposes on **manufacturers**, they must provide instructions and safety information in a language easily understood by consumers and end-users. Furthermore, they are subject to the same obligations on sample testing and product monitoring as importers (Article R3 in Annex 1 of the NLF Decision).

- Introduction of traceability requirements: New obligations are introduced for all economic operators to ensure **traceability** of products throughout the whole distribution chain. Manufacturers and importers must put their name and address on the product or, where this is not possible, on the packaging or an accompanying document. Furthermore every economic operator must be able to inform the authorities from whom he purchased a product and to whom he supplied it. This obligation does not include sales to end-users (Article R7 in Annex 1 of the NLF Decision).

- Reorganisation of **safeguard clause procedure (market surveillance)**: The safeguard clause procedure has been reorganised and streamlined. The new procedure ensures that the relevant enforcement authorities are informed about dangerous products and that similar action is taken against that product in all Member States (Articles R31-33 in Annex 1 of the NLF Decision).

Measures intended to ensure the quality of the work performed by notified bodies:

- **Reinforcement of the notification requirements** for notified bodies: To be authorised to carry out conformity assessment activities under the directives, notified bodies must satisfy certain requirements. These requirements have been reinforced and clarified. All notified bodies must follow the work of notified body coordination groups and apply guidance developed by them. They must have procedures in place which take due account of the size of the enterprise and the degree of the complexity of the prodcut assessed. Subcontractors and subsidiaries, which carry out parts of the conformity assessment, must also fulfil the notification criteria (Article R17 to R20 in Annex 1 of the NLF Decision).

- **Revised notification process**: Member States notifying a body must include information on the evaluation of competence of that body. Other Member States may object to the notification within a certain period. Where competence is demonstrated by an accreditation certificate, a facilitated procedure applies. Where Member States have not used accreditation to evaluate the body's

competence, documentary evidence must be provided and the objection period is longer (2 months) (Articles R22 and R23 in Annex 1 of the NLF Decision).

- **Requirements for notifying authorities** (i.e. the national authorities in charge of the assessment, notification and monitoring of notified bodies): Specific requirements and obligations for notifying authorities are introduced (Articles R14, R15 in Annex 1 of the NLF Decision), according to which they must be organised and operated so as to safeguard objectivity, impartiality and competence in carrying out their activity. Notifying authorities must de-notify bodies which no longer meet the notification requirements or fail to fulfil their obligations (Article R25 in Annex 1 of the NLF Decision).

- **Information and other obligations for notified bodies:** Notified bodies must inform notifying authorities about refusals, restrictions, suspensions and withdrawals of certificates and other notified bodies about negative conformity assessment results They must perform conformity assessment in a proportionate manner taking due account of the size of an enterprise, the structure of the sector, the complexity of the product technology, etc. (Article R28 in Annex 1 of the NLF Decision).

Measures intended to ensure more consistency among the directives

- **Alignment of** commonly used **definitions** and terminology: Definitions of common terms like “manufacturer”, “importer”, “placing on the market” set out in Article R2 of the NLF Decision are introduced into the directives concerned. Existing conflicting definitions are removed.

- **Alignment** of the texts and certain elements of **the conformity assessment procedures**: The existing text of the modules in the directives is aligned with the standard modules set out in Annex II to the NLF Decision.

6. IMPACTS

6.1. Overview of potential impacts and methodology for their assessment

The following impacts have been considered:

Economic impacts: functioning of the internal market, competitiveness of EU-firms, operating costs and administrative burdens, public authorities, consumers, households and other users, third countries and international relations.

Social impacts: public health and safety; impact on employment and labour markets excluded as no serious impacts expected, although indirect effects on employment can follow from the impact on competitiveness.

Environmental impacts: restriction of environmental unfriendly goods and prevention of fire, explosions and accidents leading to environmental risks.

Furthermore, the report will assess impacts in terms of simplification of the regulatory environment.

The assessment of impacts relies to a great extent on the results of stakeholder consultations. This is because, as explained in the option section, the NLF Decision already commits the Commission to aligning harmonisation legislation with the principles contained in the annexes to the NLF Decision itself unless departure is appropriate on account of sector specificities. Therefore, it was of the utmost importance to verify whether any such specificity emerged during the stakeholder consultations and whether this would lead to different impacts than those assessed prior to the adoption of the NLF.

For this reason, a very detailed consultation was carried out by drawing stakeholders' attention specifically to all measures contained in the NLF Decision (see section 5.3 above) and asking them to provide their views on the impacts expected in each sector.

Finally, since the content of options 2 and 3 is identical, the views of stakeholders as regards the appropriateness of introducing the specific measures are also identical, except for the difference in the enforceability of the measures under the two respective options.

6.2. Option 1: No policy change

In the assessment of the impacts of the no policy change option, the following development should be taken into account:

– The progressive implementation of the NLF Regulation will certainly play a positive role in relation to the problem of non-compliance by strengthening the powers of market surveillance authorities. It will also address the problem of underperformance of NB as the new system of accreditation functions by reference to binding rules and helps strengthen mutual confidence between MS

– However in the context of increasing globalisation and, in particular, as part of manufacturing activities in the relevant sectors shifts out of the EU, market surveillance and traceability of non-compliant products will become increasingly more difficult in practice.

– The ongoing information campaign on the EU rules underpinning the CE marking will increase stakeholders' awareness of their existing obligations under EU product legislation and foster their application.

6.2.1. Internal market

Current rules on the harmonisation of product requirements do not address all EO involved in the product supply chain. This causes an enforcement gap at the level of EU law and creates scope for differences between national laws as to obligations imposed on EO. It also introduces distortions in the treatment of different categories of operators (e.g. importers of products from third countries vs manufacturers based in the EU) in the internal market. The 'no policy change' option will not remedy the legislative gaps at EU level as regards the obligations of EO and so current divergences between national legislation as to the treatment of different EO will remain.

As regards conformity assessment services, the implementation of the NLF Regulation will also improve the uniformity of accreditation activities across MS and so have a positive impact on the internal market; however, it will not guarantee a uniform approach in the assessment of non accredited NB.

6.2.2. Competitiveness of EU-firms

EO in the single market consider themselves affected by unfair competition from non-compliant products[65].Under the no policy change option, a considerable boost to the competitiveness of compliant firms (regardless of their origin) will be provided by the implementation of the NLF Regulation. This is because the latter sets out clear obligations for MS to perform market surveillance activities and strengthens the powers of market surveillance authorities. The implementation of these aspects of the NLF Regulation will then lead to an increase in the number of physical and documentary checks of products made available in the internal market and therefore make it more likely that non-compliant products are taken off the market. Furthermore, increasing reliance on the new EU system of accreditation based on binding rules will help eliminate from the market unqualified or unscrupulous NB that do not assess the conformity of products according to the required procedures.

On the other hand, despite this intensification of enforcement efforts, as globalisation leads to manufacturing activities in many of these sectors (e.g. electrical and electronic goods, pressure equipment, pyrotechnic articles) moving far away from the geographical markets where products are ultimately sold, market surveillance will be increasingly hampered by the lack of general traceability obligations and insufficient clarity as to the responsibilities of importers and distributors (except for the civil explosives sector[66]).

All in all, while more market surveillance on the basis of the NLF Regulation will certainly help to reduce the number of non-compliant products and have a positive impact on all stakeholders affected, this does not appear sufficient to address all drivers of the non-compliance problem.

The possible benefit for firms producing compliant products could be quantified as a portion of the losses generated by unfair competition. According to participants to the consultation, this would range from a few percentage points up to more than 30% of annual turnover (see Figure 1: Perceived losses in % of annual turnover in section 3.1.1).

6.2.3. Operating costs and administrative burden

This option will not have any impact on operating costs and administrative burdens of EO.

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65 During the public consultation, almost 95% of EO said to be affected by the unfair competition of non-compliant products. They also mentioned that the competitive disadvantage suffered was of such an importance to affect their sales or market shares. EO provides estimates of % of turnover and market shares lost over last 5 years.

66 See section 3.1.3.

6.2.4. Public authorities

Thanks to the implementation of the NLF Regulation, under this option public authorities will benefit from a stronger regulatory framework for market surveillance that will progressively increase the effectiveness of national activities. This is because authorities will be able to rely on stronger cooperation across borders (e.g. by receiving information on investigations carried out in another MS and by requesting assistance from other MS authorities) and with custom authorities. The NLF Regulation also contains obligations to carry out an appropriate level of controls. Furthermore, the NLF Regulation has also significantly facilitated the task of public authorities related to the notification and monitoring of conformity assessment bodies using accreditation. For a detailed assessment, reference is made to the overall costs and benefits of the NLF[67].

6.2.5. Consumers, households and other users

Consumers and users in general suffer damage by unreliable and poor quality products. Indeed, the large majority of users (61%) having participated in the public consultation acknowledge that non-compliance is damaging them to some extent and estimate the seriousness of the damage as either significant (a third of them) or moderate (two thirds); only 3% consider that non-compliance does not negatively affect users.

Economic damage may cover the cost of replacing parts of faulty products, the cost of replacing the whole product and possible damage to other properties caused by the non-compliant good. Damage to health can also occur. This damage cannot be quantified in general terms because of the wide range of possible scenarios arising in each sector. However, specific examples of damage given in the consultation (mainly relating to professional goods) concerning electrical and electronic goods, pressure equipment, measuring instruments, lifts and equipment for use in potentially explosive atmospheres are illustrated in Annex 4 (see section 12.1.2.6).

Under this option consumers and users in general will benefit from the likely increase in the size and deterrent effect of market surveillance resulting from the implementation of the NLF Regulation. The benefits for users can be assumed to be equivalent to the expected reduction in the damage stemming from non-compliant and faulty products.

6.2.6. Third countries and international relations

This option does not affect specifically trade between the EU and third countries.

6.2.7. Public health and safety

The implementation of the NLF Regulation should lead to a reduction in the number of non-compliant products made available on the EU market and, in particular, products potentially dangerous to the health and safety of consumers (e.g. unsafe lifts, domestic appliances causing a risk of electrical shocks and burns), citizens in

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[67] See SEC 2007(173) http://ec.europa.eu/governance/impact/ia_carried_out/docs/ia_2007/sec_2007_0173_en.pdf

general (e.g. defective outdoor piping equipment leaking toxic or inflammable substances) and workers (e.g. pressure equipment causing accidents in the workplace, work equipment causing sparks in potentially explosive atmospheres). This impact is not always relevant to the measuring instruments sector whose legislation overall focuses on public interest other than health and safety protection, although specific categories of measuring instruments relate also to public health.

6.2.8. Environmental impacts

One of the 10 directives considered in this report, the pyrotechnic articles directive, includes among its objectives not only the protection of human health but also that of the environment, and contains a list of forbidden substances in the relevant standards (e.g. persistent organic pollutants). Moreover, the substances used in explosives and pyrotechnic articles also fall under Regulation 1907/2006 on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH). Since the NLF Regulation stengthens market surveillance it also helps in restricting the circulation of environmentally unfriendly pyrotechnic articles.

The other directives at stake do not specifically contain requirements that are meant to ensure the protection of environment. However, it can be assumed that the reduction of non-compliance for certain categories of products (namely civil explosives, equipment for use in potentially explosive atmospheres and big pressure equipment) will help in preventing the occurrence of fire, explosions, accidents and accidental emissions that could also create environmental risk.

6.2.9. Simplification of the regulatory environment

This option will have no impact on the simplification of the regulatory environment.

6.3. Option 2: Alignment via non-legislative measures

6.3.1. Internal Market

The non-legislative measures option may, by providing guidance on the responsibilities of the different categories of operators, contribute to some extent to creating a more level playing field among EO in the EU. Similarly, voluntary commitments by NB and notifying authorities to follow best practice in the area of conformity assessment activities may help establish common benchmarks across the EU also for non-accredited NB. Indeed, stakeholders have confirmed this view (see section 6.4.1).

Nevertheless, as this option does not allow authorities to take legal action against non responsible EO or NB, additional positive impacts on the internal market with respect to the no policy change option will entirely depend on the good will of stakeholders. In this respect, it is important to note that existing guidance contained in the so-called "Blue Guide"[68], which has been a reference guide for the implementation of directives for more than ten years, already points to the

[68] *Guide to the implementation of directives based on the New Approach and the Global Approach*, European Commission, September 1999. available at http://ec.europa.eu/enterprise/policies/single-market-goods/documents/blue-guide/index_en.htm

responsibilities of EO that are then clarified by the NLF Decision. However, as the Blue Guide is not enforceable, this has not been sufficient to address the issues identified. Furthermore, the NB requirements provided by the NLF Decision are already known to industry because they reflect existing (non-binding) ISO standards[69].

6.3.2. Competitiveness of EU-firms

By proposing best practices that go beyond current legal provisions applicable to EO and NB and improve current market surveillance procedures, this option may to some extent help prevent non-compliance, as also confirmed by stakeholders' (see section 6.4.2). However, the positive impact of non-legislative measures in terms of reducing the number of non-compliant products and defending the competiveness of compliant firms will entirely depend on the voluntary commitment of industry stakeholders. For instance, if EO do not voluntarily mark their names and contacts on products or do not provide upon request information on the origin of the goods traded, market surveillance authorities will be unable to trace dangerous products and stop their supply to the market. Furthermore, the competitiveness of compliant firms may be damaged if they incur additional costs to align their conduct with best practices while non-compliant firms don't.

6.3.3. Operating costs and administrative burdens

For those EO and NB that choose to act according to the best practice established via guidance, the option of non-legislative measures will have the same impact on operating costs and/or administrative burden as the alignment option (for details see section 6.4.3). These costs are overall considered by stakeholders to be moderate. On the other hand, it will have no impact on the costs of EO and NB that do not voluntarily align with best practice.

6.3.4. Public authorities

The voluntary commitment of EO to act responsibly at all levels of the supply chain (including imports and distribution) and to ensure traceability should somewhat facilitate the task of market surveillance authorities. Similarly NB voluntary commitment to follow stricter requirements and to provide information on their conformity assessment activities would be expected to help notifying authorities to monitor the quality of NB. Stakeholders have confirmed this view (see section 6.4.4). In both cases, however, the positive impact on public authorities will simply not materialise if the authorities cannot consistently rely on the cooperation of EO and NB. This is why the additional positive impact of this option by comparison with the no policy change option is expected to be rather limited. No specific additional costs or administrative burden have been identified for authorities.

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[69] The relevant standards 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, General requirements for the competence of testing and calibration laboratories.

6.3.5. Consumers, households and other users

By proposing best practices that go beyond current legal provisions applicable to EO and NB and improve current market surveillance procedures, this option may to some extent help prevent material damage to consumers and users in general. However this will entirely depend on the voluntary commitment of stakeholders in each sector. As EO and NB will only bear, if any, additional moderate compliance costs, option 2 is not expected to give rise to price increases for consumers/users.

6.3.6. Third countries and international relations

Better information on products originating from third countries will be possible only by relying on importers' voluntary commitment to act responsibly and ensure traceability. This will not constitute any new technical trade barrier. Responsible manufacturers and other trading parties located in third countries will not be adversely affected by these provisions. To the extent that importers act according to the guidance provided, there will be a positive impact in terms of increased transparency in the operations of EU, distributors at lower levels of the supply chain (downstream) which overall may even facilitate international trade. However the real impacts will entirely depend on the goodwill of stakeholders.

Non-legislative measures concerning NB and notification activities will have no impact on international relations as the recognition of third country conformity assessment bodies will still depend on mutual recognition agreements.

6.3.7. Public health and safety

The commitment of EO and NB to act according to proposed best practice, which go beyond the current provisions of the NLF Regulation, might in principle lead to a greater reduction of non-compliant products that may endanger the health and safety of consumers and workers in the EU (see stakeholders' view on the potential impact of the proposed measures in section 6.4.7). However, since this option does not allow authorities to enforce those practices, a stronger positive impact than under the no policy change scenario cannot be guaranteed.

6.3.8. Environmental impacts

The commitment of EO and NB to act according to proposed best practice, which goes beyond the current provisions of the NLF Regulation, might in principle lead to a greater reduction of environmentally unfriendly pyrotechnic articles or other products that might create environmental risks in case of fire, explosions and accidents. However, since this option does not allow authorities to enforce those practices, a stronger positive impact than under the no-policy change scenario cannot be guaranteed.

6.3.9. Simplification of the regulatory environment

This option will have no impact on the simplification of the regulatory environment. The problem of complexity and inconsistencies throughout the directives cannot be satisfactorily addressed by this option. Guidance documents can clarify unclear provisions but where the problems are rooted in differences in the legal provisions, guidance documents cannot prevail over these provisions.

6.4. Option 3: Alignment via legislative measures

6.4.1. Internal Market

Pursuant to alignment, the relevant product directives will include clear obligations applying to all EO throughout the EU and market surveillance procedures that will eliminate the current differences in national legislation and create a more level playing field among EO. Furthermore, the alignment of market surveillance (safeguard clause) procedures will ultimately lead to the adoption of equivalent measures across the EU in relation to products presenting a risk.

The results of the public consultation largely support the conclusion that the specification of EO obligations will have a positive impact on the internal market for all sectors. This view is shared by three quarters (65 to 77%) of EO and NB and two thirds (60 to 72%) of authorities that participated in the consultation. Furthermore, the majority of those who identified a positive impact evaluate the impact of the alignment of obligations and market surveillance procedures as significant. The detailed analysis of the results of the consultations is presented in the annex (see section 12.1.2.1 in Annex 4).

Pursuant to alignment, the relevant product directives will include stricter requirements that will constitute a common benchmark for the assessment of NB throughout the EU regardless of the country in which they are active and of the specific NB providing the service. Moreover, according to the revised notification process, the notifying authority in a given MS will be able to scrutinise and object to notifications put forward by another MS. Therefore NB will be subject to more transparent and more coherent assessment and this will strengthen the conditions for a level playing field.

The results of the public consultation largely support the conclusion that changes to NB requirements and notification process will have a positive impact on the internal market for all sectors. This view is shared by two thirds of EO, of NB and authorities that participated in the consultation. Furthermore, the majority of those who identified a positive impact evaluate the benefit of the reinforcement of the notification requirements as significant, while they evaluate the impact of revised procedures and information obligations as more moderate. More details on the findings can be found in Annex 4 (see section 12.2.1.1).

6.4.2. Competitiveness of EU-firms

By imposing clear obligations on EO and market surveillance procedures the alignment is expected to help reducing the number of non-compliant products. In particular, the introduction of traceability requirements for all operators will help the competent authorities to trace the non-compliant product and stop its circulation. Furthermore, the introduction of clear obligations for importers and distributors regarding product compliance will allow action at all levels of the supply chain. This action will then help defend the competiveness of compliant firms (regardless of their nationality) from unfair competition.

This conclusion is strongly supported by stakeholders of all sectors as about three quarters (73 to 76%) of EO and SME[70] participating in the public consultation believed this policy action would help defend the competiveness of EU business vis-à-vis unfair competition from non-compliant products. Furthermore, the majority of those who identified a positive impact evaluated the benefit of the clarifications of EO obligations and market surveillance procedures as significant. More details on the findings can be found in the annex (see section 12.1.2.2 in Annex 4).

The alignment will also introduce stricter requirements on NB and notification authorities and changes in the notification process that will allow the exclusion from the single market of those conformity assessment bodies that do not possess the necessary competence or whose evaluations are affected by a conflict of interests. The exclusion of the latter will both help reduce the scope for unfair competition amongst NB and help defend the competiveness of firms that have their products properly assessed.

This conclusion is strongly supported by stakeholders as 60-62% of EO participating in the public consultation believed this policy action would help defend the competiveness of EU business vis-à-vis unfair competition from non-compliant products. Furthermore, the majority of those who identified a positive impact evaluated the benefit of the reinforcement of notification requirements as significant, while they evaluated the benefit of revised procedures and information obligations as more moderate. More details on the findings can be found in the annex (see section 12.2.1.2 in Annex 4).

6.4.3. Operating costs and administrative burden

6.4.3.1. Costs and administrative burden for EO

The specification of obligations for manufacturers, importers and distributors and new market surveillance procedures in the relevant sector directives is not expected to increase the overall costs of economic operators. Most of the EO obligations in the NLF Decision codify what is normal practice for a responsible/compliant firm. It is no coincidence that some of the principles underlying those provisions are already presented in the "Blue Guide"[71].

This is particularly relevant for obligations on importers and distributors and for the cooperation between EO and market surveillance authorities. Therefore, while the alignment of sector directives will make these obligations formally enforceable, in principle it will not lead to additional adjustments for those operators that have been acting responsibly. On the other hand, the fact that EO which have not hitherto taken their responsibilities seriously will need to incur the necessary compliance costs, should be seen as a benefit (positive impact) of this policy action.

As regards traceability obligations for EO, some impact on operating costs and/or administrative burden is possible as manufacturers and importers must indicate on products their names, addresses and batches or serial numbers. However, the traceability obligations will be an administrative burden only if EO do not already

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[70] The percentage is slightly lower (62 to 68%) for post-marketing obligations.

[71] See footnote 68 above.

have a system in place as part of quality management controls or pursuant to legal obligations already in force. For instance, manufacturers are already obliged to indicate their names on products on the basis of current directives, while batches or serial numbers are normally used by EO for internal management reasons. Furthermore, the NLF Decision leaves EO free as to the choice of specific technical solution.

The views expressed by those who participated in the consultation (55% of general EO and 30-33% of SME) overall point to some, moderate impact on costs due to obligations for importers/distributors and traceability obligations.[72] Only 1-5% of EO and 12-15% of SME expect significant increases in costs.

As to post-marketing obligations on manufacturers, their possible impact on cost will be negligible as they involve few additional elements that relate to existing responsibilities. These obligations merely require the establishment – if not already put in place by the operator - of basic procedures for the quality control of marketed products (e.g. keep a register of complaints and defective products). 42% of general EO participating in the public consultation and 23% of SME attribute no or no significant cost increases to these elements. However 30% of SME expect a moderate increase in costs and 18% a significant increase.

The possibility of cost reductions due to these provisions should also be mentioned, since by clearly identifying the responsibilities of EO at different levels of the value chain, the provisions may help responsible operators to save costs previously incurred in insuring against unfair practices of suppliers or other traders, or additional testing of procured products. A small percentage of respondents (1-5% of EO and 4-6% of SME) also acknowledged that the alignment would lead to a reduction of costs (e.g. costs to gather information on the reliability of products supplied to them by importers or distributors; costs of insurance to cover risks due to non-compliant products)[73].

Specific concerns voiced by the electrical and electronic goods industry and by the NAWI sector of relate to the costs of translating technical documentation and preparing the declaration of conformity. It is then important to clarify that the alignment does not introduce an obligation to translate technical documentation[74]. As regards the declaration of conformity, this is normally a document of less than one page for which a template in all official languages is already provided in the Official

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72 SME appeared less concerned than general EO about these obligations as the possibility of cost increases is supported only by a relative majority of SME, while a third of them believe that these obligations will not imply new costs or burden.

73 A further reason for cost reductions should be mentioned for SME in the area of conformity assessment procedures. This is because the alignment of NB requirements will also allow NB to take into account the size of economic operators when performing conformity assessment (see Article R17 (6) (c) of the NLF Decision).

74 The relevant parts of technical documentation may need – but not systematically – to be made available to market surveillance authorities in their national language. Initially however the authority may be provided with only a summary of it. More detailed information will be requested in cases of serious doubt about the conformity of the products. Furthermore, if technical documentation is available in a language that the authority can understand, the latter will avoid asking for translations. See *Guide to the implementation of directives based on the New Approach and the Global Approach*, European Commission, September 1999, section 8.2, pages 49-50.

Journal of the EU, accessible via the website of the Commission[75]. Information to be included relates mainly to names, addresses and numerical references (product identification number, relevant directives and standards, etc.).

Only a minority of respondents (17% of general EO and 22% of SME) provided indicative estimates of the magnitude of cost increases expected as a result of all these provisions. The large majority of general EO (65%) and 40% of SME estimated the increase in cost at up to 5% of current operating costs, while a further 30% of SME provided estimates between 6% and 10%.

On the basis of this information, it is concluded that the burden of the measures proposed through the alignment will not be disproportionate either on general EO or on SME.

Furthermore, possible cost increases due to the alignment should be compared with the benefits of reducing non-compliance in the relevant sector. In this respect, it should be noted that 38% of EO[76] participating in the consultation considered those cost increases quite reasonable in relation to the objective of reducing non-compliance, while only 14% of respondents considered the increase unreasonable.

The detailed results of the consultation and the comparisons of perceived costs and benefits for both EO in general and SME can be found in Annex 4 (see sections 12.1.2.3 and 12.1.2.4).

6.4.3.2. Costs and administrative burdens for NB

The strengthening of NB requirements is not expected to lead to any additional operating costs and/or administrative burden on NB that act in accordance with recognised professional standards. Indeed, while the alignment will strengthen the wording of current directives, in practice the relevant benchmark for the assessment of conformity assessment bodies (both in the context of accreditation and the assessment carried out by notifying authorities) has been the relevant series within the EN 45000 and EN ISO/IEC17000 standards[77]. The latter, as attested by the European co-operation for Accreditation (EA), which pools together all EU accreditation bodies, already reflect the requirements included in the NLF Decision[78]. Indeed those standards have been the relevant benchmark for assessing the competence and independence of conformity assessment bodies for some time. Therefore, while the alignment of sector directives as regards those requirements will make them formally enforceable, it will not involve additional effort on the part of those conformity assessment bodies which were already complying with the spirit of the legislation. A moderate (temporary) increase in administrative burden of NB is expected since they will need to request new notification and produce updated evidence to show compliance with the requirements (e.g. accreditation and/or other

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75 http://ec.europa.eu/enterprise/policies/single-market-goods/regulatory-policies-common-rules-for-products/new-legislative-framework/index_en.htm

76 This question was not asked to SME to whom it was addressed a simplified questionnaire. SME however have clearly signalled that they expect benefits from the alignment.

77 See footnote 69 above.

78 EA-2/17- EA Guidance on the horizontal requirements for the accreditation of conformity assessment bodies for notification purposes, http://www.european-accreditation.org.

certificates showing professional qualifications); however, any re-notification of a properly assessed and monitored body should be a mere formality.

On the other hand, the costs of compliance efforts by those NB that, by thriving on enforcement difficulties did not previously meet the substantive requirements for conformity assessment, should be considered benefits (positive impact) of this policy action.

The Commission thought that the revision of the notification process would provide an incentive to NB to move towards accreditation and would thus lead to additional costs for them. The incentive was thought to derive from the fact that, although accreditation would not be made mandatory by alignment with the NLF Decision, notifications accompanied by an accreditation certificate will benefit from a facilitated notification procedure (shorter objection period). However, detailed analysis of the scope of accreditation actually shows that the large majority of NB has already chosen to be accredited regardless of the alignment. Currently, except for the Measuring Instruments Directive[79], the percentage of NB which are not formally accredited is relatively limited, ranging from 5 to 37% (see the table below). Thus, overall any move towards accreditation induced by alignment would – even in the most extreme scenario – involve no more than a third of NB in each sector. Furthermore, as regards the cost of accreditation, the EA stresses that conformity assessment bodies apply for accreditation the scope of which is considerably wider than that required for the NB activity. It follows that these cost are spread on a basis that is much wider and normally have a limited impact on the costs of specific services. Indicative estimates of accreditation fees are provided in Table 35: Accreditation fees charged by one European NAB in 2010 (EUR).

Table 4: Share of accredited/not accredited EU NB per sector

Directive	**Total EU NB**	**EU NB accredited?**	
		Yes	*No*
Pyrotechnic	10	7	3
%		70%	30%
Civil Explosives	13	9	4
%		69%	31%
EMC	131	95	36
%		73%	27%
LVD	148	119	29
%		80%	20%
ATEX	55	40	15
%		73%	27%
MID	140	32	108
%		23%	77%
NAWI	270	230	40
%		85%	15%
SPVD	95	90	5
%		95%	5%

[79] The lower rate of accreditation of NB under the Measuring Instrument Directive appear to be explained by the fact that a number of them are actually public authorities who did not consider necessary to require an accreditation certificate to demonstrate the fulfilment of legal requirements.

PED[80]		237	179	58
	%		76%	24%
Lifts		192	121	71
	%		63%	37%

Source: Commission estimates on the basis of information in the Nando (New Approach Notified and Designated Organisations) Information System (3 January 2011)

The introduction of information obligations is expected to lead to an additional – but overall negligible- administrative burden (i.e. basically the costs of transmitting the required information). This information will only be provided on an *ad hoc* basis as required by the nature of the information itself (i.e. information on refusals, restrictions, suspensions and withdrawals of certificates to be addressed to the notifying authority, and information on negative conformity assessment results to be addressed the other NB[81]). Furthermore, NB are free to choose the format of the transmission of information.

In conclusion, overall this policy option will not have a big impact on costs/administrative burden for NB. The impact of certain modifications to the notification process needs to be taken into account as it may push NB to incur accreditation costs. However possible cost increases in relation to the directive concerned should be regarded as limited. Furthermore, the costs will be more than outweighed by the benefits of the alignment, notably the legal basis necessary to enforce the NB requirements and to exclude underperforming NB from the single market.

The results of the public consultation overall support this assessment, as 34-46% of respondents considered there would be no or no significant increase in operating costs and/or administrative burden linked to this policy action or that the latter would generate savings, 32-37% of them expected a moderate increase and only 14-24% expected a significant increase in operating costs and/or administrative burden. Information obligations represent the category raising the least concern.

Furthermore, as regards the specific reasons for cost increases, while the majority of respondents did not provide any indication, 30% indicated accreditation (nevertheless, the public consultation did not allow meaningful estimates of cost increases expected due to accreditation to be collected since only a few stakeholders provided figures). One or two respondents pointed to an increase in costs for the employment or contracting of qualified personnel. However this would only increase existing costs of NB, if they do not already employ qualified personnel.

Finally 37% of NB participating in the consultation considered that the possible cost increase is reasonable in relation to the objective of enhancing the quality of the conformity assessment services provided. Only 16% of NB considered the increase unreasonable, while the remaining stakeholders did not express a view.

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80 These figures include also conformity assessment bodies that are specific to the Pressure Equipment Directive (i.e. Recognised Third Parties Organisations and User Inspectorates).

81 This latter exchange can take place in the context of notified bodies groups (see Article R30 of the NLF Decision).

The detailed results of the consultation can be found in the annex (see section 12.2.1.3 in Annex 4).

6.4.4. Public authorities

The measures concerning clear obligations for all EO and clearer market surveillance procedures are expected to substantially increase the effectiveness of public authorities' enforcement activities, while they are not expected in general to have budgetary consequences.

In particular the additional obligations for EO will make it easier for market surveillance authorities to obtain documentation and information from importers and distributors and to trace non-compliant products, including those imported from third countries. The EO obligations will not lead to additional costs or administrative burden for authorities. They may even reduce authorities' investigation costs (e.g. the traceability obligation will facilitate the identification of EO having marketed non-compliant products).

As regards the common safeguard procedure, if compared to the current legal texts the new procedure contains a much more detailed description of the steps that the authorities have to take to deal with products presenting a risk. These are, however, not new tasks for market surveillance authorities but part of their daily work under the current situation. While the NLF Regulation establishes specific tools for the exchange of information among national authorities, the procedure laid down in the NLF Decision specifies when the relevant information should be exchanged in order to be useful for cross-border authorities[82]. : this will allow surveillance authorities to work more efficiently, as efforts already undertaken by the authorities in one MS will not need to be duplicated. Furthermore it will allow authorities to take coordinated action in cases of non-compliant products marketed in more than one MS. The NLF Decision also clarifies and streamlines the procedure according to which in certain cases the Commission is called on to express its view on the measures adopted by MS so that ultimately a uniform approach has to be followed by all national authorities.

The appropriateness of the alignment in this regard is acknowledged by the majority of stakeholders that participated in the public consultations (i.e. between 67% and 71% of EO, between 66% and 83% of NB, between 57% and 71% of authorities and between 73% and 80% of users). As regards the extent to which the alignment may improve the current situation, the majority of EO who identified a positive improvement evaluated the contribution made by traceability obligations as significant, while they evaluated the contribution made by the other measures as more moderate; the views of authorities are more or less equally shared between significant and moderate impact; in general the majority of NB and users considered the impact significant. For more details see section 12.1.2.4 in Annex 4.

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82 For instance a first exchange of information should take place after the authorities have checked the product, have found it not compliant and have asked the relevant economic operator to take action to bring the product into conformity and to restrict the marketing of the product. A second exchange of information, if necessary, will take place after inaction of the economic operator and the adoption of compulsory restrictive measures by the authority.

The reinforced notification requirements for conformity assessment bodies, the revised notification procedures, and the information obligations on NB are expected to increase the effectiveness of the controls carried out by notifying authorities. In particular, the alignment of sector directives with the NLF Decision will provide national authorities with the legal basis necessary to enforce the NB requirements and to exclude underperforming conformity assessment bodies from the single market.

The appropriateness of the alignment in this regard is acknowledged by the majority of stakeholders who participated in the public and SME consultations (i.e. between 62% and 83% of EO, between 60% and 84% of NB[83], between 65% and 72% of authorities, between 46% and 51% of SME). As regards the extent to which the alignment may improve the current situation, the majority of EO, SME and authorities who identified a positive improvement evaluated the contribution made by the reinforcement of the notification requirements as significant, while they evaluated the contribution made by revised procedures and information obligations as more moderate. The NB considered the improvement moderate for each of the three measures. For more details see section 12.2.1.4 in Annex 4.

On the other hand, laying down formally the criteria for NB will trigger a need for public authorities to re-notify existing NB. However, re-notification work will be more or less a formality for NB that are already accredited or whose requirements have in any case already been assessed by the notifying authority against the relevant EN 45000 and EN ISO/IEC17000 standards. Furthermore, bearing in mind the total number of NB per sector, the maximum average number of re-notifications to be handled by a single authority appears limited. Indeed the analysis of the Commission shows (see Table 42: Number of NB per Member States and per relevant directive in the annex) that for the large majority of MS and directives the estimated number of re-notifications necessary is very small and often negligible. Germany, Italy, Poland and UK may be faced with bigger - but overall very reasonable - numbers (e.g. from 35 to 50) in a couple of sectors. Only Italy and the UK may be faced in one sector (non-automatic weighting instruments) with a sizeable number of re-notifications (respectively 106 and 142). These estimates are based on the current number of NB. However it is reasonable to assume that some of them will not apply for re-notification, which should further reduce authorities' workload.

In any case, in order to address the matter, the Commission services will introduce a specific transitional provision which allows for the application of the notification procedure before the general date of applicability of the directives. This will allow MS the time necessary to ensure that re-notification tasks are accomplished by the time the directives become applicable.

As regards the revision of the notification process, the alignment will introduce the possibility for other MS and the Commission to object to a notification. For notifications based on accreditation the period for raising such objections is two weeks, whereas for notifications not based on accreditation the period is two months. The impact of the objection procedure should be assessed bearing in mind the overall

[83] It is worth noting that 32% of NB disagrees on the effectiveness of the introduction of information obligations.

regulatory framework for notification[84]. The objection procedure is expected to be used mainly for notifications of non-accredited conformity bodies, which are nowadays less common than notifications underpinned by accreditation. The objection procedure may give rise to some administrative burden for an authority whose notification is challenged. However this is only likely to occur if the authority has not carried out an accurate assessment of the NB. Therefore, objections should rather be seen as a sign that the new notification procedure meets the goal of ensuring that conformity assessment bodies are notified only following a comprehensive assessment.

The information obligations imposed on the notified bodies will not increase costs for public authorities and should rather diminish the costs of monitoring NB.

The alignment with the NLF Decision will introduce requirements for notifying authorities that will clarify their responsibilities (assessing, notifying and monitoring of notified bodies) and the possibility to delegate certain tasks, in particular to accreditation bodies. A further set of criteria seeks to guarantee impartiality and to avoid conflicts of interests. For the majority of notifying authorities, complying with these criteria and obligations should in principle involve neither organisational changes nor additional tasks. In the measuring instrument sector, where national authorities carry out the function of notified bodies as well as the function of notifying authorities the new requirements might trigger a need for some organisational rearrangements that should not, however, be a source of major concern for MS.

This assessment also reflects the view expressed by the authorities participating in the public consultation. About a third (31-37%) indicated that there would be no or no significant increase in costs and/or administrative burden or considered that would be a reduction in costs, another third (25-36%) considered that there would be a moderate increase, and virtually none (0-2%) pointed to a significant increase. It is also important to note that 32-38% of respondents either did not answer the question or declared they were unable to evaluate impacts. The detailed results of the consultation can be found in the annex (see section 12.2.1.5 in Annex 4).

6.4.5. Consumers, households and other users

Under the alignment option, consumers and users in general will benefit from the likely increase in the size and deterrent effect of market surveillance resulting not only from the implementation of the NLF Regulation, but also from the extension of traceability obligations and from more systematic coordination at EU level.

Due to the overall limited impact of alignment on costs, the new obligations on EO and NB are not expected to give rise to price increases for consumers/users. If, for

[84] It has always been the responsibility of Member States to appropriately assess and monitor the bodies they are notifying. However, until the entry into force of Regulation 765/2008 the notification process did not have the tools to check how this obligation has been complied with. In this connection, the Regulation, on the one hand, reinforces the regulatory framework for accreditation and, on the other hand, establishes in Article 5(2) that when accreditation is not used notifying authorities have to provide evidence that the body has been adequately assessed.

specific products, moderate price increases occur, it is expected that the latter would be largely offset by the benefit of greater confidence in product quality.

6.4.6. Third countries and international relations

The obligations of EO as such do not constitute new technical trade barriers. Instead, they guarantee the free movement of safe goods, regardless of origin. According to the NLF Decision, importers of products from third countries are obliged to be better informed about their products and sources, which is a minimum and proportionate requirement. The import of products from unknown sources is expected to become more difficult, precisely because this is likely to lead to non-compliance. Responsible importers who establish clear commercial relations with their trading parties and responsible manufacturers located in third countries will not be negatively affected by these provisions. Increased transparency may encourage distributors to buy imported products and may facilitate international trade.

The alignment of provisions concerning NB and notifications activities will have no impact on international relations as the recognition of third country conformity assessment bodies will still depend on mutual recognition agreements and no additional restrictions are introduced. In the lift sector, where a third country has repeatedly complained about the poor quality of NB located in certain MS and of the bodies located in its own territory to which activities were subcontracted, it is felt that the new requirements will have a positive impact on international cooperation.

6.4.7. Public health and safety

The alignment of provisions concerning EO obligations and market surveillance procedures is expected to help in reducing the number of non-compliant products on the market and thus the number of products potentially dangerous to the health and safety of consumers and workers.

The assessment is largely supported by the results of the public consultation as 58-78% of EO, 72-78% of NB, 58-62% of authorities and about 72-79% of users participating in the consultation (excluding the measuring instrument sector[85]) agreed that clarification of EO obligations and market surveillance procedures would help protect public health and safety. In general the majority of those EO and authorities who acknowledged a positive impact considered it moderate, while in general the majority of those NB and users who acknowledged a positive impact considered it significant. The detailed results of the consultation are illustrated in the annex (see section 12.1.2.7 in Annex 4).

The alignment of provisions concerning NB requirements and notifications activities is also expected to have a positive, although indirect, effect on the protection of public health and safety. The assessment is supported by the results of the public consultation as 50-72% of EO, 73-85% of NB and 68-77% of authorities

[85] In the case of measuring instruments the relevant directives pursue mainly public interests other than health and safety protection and for this reasons the question asked during the consultation did ot apply to this sector. Having said that, specific categories of measuring instruments may also relate to health and safety aspects (e.g. determination of mass in the practice of medicine and pharmacy).

participating in the consultation (excluding the measuring instrument sector[86]) agreed that changes to the NB requirements and notifications activities would help protect public health and safety. In general the majority of those who acknowledged a positive impact consider it moderate, although a good share of respondents qualified the impact as significant. The detailed results of the consultation are illustrated in the annex (see section 12.2.1.6 in Annex 4).

6.4.8. Environmental impacts

The alignment of provisions concerning EO obligations and market surveillance procedures is expected to lead to a greater reduction of environmentally unfriendly pyrotechnic articles or other products that may create environmental risks than under the no-policy change scenario.

6.4.9. Simplification of the regulatory environment

This option will fully address the problem of current inconsistencies in overlapping legislation as consistent terminology will be inserted in the definitions provisions and in the different modules for conformity assessment procedures contained in all these directives.

7. COMPARISON OF OPTIONS

The first table below provides an overview of the impacts assessed for each option. Costs and benefits are identified by using respectively the "-" and "+" symbols. The magnitude of each impact is assessed according to the following indications:

- (+++): significant positive impact
- (++): moderate positive impact
- (+): minor positive impact
- (0): no impact/baseline
- (-): minor negative impact/ small increase in costs
- (--): moderate negative impact/increase in costs
- (---): significant negative impact/increase in costs

The comparisons show that the option of non-legislative measures is considered far less effective than the alignment by legislative measures option and barely more effective than the no policy change option. This is because, as regards the problem of non-compliance, non legislative measures would not improve the current situation where responsible EO already fulfil a number of obligations that are part of existing guidance provided to industry, while unscrupulous ones exploit the fact that this best practice is not legally binding. Furthermore, as regards the inappropriate

[86] See previous footnote.

performance of NB, it is doubtful that the option of non-legislative measures would make it possible to exclude from the single market those conformity assessment bodies that do not possess the necessary competence or whose evaluations are affected by conflicts of interests. This is because informal guidance will be taken into account by conformity assessment bodies and notifying authorities that are willing to provide good quality services but appears insufficient to motivate less responsible bodies. Furthermore, notifying authorities would normally need a formal legal basis to refuse or withdraw a notification. Finally, option 2 will not be effective to address divergences in terminology used by existing directives, which presuppose a modification of the legal provisions.

This view is strongly supported by the results of the public consultation as the large majority of all stakeholders (EO, NB, authorities, users) that participated in the consultation considered the option of alignment by non legislative measures as ineffective overall, in relation to the objectives of reducing the number of non-compliant products, ensuring strict and uniform control of NB across the EU and achieving consistency of directives. Stakeholders, on the other hand, very largely agreed on the effectiveness of the alignment by legislative measures. Additional details on the view expressed by the different categories of stakeholders on the relative effectiveness of option 2 and 3 are provided in the annex (see section 12.4 in Annex 4).

Table 5: Overview of the impacts attributed to the listed options

	ECONOMIC IMPACTS							SOCIAL IMPACTS	ENVIRONMENTAL IMPACTS	OTHER IMPACTS
	Internal market	**Competitiveness**	**Costs and admin. Burdens for EO or NB**	**Public authorities**		**Third countries relations**	**Consumers and users**	**Public health**	**Restriction of polluting goods/ Likelyhood of environm. Risks**	**Simplification**
				Benefits	**Costs**					
Option 1**: No-change (Benefits and costs mainly due to application of Regulation 765/2008)**	**(0)**	**(0)**	**(0)**	**(0)**	**(0)**	**(0)**	**(0)**	**(0)**	**(0)**	**(0)**
Option 2**: Alignment via non-legislative measures**	**(+)**	**(–)/(+)**	**(–/ – –) if follow guidance**	**(0)**	**(0)**	**(0)**	**(+)**	**(+)**	**(+)**	**(0)**
Option 3**: Alignment via legislative measures**	**(+++)**	**(++)/(+++)**	**(– / – –)**	**(++)/(+++)**	**(0/ –)**	**(0/ +)**	**(+++)**	**(++)/(+++)**	**(++)**	**(++)/(+++)**

The second table compares the policy options according to the criteria of effectiveness (i.e. to what extent they fulfil the specific objectives), efficiency (i.e. at which costs they do so) and coherence with other EU policies.

Table 6: 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 non-compliant products and scope for unfair competition. Effective as to simplification.**	High**: important benefits for all stakeholders vs small or moderate additional costs**	Coherent **with other NLF instrument and policy commitment underpinning NLF Decision**

In terms of efficiency, the non-legislative measure represents the option with the lowest score since, on the one hand it does not guarantee additional benefits with respect to the no policy change scenario, despite the additional compliance costs to be borne by those EO and NB who voluntarily align with the proposed best practices. As a matter of fact, this option would increase the compliance gap between responsible and unscrupulous EO/NB.

As regards coherence, the alignment option appears to be the only option that is truly coherent with the NLF Regulation, to which it represents the natural complement, and with the commitment of the EU institutions to progressively aligning product legislation with the 'model' legislation introduced by the NLF Decision[87].

In the light of these criteria, option 3 stands out as the preferred option.

8. MONITORING AND EVALUATION

8.1. Timing aspects

The adoption of the proposal for the alignment of the ten directives with the NLF by the Commission is planned for summer 2011. After the adoption by the European Parliament and the Council, there will be a two-year transposition period. Hence the new legislation might possibly take effect in the second half of 2014.

8.2. Evaluation arrangements

No additional evaluation arrangements will be introduced. Specific reporting obligations are already envisaged for the lifts directive and the measuring instruments directive. 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 (expert groups, administrative cooperation groups (ADCOs), notified body groups). These groups meet regularly to discuss particular aspects relating to the functioning and enforcement (ADCOs) of the directives. Additional feedback will be obtained from the new or expanded cooperation and information exchange mechanisms provided for by NLF Regulation.

In 2018 the Commission will produce a comprehensive report on the functioning of market surveillance.[88] Which will also allow conclusions to be drawn for the evaluation of this initiative.

8.3. Monitoring

8.3.1. Reduction of non-compliant products

The monitoring of the reduction of non-compliance will be possible on the basis of a number of enforcement indicators (e.g. number of products checked, number of non-compliant products among those checked, type of non-compliance found, number of non-compliant products whose manufacturer/importer was identified, number of products refused at the border). These enforcement indicators will be based on information provided via:

– the RAPEX system that since 1 January 2010 covers all products falling under the scope of the 10 directives. RAPEX is the EU rapid alert system for all dangerous consumer and non-consumer harmonised products. The system

[87] See footnote 14.

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

allows for the rapid exchange of information between MS and the Commission of measures taken to prevent or restrict the marketing of those products. Both measures ordered by national authorities and measures taken voluntarily by producers and distributors are covered by RAPEX;

– a general database established under Article 23 of the NLF Regulation for the exchange of information among MS on market surveillance activities and non-compliant products

– the data provided by customs authorities that on the basis of the NLF Regulation have a duty to cooperate with market surveillance authorities;

– the National Market Surveillance Programmes established by MS on the basis of the NLF regulation and their report on the state of the implementation of activities programmed;

– the safeguard clause notification procedures established under the relevant sector directives according to which MS notify restrictive measures adopted against non-compliant products.

If the obligations set up by the NLF work well, initially an increase in the number of products checked and in non-compliant products found can be expected. In the long run however the number of non-compliant products found would go down. The increased traceability will be measured by looking at the share of products checked for which it has been possible to identify the main economic operators involved in the value chain, namely the manufacturer and/or the importer.

8.3.2. Improving the quality of services delivered by notified bodies

The monitoring of the quality of notified bodies will be based on indicators relating to notification practices of Member States (number of notifications, information provided on assessment of the body notified , frequency of reassessment, objections, de-notification requests, etc..) as well as on indicators relating to conformity assessment practices

These indicators will be based on information obtained via

– the NANDO database

– feedback from Notified Body Groups

The first results should already become visible on the re-notification of existing notified bodies. Tighter notification requirements and the revised notification process should lead to a reduction of the current number of notified bodies operating under the directives. Indicators pointing to more coherent assessment practices will be an increase in notifications based on accreditation and the need to have recourse to the objection procedure. A more coordinated approach towards conformity assessment should be reflected in the increased participation of notified bodies in coordination activities. This will in particular be monitored by the notified body groups.

9. ANNEX 1: GLOSSARY AND LIST OF ACRONYMS

The following acronyms are used throughout the document:

Acronym or abbreviations	*Meaning*	*Additional details*
ATEX	**ATEX Directive**	**Directive 94/9/EC of the European Parliament and the Council on the approximation of the laws of the Member States concerning equipment and protective systems intended for use in potentially explosive atmospheres**
BO	**Business Organisation**	**Expression used in the questionnaires for the public consultation to identify organisation representing the interests of several economic operators.**
Civil Explosives	**Civil Explosives Directive**	**Council Directive 93/15/EEC on the harmonisation of the provisions relating to the placing on the market and supervision of explosives for civil use**
CO	**Consumer organisation**	
EA	**European Co-operation for Accreditation**	**EA is the European network of nationally recognised accreditation bodies located in the European geographical area. The EA is the body recognised pursuant to Article 14(1) of the NLF Regulation**
EMC	**Electromagnetic Compatibility Directive**	**Directive 2004/108/EC on the approximation of the laws of the Member States relating to electromagnetic compatibility and repealing Directive 89/336/EEC**
EO	**Economic Operator(s)**	**Typical economic operators are manufacturers, importers and distributors. Some directives envisage additional categories of EO (e.g. lift installers).**
Lifts	**Lifts Directive**	**European Parliament and Council Directive 95/16/EC of 29 June 1995 on the approximation of the laws of the Member States relating to lifts**
LVD	**Low Voltage Directive**	**Directive 2006/95/EEC on the harmonisation of the laws of Member States relating to electrical equipment designed for use within certain voltage limits**
MID	**Measuring Instruments Directive**	**Directive 2004/22/EC of the European Parliament and of the Council on measuring instruments**
MS	**Member State(s)**	**Member State(s) of the EU**

NAWI	**Non-automatic Weighing Instruments Directive**	**Council Directive 2009/23/EEC on the harmonisation of the laws of the Member States relating to non-automatic weighing instruments**
NANDO	**New Approach Notified and Designated Organisations**	**Information System containing information on all conformity assessment bodies notified under New Approach Directives by MS, EFTA countries (EEA members) and other countries with which the EC has concluded Mutual Recognition Agreements (MRAs) and Protocols to the Europe Agreements on Conformity Assessment and Acceptance of Industrial Products (PECAs)**
NB	**Notified Body(ies)**	**Body notified by a Member State to the Commission as entitled to carry out conformity assessment (e.g. calibration, testing, certification and inspection) of products covered by a given product harmonisation directive.**
NLF	**New Legislative Framework**	**Consisting of two complementary instruments: (i) Regulation 765/2008 on accreditation and market surveillance and (ii) Decision 768/2008 establishing a common framework for the marketing of products.**
NLF Decision	**Decision 768/2008**	
NLF Regulation	**Regulation 765/2008**	
PED	**Pressure Equipment Directive**	**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**
Pyrotechnic	**Pyrotechnic Articles Directive**	**Directive 2007/23/EC on the placing on the market of pyrotechnic articles**
RTPO	**Recognised Third Party Organisation**	**Conformity assessment body under Article 13 of the PED for a limited list of services**
SME	**Small and medium enterprise**	**Expression used in the documents to identify the small and medium enterprises having participated in the consultation run through the Enterprise Europe Network.**
SPVD	**Simple Pressure Vessels Directive**	**Council Directive 2009//105/EC on the harmonisation of the laws of the Member States relating to simple pressure vessels**
UI	**User Inspectorate**	**Conformity assessment body under Article 14 of the PED for a limited list of services**

10. ANNEX 2: DETAILED SECTOR DESCRIPTION

10.1. Civil Explosives

10.1.1. The Civil Explosives Directive 1993/15/EEC

The Civil Explosives Directive was adopted in 1993. Its main objective is the establishment of a single market for explosives, while maintaining a high level of safety protection. In addition, it aims at improving security in the industry by setting out how the movement of explosives between Member States should be supervised. It therefore contains strict rules on the registration and documentation of the whereabouts of explosives.

The directive applies to civil explosives, i.e. to explosive substances and articles which are not used by the armed forces or the police, but commercially. The main end-users of civil explosives are the mining industry, the quarrying industry, and the construction and civil engineering industry (primarily for demolition, land clearance and tunnelling).

The conformity assessment procedures provided for in the directive make mandatory use of the services of notified bodies. 13 bodies are currently notified under the Civil Explosives Directive.

10.1.2. The civil explosives sector

The civil explosives sector in Western Europe (mainly the old EU 15) has a consumption in excess of 250 000 metric tons per year, while in Eastern Europe (mainly the new Member States), the figure is around 350 000 metric tons. Altogether, as shown in table 7 and 8 below, more than 550 000 metric tons of explosives at a value of around EUR 700 million are placed on the EU-27 market every year.

Table 7: EU 27 Civil Explosives sold in 1000kg (Source: EUROSTAT, Prodcom)

EU 27 Civil Explosives sold (in 1000kg)					
Type of Civil Explosives	**2004**	**2005**	**2006**	**2007**	**2008**
Prepared explosives (excluding propellent powders)	486,649	435,930	485,656	485,961	549,546
Propellent powders	7,762	8,296	10,382	23,754	8,915
Safety fuses; detonating fuses	199	198	192	178	191
Total	**494,610**	**444,425**	**496,230**	**509,892**	**558,652**

Table 8: EU 27 Civil Explosives sold in EUR (Source: EUROSTAT, Prodcom)

EU 27 Civil Explosives sold (in EUR)					
Type of Civil Explosives	**2004**	**2005**	**2006**	**2007**	**2008**
Prepared explosives (excluding propellent powders)	508,772,694	494,115,602	538,996,396	579,364,617	568,264,920
Propellent powders	78,525,105	81,861,678	90,777,257	97,336,385	101,994,321
Safety fuses; detonating fuses	38,600,347	37,869,040	37,880,126	36,592,109	35,054,003
Total	**625,898,146**	**613,846,320**	**667,653,779**	**713,293,111**	**705,313,244**

While quarrying is the most important sector of the Western European mining industry, representing 58% of the market in 2003, coal mining is the most important activity in Eastern Europe, accounting for an estimated 53% of total consumption in 2003. However, in the EU, the mining and quarrying industries typically make up a much lower share of overall explosives consumption than elsewhere in the world. That is, explosives used for civil engineering purposes, in particular for demolition works in the construction sector, are an important source of demand in the EU and constitute a significant market.

In addition, the sector covered by the Civil Explosives Directive also comprises initiating systems, which include detonators. In the EU, around 68 million units of detonators at a value of approximately EUR 70 million are produced annually for EU-consumption. Explosives are rarely sold individually, but mostly as part of larger service packages, which can include such initiating systems (detonators and detonating cords), storage, drilling, filling and blasting advice and execution, as well as dragging and even crushing.

The business volume of the explosives sector, including blasting and drilling devices, amounts to EUR 1.1 billion. Adding the value of EUR 250 million generated by distributors in the sector, the total market size of the EU civil explosives industry amounts to EUR 1.35 billion. As demonstrated in the first table above, the overall consumption of civil explosives in the EU is more or less stable. However, growing demand by developing countries is expected.

As far as businesses in the civil explosives sector are concerned, 20 manufacturers of explosives, as well as approximately 500 dealers and distributors are active in the EU. At the manufacturers' level, there are no SMEs, as major investments are needed to fulfil safety and security conditions for market entry. Around 4 000 people are directly employed by these companies. Nearly all of the distributors, on the other hand, are SMEs and altogether employ around 5 000 people. Thus, a total of 9 000 people are employed by the civil explosives industry in the EU.

All businesses operating in the civil explosives sector face a highly competitive environment. Most of them have overcapacity and consumption is not growing, forcing manufacturers to rationalize and concentrate their operations. As a result, the trend in the industry is towards consolidation. Larger competitors buy up smaller ones to expand their businesses across national borders. Consequently, a small

number of international groups have emerged. Companies operating in more than one country is a feature which is expected to continue to develop.

The industry's trade patterns reflect these trends. While businesses still derive the majority of their income from their respective national markets, intra-community trade is increasing. Trade between EU Member States amounts to about 35 000 metric tons per year, i.e. to around 6% of total EU explosives consumption. For safety and security reasons, most of this cross-border trade occurs between existing explosives manufacturers at intra-company level. With more and more manufacturers establishing subsidiaries in several Member States, intra-company trade across borders can be expected to intensify.

Trade with third countries is limited in the civil explosives sector, since explosives are bulk products with strict safety and security requirements causing high transportation costs. This makes the proximity of production units to the sites of use a crucial factor for success and is another reason for the increased consolidation activity in the sector. Concerning exports, 100 000 tons of explosives and 30 million units of detonators corresponding to 16% of sales of EU companies are generated in the global market. Imports, on the other hand, play a significant role only in niche markets like explosives used for offshore drilling operations. Important trading partners are Norway, Switzerland and the USA. Importers in the EU are generally large companies with specific demands, for example in the oil drilling industry.

Accidents with civil explosives can have severe consequences including casualties or serious injuries and may cause significant economic damage to surrounding infrastructures. They are rather rare, given the tonnage of explosives used annually in the EU.

10.2. Pyrotechnic Articles

10.2.1. The Pyrotechnic Articles Directive 2007/23/EC

The Pyrotechnic Articles Directive was adopted in 2007. It is thus a very new directive, which has to be applied by Member States from July 2010 for consumer fireworks and from July 2013 for all other pyrotechnic articles. The directive's main objectives are to protect human health and safety and to create a single market for pyrotechnic articles in the EU.

The directive regulates the placing on the market of pyrotechnic articles. As such, it mainly applies to fireworks, theatrical pyrotechnic articles and pyrotechnic articles for technical purposes in vehicles (automotive restraint systems, i.e. most importantly gas generators used in airbags and seatbelt tensioners). Some pyrotechnic articles are excluded from the scope of the directive, such as ammunition, and products used in marine equipment, in the aerospace industry and by the armed forces, the police or fire departments.

Conformity assessment procedures in the directive make the involvement of notified bodies obligatory. Until now, 10 bodies have been notified under the Directive A particular challenge for notified bodies dealing with consumer fireworks arises from the fact that more than 95% are manufactured overseas, notably in China, which makes it more difficult to apply quality assurance modules that necessitate an audit

of the quality system put in place by the manufacturer, and raises questions about subcontracting to non-EU entities.

10.2.2. The pyrotechnics sector

The products covered by the Pyrotechnics Articles Directive, correspond in principle to two sectors: fireworks and automotive occupant restraint systems.

The total EU market for fireworks is estimated by industry at around EUR 1.4 billion per year. This is equally distributed between sales to consumers (categories 1, 2 and 3 of the directive) and sales to professionals only (category 4 of the directive).

Automotive occupant restraint systems mainly comprise airbags and seatbelt tensioners. In 2009, around 65 million airbag systems were produced in the EU market, representing a market value of around EUR 1.8 billion. As regards seatbelts, approximately 80 million units at a value of about EUR 1 billion were produced in the EU in 2009. This amounts to a total market size of roughly EUR 2.8 billion for automotive occupant restraint systems.

The overall market size of the pyrotechnics sector covered by the Directive is thus in the region of EUR 4.2 billion per year. While sales of fireworks are stagnant, sales of automotive pyrotechnic articles depend on the number of cars sold. The difficult economic situation in 2009, especially for the car industry, must thus be taken into account when considering the market size of automotive pyrotechnic articles. Depending on future recovery, this could grow significantly.

Concerning the structure of businesses operating in the pyrotechnics sector, the fireworks and automotive sectors must again be distinguished. The EU fireworks industry mainly consists of SMEs and altogether employs an estimated 15000 to 20000 people in the EU. However, as most companies operate in more than just the fireworks area and additionally employ seasonal workers for the peak season from late November onwards, this number is very hard to judge. In general, most businesses in the pyrotechnics sector are engaged in the purchase, distribution, storage or professional display of fireworks. There are roughly 500 importers in the EU, serving an estimated number of 200 000 distributors (including large chain stores etc.). The manufacture of fireworks in the EU has diminished significantly over the last decades and is very limited today. It mainly takes place in Germany, Italy, France, Spain, Portugal and the UK and focuses on fireworks for professional use (category 4). As shown in table 1 below, other manufacturing has primarily moved to China, where by far the most European imports come from today.

The situation for automotive pyrotechnic articles is very different. The enterprises active in this sector in the EU are big international automotive supplier companies and have around 40 000 employees. These companies generate about two thirds of pyrotechnic articles sales in the EU. Three international groups active in the automobile occupant restraint sector account for about 75% of the global market.

Differences between the fireworks and the automotive pyrotechnics sectors are also evident with regard to trade patterns. Whereas, as illustrated by the tables below, the EU is a net importer of fireworks, it is a net exporter of automotive components containing pyrotechnic articles.

Table 9: EU 27 Trade in fireworks (Source: EUROSTAT, Comext)

EU 27 Trade in fireworks (in 100kg)				
Period	**Total imports**	**Imports from China**		**Total exports**
		in 100kg	**% of total**	
2004	1,094,751	1,059,577	96.79%	9,182
2005	1,049,011	837,278	79.82%	17,077
2006	1,113,285	1,062,821	95.47%	13,138
2007	1,182,618	1,143,455	96.69%	16,202
2008	1,103,475	1,088,056	98.60%	18,093

The available import and export figures for airbag systems are given in table 2 and demonstrate the EU's export activity in this field. However, it must be noted that more airbag systems are exported as part of assembled motor vehicles.

Table 10: EU 27 Trade in airbags (Source: EUROSTAT, Comext)

EU 27 Trade in airbags (in EUR)		
	2007	2008
Import	202,567,266	208,777,513
Export	229,243,222	320,151,508

Defective fireworks, e.g. fireworks which ignite prematurely, can lead to ear damage caused by excessive sound levels, severe burns and eye injuries, and in some cases even death. As in other sectors, it is often difficult to determine if accidents caused by fireworks were caused by malfunction or by misuse. According to a projection by the EU injury database[89], there are about 27.000 injuries due to fireworks in the EU annually. This represents 0.07% of all injuries. It is estimated that misuse is responsible for most of these injuries although high product failure rates (sometimes more than 50 per cent) are reported by notified bodies when they perform conformity assessment.

89 Kuratorium für Verkehrssicherheit KfV (Ed.) (2010) Data Report "Injuries with Fireworks in the EU", EU Injury Data & Reporting Services. Vienna: KfV; Source: EU Injury Database (IDB) of the European Commission, DG SANCO, and the network of national IDB data providers at https://webgate.ec.europa.eu/idb/"

10.3. Pressure Equipment

10.3.1. The Simple Pressure Vessels Directive 2009/105/EC

The SPVD was adopted in 1987 (87/404/EEC). As such, it is the oldest directive based on the 1985 New Approach. Its main objective is to guarantee the free movement of simple pressure vessels in the internal market, while maintaining a high level of safety. The directive was recently codified, integrating the amendments to the original directive in a new single legal document 2009/105/EC without changing the technical content.

The SPVD applies to simple pressure vessels manufactured in series. These are defined as "any welded vessel subjected to an internal gauge pressure greater than 0,5 bar which is intended to contain air or nitrogen and which is not intended to be fired" (Art. 1(2)). The types of vessels covered include air receivers and vessels used in braking systems of trucks and railway vehicles.

Simple pressure vessels are classified depending on their total energetic content, which is determined by the pressure and the volume of the vessel. Depending on this category, different conformity assessment procedures apply, which mostly require the involvement of a notified body. 95 bodies are currently notified under the SPVD.

10.3.2. The Pressure Equipment Directive 97/23/EC

The PED was adopted in 1997. It primarily aims at ensuring the free placing on the market and putting into service of pressure equipment within the internal market, while maintaining a high level of safety.

The PED covers stationary pressure equipment and assemblies with a maximum allowable pressure greater than 0,5 bar, as designed and specified by the manufacturer. The products covered by the directive can roughly be grouped into vessels (e.g. vessels for liquefied gas storage, chemical reactors and distillation columns, industrial compressed air receivers, etc.), boilers (e.g. hot water boilers, steam generators, etc.), piping (i.e. systems of pipes used to convey fluids), pressure and safety accessories (e.g. valves, pressure regulators, etc.) and assemblies, which integrate pressure equipment into a functional whole (e.g. (petro)chemical process plants, air conditioning systems, etc.).

Most products covered by the PED are used in an industrial environment (process industries, energy production), but there are also some consumer products, such as pressure cookers and fire extinguishers.

Significant subsets of products, covered by other (harmonised) legislation, are excluded from the scope of the directive (e.g. automobile, machinery, medical devices, etc.).

Regarding conformity assessment, the PED provides for a wide range of modules (or combinations thereof) depending on the product category. Even though the services of a notified body are not always mandatory, most procedures require the involvement of a notified body. Currently, 166 European NBs operate under the PED. In addition, there are 53 Recognised Third Party Organisations (RTPO) and 20

User Inspectorates (UI) with specific and limited responsibilities, defined in the directive.

10.3.3. The pressure equipment sector

Describing the market characteristics of the sector covered by the PED and the SPVD is difficult. The problem is that the pressure equipment sector as such does not exist on the market. Most pressure equipment is used as components of a larger whole (e.g. pressure vessels and piping in chemical plants, components of machinery, etc.) and is thus very hard to trace in terms of market data. While most pressure equipment is used industrially, there are also some consumer products (e.g. pressure cookers, domestic air conditioning systems, fire extinguishers, high pressure cleaning systems, etc.), adding to the overall diversity. As a result, the market characteristics of pressure equipment covered by the PED and the SPVD may vary substantially, even within just one product category such as boilers.[90]

Market data on these sectors is almost impossible to obtain. Information sources are restricted, as there is no single EU professional association representing the whole pressure equipment sector. Official statistical classification systems only reference a limited number of relevant products.[91] Several attempts undertaken in the past to quantify the market for pressure equipment in Europe have failed.

A complete picture of the sector in quantitative terms cannot therefore be given. However, some general trends can be discerned. Most importantly, the manufacturing of pressure equipment is gradually shifting to low cost countries. This certainly applies to mainstream pressure equipment, but also (and increasingly) more complex products. While these are for the most part still designed in Europe, low cost countries are catching up quickly with regard to know-how and worker qualifications. More competition is expected, especially from Asian countries, on the worldwide market in all product groups.

Production of, and trade in, fire extinguishers is a good illustration of this trend. Within two years, China developed into the leading export country to the EU. Nearly half (11 million units) of all fire extinguishers imported into the EU 27 in 2005 (22 million units) originated in China.

Failure of pressure equipment can have catastrophic consequences. The explosion of a boiler or a reactor vessel in a chemical plant is likely to lead to casualties or serious injuries and may cause significant economic damage to surrounding infrastructures.

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90 For this example, a distinction between boilers for small applications (e.g. warm water production for domestic use), boilers for smaller and bigger industrial applications (e.g. hot water or steam production), and specifically designed boilers for the (petro-)chemical industry or for power generation would have to be made. Evidently, the market situation for each of these products would be very different and what is valid for one category might not be valid at all for another.

91 Within Eurostat's classifications, the classes of NACE (Rev. 2, currently used alongside the older version Rev. 1.1) 24 covering the "manufacture of basic metals" and NACE 25 on the "manufacture of fabricated metal products, except machinery and equipment" are of particular importance. The two most relevant sub-classes are NACE 25.21 ("manufacture of tanks, reservoirs and containers of metal" – "manufacture of central heating radiators and boilers") and NACE 25.3 ("manufacture of steam generators, except central heating hot water boilers").

10.4. The Low Voltage Directive

10.4.1. Definitions and scope

For the purposes of the LVD, "electrical equipment" means any equipment designed for use with a voltage rating of between 50v and 1000v for alternating current and between 75v and 1500v for direct current, other than the equipment and phenomena listed in Annex II (see below).

The LVD ensures that electrical equipment within certain voltage limits provides a high level of protection for European citizens. It covers a broad variety of electrical and electronic products, as well as equipment and systems.

According to the Statistical Classification of Economic Activities in the European Community (NACE) the products covered by the Directive are: electric welding and soldering tools, electric domestic appliances, computers and other information processing equipment, electric motors, generators and transformers. Electricity distribution and control apparatus, insulated wire and cable, lighting equipment and electric lamps, other electrical equipment, electronic valves and tubes and other electronic components, television and radio receivers, sound or video recording or video recording or reproducing apparatus and associated goods.

Equipment listed in Annex II is outside the scope of the Directive: electrical equipment for use in an explosive atmosphere (which is covered by the ATEX directive, also included in this alignment exercise), electrical equipment for radiology and medical purposes, electrical parts for goods and passenger lifts, electricity meters, plugs and socket outlets for domestic use, electric fence controllers, radio-electrical interference, specialized electrical equipment, for use on ships, aircraft or railways.

10.4.2. Facts and figures

The EU is the most open market for electrical equipment and appliances among large trade blocs and industrial countries. The EU legislation that most directly concerns electrical equipment of low voltage is the LVD. The absence of third-party intervention in the conformity assessment procedures laid down by the LVD greatly reduces the burden on the manufacturer. This is a model of business friendly legislation for other trade blocs. The LVD has substantially contributed to the EU internal market for electrical and electronic products since 1973.

Most electrical equipment is also subject to the Directive on Electromagnetic compatibility (EMC Directive). Although recognising the need for and benefits of harmonisation, industry believes that the cumulative effect of legislation originating from various policy areas and levels can pose problems, particularly for SMEs.

The total output of the electrical, electronic and telecom sector was €501,771 million in 2007 of which €235,585 million was attributable to products covered by the LVD.

The balance of trade is negative for these products in Europe with €103,929 million of imports and €83,091 million of exports. This is due to the sustained increase in ICT imports from south-east Asian countries in the last four years. Most imports of

these products come from China, followed at a considerable distance by the USA, Japan and South Korea.

Internal consumption is estimated at € 256,423 million.

The number of enterprises involved in the sector is 60,485 employing 1,645,495 people. The structure of the industry is characterised by a few large corporations producing a wide range of electrical equipment, and many small companies specialised in niche markets.

During the last decade, production, exports and the internal market have steadily grown. This trend was abruptly stopped by the economic crisis.

Defective electronic products can present a risk of electric shock or burns. Electronic products are among the product categories most frequently notified through the Commission's RAPEX system (Rapid Alert system for non-food consumer products), a system that contains products which pose a serious risk to the health and safety of consumers. 138 RAPEX notifications were registered in 2009[92] corresponding to 8% of the total number of RAPEX notifications. Given that most notifications are not linked to accidents, the number is relatively low in view of a total of 2 million product types in a market of more than € 250 billion/year and 500 million citizens.

10.5. The Electromagnetic Compatibility Directive

10.5.1. Definitions and scope

The EMC applies to a vast range of equipment encompassing electrical and electronic appliances, systems and installations. The main objective of the EMC is to guarantee the free movement of apparatus and create an acceptable electromagnetic environment in the Community. To achieve this, the EMC requires a harmonised and acceptable level of protection, leading to full EU harmonisation.

The main objectives of the EMC are:

(1) To ensure that electromagnetic disturbance produced by equipment does not affect the correct functioning of other apparatus and radio and telecommunications networks, related equipment and electricity distribution networks.

(2) To ensure that equipment has an adequate level of intrinsic immunity to electromagnetic disturbances to enable them to operate as intended.

The involvement of the Notified Body is rather limited. It is voluntary and the purpose of the body is to help the manufacturer by reviewing the technical documentation for apparatus drawn up by the manufacturer.

According to the Statistical Classification of Economic Activities in the European Community (NACE) the group of products that could be covered by the Directive

[92] See 2009 Annual Report on the operation of the Rapid Alert system for non-food consumer products. http://ec.europa.eu/consumers/safety/rapex/docs/2009_rapex_report_en.pdf

are: electric welding and soldering tools, electric domestic appliances, computers and other information processing equipment, electric motors, generators and transformers, electricity distribution and control apparatus, other electrical equipment, television and radio receivers, sound or video recording or video recording or reproducing apparatus and associated goods.

Equipment outside the scope of the Directive: radio equipment and telecommunication terminal equipment, aeronautical products, radio equipment used by radio amateurs as defined in the International Telecommunications Union Regulations, motor vehicles, medical devices, measuring instruments, and any kind of inherently benign equipment, this is to say equipment whose inherent physical characteristics are such that it is incapable of generating or contributing to electromagnetic emissions which exceed a level allowing radio and telecommunications equipment and other equipment to operate as intended, and that it will operate without unacceptable degradation in the presence of the electromagnetic disturbance normally present in its intended environment.

10.5.2. Facts and figures

This Directive is based on manufacturer self-declaration of conformity and is much appreciated by industry. Most electrical equipment is also subjected to the LVD.

The total output of the electrical, electronic and telecom sector was €501,771 million in 2007 of which €200,117 million relates to the products covered by the Electromagnetic Compatibility Directive.

The balance of trade is negative for these products with €100,775 million of imports and €76,066 million of exports. This is due to the sustained increase of ICT imports from south-east Asian countries in the last four years. Most imports of these products come from China, followed at a considerable distance by the USA, Japan and South Korea.

Internal consumption is estimated at €224,826 million.

The number of the enterprises involved in the sector is 51,362 employing 1,209,533 people. The structure of the industry is characterised by a few large corporations producing a wide range of electrical equipment, and many small companies specialised in niche markets.

During the last decade, production, exports and the internal market have steadily grown. This trend was abruptly stopped by the economic crisis.

Electrical equipment that does not comply with the essential requirements of the EMC directive could produce electromagnetic disturbances that affect the correct functioning of other apparatus like TVs or radio and telecommunications networks. If it does not have the required level of electromagnetic immunity it will not operate as intended in the electromagnetic environment for which it is intended.

10.6. The ATEX Directive

10.6.1. Definitions and scope

The ATEX Directive 94/9/EC (in force since 1 July 2003) regulates Equipment and Protective systems intended for use in Potentially Explosive Atmospheres.

A potentially explosive atmosphere is composed by air mixtures of gases, vapors, mists or dusts, which can ignite under certain operating conditions.

ATEX provides the technical requirements to be applied and the relevant conformity assessment procedures before placing this equipment on the European market. These requirements are given technical expression by "Harmonized Standards", developed by the European Standardization Organizations.

Member States and others who apply the requirements of ATEX are directly responsible for its implementation and enforcement, as well as, for example, the management of notified bodies.

Equipment and protective systems intended for use in potentially explosive atmospheres cover quite a large range of products, including equipment used on fixed offshore platforms and in petrochemical plants, mines, flour mills and other areas where a potentially explosive atmosphere may be present.

Products affected by this Directive are some of the mechanical and electrical sectors specially manufactured to be used in potentially explosive atmospheres such as: pumps and compressors, bearings, gears and driving elements, lifting and handling equipment, non-domestic cooling and ventilation equipment, machinery for mining, quarrying and construction, electric motors, generators and transformers, electric distributing and control apparatus, lighting equipment and electric lamps and industrial process control equipment.

10.6.2. Facts and figures

The group of products covered by ATEX cannot be considered an economic sector in the usual sense of the term. It includes both mechanical and electrical equipment, and even telecom equipment, including non-consumer goods but with specific industrial products in a relatively restricted sector. The ATEX sector is a very specific market, primarily with products for oil, gas and petro-chemical plants.

Only a small number of enterprises specialise in ATEX equipment in Europe. ATEX equipment of different kinds and categories is used as part of a wider production process, as "ATEX-adaptation" of basic equipment. In this sense, it is quite difficult to evaluate the real turnover and market share of ATEX equipment for these enterprises.

The production value of ATEX products is estimated at € 2.2 billion of which we export around 32%. Imports amount to €400 million. Consequently, our internal consumption is estimated at € 1.9 billion, 86% of our production.

ATEX equipment manufactured in Europe is mainly aimed at the internal market, but is also exported to other European countries outside the EEA as well as to the United

States of America and to Asian countries. The most important countries of origin of imports are the USA, China, Japan, South Korea and Canada.

More than 750 companies produce ATEX products in Europe, employing around 15,600 people. There are relatively few “real ATEX” manufacturers, operating in niche markets with few competitors.

There are around 100 importers, mainly international/multinational companies. The ATEX sector is characterized by a large number of SME’s and micro enterprises, around 90%, mainly based in France, Germany, Italy and the United Kingdom, but also with a significant presence and market share in Denmark, the Netherlands, Norway, Poland, Spain, Sweden as well as in Switzerland. In many cases, the largest companies have local branches and/or factories in other European and non-European countries.

On the European market there is also a significant presence and market share of ATEX equipment produced by companies with factories, production and/or distribution centres in Europe but owned by non-European groups, or directly imported from non-European countries.

As noted by market analysts, legislation on hazardous areas contributed to significant market growth. During the first period of the implementation of the ATEX Directive (from publication to entry into force on 1st July 2003), the market did not record relevant changes, given that a large number of products already fall under “Old Approach” legislation. During the second period (from entry into force on 1st July 2003 onwards), taking into consideration also the general growth of production in the oil, gas, chemical and pharmaceutical sectors, the market evolved towards a re-organisation and increasing effectiveness: the number of producers continues to decrease, via a series of mergers or acquisitions, with both European and non-European entities, in order to enable greater economies of scale and cost-sharing relating to the development of new products and innovative solutions, in particular for intrinsic safety.

At present, there are 55 ATEX Notified Bodies in the European Union.

Non-compliance of equipment used in potentially explosive atmospheres can have catastrophic effects. In fact, risks derive from equipment capable of causing an explosion through its own potential sources of ignition, for example electric sparks, electrostatic discharges or hot surfaces. Consequences of this kind of explosion include severe or deadly injuries to persons, serious damage to installations and surrounding civil and industrial infrastructures. Recent accidents in the EU related to the sector (e.g. in chemical plants, coal mines or agricultural premises), do not seem to be caused by non-compliant or unsafe equipment as such, but rather by the use of equipment not suitable for specific hazard zones, failure to identify environments with potentially explosive atmospheres, failure to take specific safety measures, or even by the incorrect operation and misuse of equipment.[93]

[93] In any case, investigation of accidents in these cases is normally quite difficult and complex, due to the large number of factors and operational aspects to be taken into consideration, as well as their interconnections ("chain of events"). Main source of reference for accidents: Marzio Marigo, "Rischio

10.7. The Lifts Directive

10.7.1. Definition and scope

Lifts provide an essential means of comfortable and safe access to modern buildings. The provision of lifts in new buildings has an increasingly important role to play in an ageing society giving growing priority to the social integration of people with special needs.

European Parliament and Council Directive 95/16/EC of 29 June 1995 on the approximation of the laws of the Member States relating to lifts establishes European legal requirements for the design, installation and placing on the market of new lifts. It also sets out the conformity assessment procedures to be followed by lift installers to ensure conformity with these requirements. The provisions of the Directive are implemented in the national law of each Member State of the European Union.

The Directive has the twin aims of facilitating the free circulation of lifts and its safety components within the internal EU market and ensuring a high level of safety for lift users and maintenance staff.

While harmonized European legislation governing the design, manufacturer and installation of lifts is mainly addressed to lift installers and components manufacturers, it also has important implications for owners and users of lifts

The Directive covers new lifts permanently installed in buildings and constructions for carrying passengers or passengers and loads. It also applies to certain safety components for lifts listed in Annex IV to the Directive.

In the European classification of activities, the scope of this Directive would be covered by heading 28221630 ‘Electrically operated lifts and skip hoists’ and in the Combined Nomenclature by heading 84281020.

10.7.2. Facts and figures

Europe is by far the leading continent in terms of lifts installed, 56% of world lifts compared to 14% in North America and 30% in Asia Pacific, in 2009.

Although Europe, with 150 000 new lifts/year (30% of world total), is still the leader, the manufacturing of new lifts is shifting to Asia (China – 315,000 new lifts/year and North America – 35,000 new lifts/year). However, Europe also leads the way in lift technology development. Furthermore, European standards for lifts are used widely around the world and more than 85% of lifts and escalators are based on those standards.

In 2009, the production value of lifts in Europe amounted to €3.167 billion.

EU trade balance is positive with €36 million of imports and €693 million of exports.

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atmosfere esplosive: classificazione, valutazione, prevenzione e protezione". IPSOA-Indicitalia, Milano 2009. Pages 13-29

Consumption in the internal market was €2.51 billion.

In Europe the main producing countries are Spain, Germany and France, showing a steady progression over recent years. 17,778 enterprises make lifting and handling equipment in Europe. Around 134,000 employees work in the sector.

The main countries of origin of imports are China and Turkey.

The European market is dominated by 4 big companies but there is also a significant number of SMEs. Manufacturers usually outsource the production of many components and buy from suppliers.

"Machine-room less lifts" are now the leading technology in Europe.

In 2009, the number of lifts in Europe (incl. Switzerland and Norway) reached 4.7 million units.

Production progressed over recent years before the economic slowdown, increasing by 9% between 2006 and 2007 and by 5% between 2008 and 2007.

A lift that lacks appropriate free spaces or refuge when the lift car is in one of its extreme positions can create a risk of crushing. Although lifts are used 1 billion times a day across Europe, only a small number of persons killed using lifts has been recorded. The most frequent cause of accidents is the absence of a lift door, locking problems or bad stopping accuracy despite all these being regulated by the provisions of the Lifts Directive.

10.8. Measuring Instruments

10.8.1. The Non-Automatic Weighing Instruments Directive 2009/23/EC

NAWI was adopted in 1990 and is thus one of the oldest directives based on the 1985 New Approach. It was recently codified in a new single legal document 2009/23/EC integrating all amendments to the original directive, without however substantially changing its technical content.

NAWI applies to all non-automatic weighing instruments, i.e. to measuring instruments serving to determine the mass of a body and requiring the intervention of an operator during weighing. Such instruments are used for a broad variety of purposes, for instance the calculation of payments, the application of laws or regulations, for determining a price of sale on the basis of mass, making up medicines on prescription in a pharmacy, etc. They are used in quite sensitive areas. Apart from ensuring their free movement, an important objective of the directive is therefore the protection of the public (users and third parties) against incorrect results of weighing operations.

As regards conformity assessment, NAWI provides for a choice between two different procedures. However, both procedures envisage the involvement of notified bodies, making them an integral part of NAWI conformity assessment. 270 bodies are currently notified under NAWI, many of which are local public authorities like city councils.

10.8.2. The Measuring Instruments Directive 2004/22/EC

MID was adopted in 2004, repealing a number of old directives on specific measuring instruments and bringing the whole field under the New Approach. The main objective of the MID is to ensure the free movement of measuring instruments and in particular to avoid barriers to trade because of different provisions of legal metrological control in the Member States. In the context of such legal metrological control, public health and safety as well as the protection of the environment and the consumer are also concerns of the MID.

The MID covers 10 categories of devices and systems with a measuring function, namely water meters, gas meters, electricity meters, heat meters, meters for liquids other than water, weighing machines, taximeters, material measures to measure length, dimensional measuring instruments and exhaust gas analysers. Each of these diverse categories is defined in more detail in the annexes to the directive, where the respective essential requirements as well as the conformity assessment procedures are specified.

Overall, the MID provides for a very wide range of conformity assessment modules. Depending on the category of product, different combinations of modules may be used at the choice of the manufacturer. However, the involvement of a notified body is always obligatory. Currently, 140 bodies are notified under the MID.

10.8.3. The measuring instruments sector

An important sub-sector of the measuring instruments sector is the weighing industry. In 2008, production of weighing instruments covered by NAWI amounted to €2.5 billion.

Only a limited number of companies manufacture weighing instruments in the EU, such as balances and scales, from beginning to end. The majority of companies assemble components from different manufacturers. Regarding the size of companies in the EU weighing industry, the sector is without a doubt carried by SME. In fact, bigger companies with more than 250 employees account for only 4% of the total number of businesses in the industry. While medium sized enterprises (of less than 250 but more than 50 employees) represent 35%, small companies (of less than 50 employees) make up 60%. Altogether, 25 000 people work in the industry, more than half employed by SME.

Apart from these companies, another 4000 to 5000 micro companies of only 1 to 3 employees, i.e. a total of about 10000 people, are involved in the weighing industry. They mostly provide services, but occasionally assemble scales in limited editions.

Market for legal metrology instruments covered by the MID

The MID applies to around 345 million units of measuring instruments sold annually in the EU with a total sales value of around €3.25 billion. Around 900 manufacturers operate in the 10 sectors covered by the MID not including the large number of SME operating as distributors, importers or providers of repair services. The number of employees in the sector is around 175,000- 205,000.

Table 11: – Total size of market covered by the MID

	Market size – number of items sold annually (000s)	Market size-value of items sold annually (million €s)	Share in total Mis market	Employees occupied in sector (1000s)
MI-001: Water Meters	18,000	450	**13.8%**	25
MI-002: Gas Meters & Conversion Devices	6,900	410	**12.6%**	30
MI-003: Active Electricity Energy Meters	14,000	610	**18.8%**	32
MI-004: Heat Meters	800	290	**8.9%**	18
MI-005: Measuring Systems for Liquids other than Water	31.2	240	**7.4%**	14-16
MI-006: Automatic Weighing Instr.	21	550	**16.9%**	25
MI-007: Taximeters	50	25-40	**1%**	1
MI-008: Material Measures[94]	300,000	440-490	**14.3%**	34
MI-009:Dimensional Measuring Instr.	300-400	70-80	**2.3%**	7
MI-010: Exhaust Gas Analysers	25-35	130	**4.0%**	17.5
Total	**345,000**	**3,250**	**100%**	**190**

Around 20-25% of measuring instruments in the EU27 are imported while 25-30% of measuring instruments produced in the EU27 are exported to third countries. There is however considerable variation among the different categories of measuring instruments. Trade levels in both directions are particularly high (over 50% of total) for the less technology-intensive categories of material measures (MI-008) and dimensional measuring instruments (MI-009) but also for electricity meters (65%). At the same time, the share of production exported is particularly high in the case of more advanced technology instruments such as Automatic Weighing Instruments (up to 42% for the sub-category of automatic gravimetric filling instruments) and in the Gas Meters category (44%) where EU firms are world leaders.

[94] Data refer to all material measures of length in the market. Not only MID certified.

11. ANNEX 3: OVERVIEW OF STAKEHOLDERS CONSULTED

11.1. Discussions in sector specific working groups

Discussions with stakeholders took place under the sector specific working groups established under the different directives concerned:

- Electrical and electronic goods: the LVD Working Party established under Directive 2006/95/EEC discussed the alignment to the NLF Decision on 12 March 2009 (LVD WP 14) and 27 May 2010 (LVD WP 15). Furthermore the EMC Working Party (Directive 2004/108/EC) discussed the issue on 30 June 2009 (EMC WP 15)and on 8 June 2010 (EMC WP 16).

- Equipment intended for use in potentially explosive atmospheres: Experts Working Group of the Standing Committee set-up according to ATEX Directive 94/9/EC debated on the alignment to the NLF Decision at its meetings on 23 January 2009, 22 June 2009, 16 December 2009, 7 July 2010 and 21 January 2011.

- Pressure equipment: the Working Group Pressure established under the PED (Directive 97/23/EC) and SPVD (Directive 2009//105/EC) debated on the alignment to the NLF Decision at its meetings on 16 October 2009, 31 March 2010 and 24 November 2010. Furthermore the Conformity Assessment Bodies Forum for PED/SPVD discussed the alignment on 17 and 18 November 2009, 2 and 3 March 2010, 1 and 2 June 2010.

- Measuring instruments: the Working Group on Measuring Instruments established under the MID (Directive 2004/22/EC) and NAWI (Directive 2009/23/EEC) discussed the alignment to the NLF Decision 6 July 2009, 4 November 2009, 12 March 2010, 2 July 2010 and 12 November 2010.

- Lifts: the Committee set up under Article 6(3) of the Directive 95/16/EC discussed the alignment to the NLF Decision on 10 February 2009, 1-2 March 2010 and. 17 January 2011.

- Civil explosives: The Civil Explosives Working Group established under Directive 93/15/EEC discussed the alignment to the NLF Decision at its meetings on 12 October 2009 and 22 October 2010.

- Pyrotechnic articles: The Pyrotechnics Working Group established under Directive 2007/23/EC discussed the alignment of on 27 March 2009 and 5 March 2010.

11.2. Overview of stakeholders having participated in the public and SME consultations

- The following table gives details of the number of stakeholders having participated in the SME and public consultations by category of respondents and by sector.

Table 12: Overview of stakeholders by category of respondent and by sector

	Electrical & Electronic goods	Lifts	Pressure equip	Measuring Instr.	Civil explosive.	Pyrotechnic articles	Equp. For use in explosive atmospheres
SME	332	63	78	67	8	24	25
EO	44 (14 BO)	8 (2 BO)	6	35 (8 BO)	0	1	4
NB	16	9	23	13	4	2	9
AUT	28	11	15	21	6	9	11
Users	5	1 (CO)	11	6	0	2	8

The views expressed are overall considered representative of the positions of the different stakeholder categories. Specific considerations should be taken into account regarding how representative the replies are by sector:

– Electrical and Electronic goods: replies are considered representative of industry's position in view of the overall number of responses (EO+SME). Furthermore, the main industry associations participated in the consultation and the views expressed are in line with those communicated to the Commission via other channels.

– Lifts: even if only a small part of the lift industry EO participated in the consultations, it appears that the data reflect the views of all parties in the lifts sector due to the participation of 2 business organizations representing respectively the interest of SME and big EO.

– Pressure equipment: only a small group of EO (and no BO) participated in the public consultation. This is not surprising as directives on pressure equipment cover a wide range of products and EO whose interests can hardly be represented by one main industry association. However a respectable number of SME, NB and to some extent authorities participated in the consultation and this strengthens the sectoral data. Users' replies focus on professional users rather than consumers.

– Measuring instruments: there is overall a good response (EO+SME), although most of the 35 EO replies come from a single MS. This is offset by the fact that answers from SME, NB and authorities have a much wider geographical coverage. Furthermore, participants in the consultation include the main EU-wide industry association with which the Commission has also discussed bilaterally various aspects of the alignment option.

– Civil explosives and pyrotechnic articles: there is overall a small response from EO and NB (although, in view of the small size of these sectors, the participation of SME and

authorities is not negligible). In order to cross check the representativeness of the views expressed, the Commission has had bilateral contact with some European industry associations.

– Equipment for use in potentially explosive atmospheres: there is a small response. This is because EO dealing with equipment for use in potentially explosive atmospheres deal more generally with mechanical, electrical and also telecom equipment which is then “adapted” for specific use in potentially explosive atmospheres (e.g. underground mines, chemical plants, mills).. In practice respondents may have preferred to identify themselves with other sectors (notably electrical and electronic goods). This is confirmed by the replies provided in section D of the questionnaire where many respondents indicated that they apply ATEX together with another of the directives covered by the consultation. Thus, to some extent, the interests of stakeholders dealing with this special equipment can be considered better represented then at first appears. Furthermore, the views expressed during the public consultation are in line with information the Commission has received from working parties and regulator contacts with interested parties.

12. ANNEX 4: DETAILED ANALYSIS OF INFORMATION COLLECTED

This annex contains some detailed analysis of information collected via different information sources (public consultation of stakeholders, SME consultation, analysis based on the Commission database of NB and figures provided by EA).

In what follows, the expressions “Action 1”, “Action 2” and “Action 3” refer to the content of the policy measures which are respectively intended to address problems of non-compliance, to ensure the quality of the work performed by notified bodies and intended to ensure more consistency amongst the directives.

12.1. Non-compliance with product requirements

12.1.1. Problem Description

Table 13: Differences in approaches of national market surveillance authorities (EO replies)

	Number of requested records	% Requested records (77)	% of total number records (98)
MSA in different EU countries do not impose the same obligations on importers	46	59,74%	46,94%
MSA in different EU countries do not impose the same obligations on distributors	49	63,64%	50,00%
MSA in different EU countries do not impose the same obligations on manufacturers	56	72,73%	57,14%
MSA in EU countries act differently when they deal with products presenting a risk (i.e. when they verify if products comply with legal requirements and when they address any risk found)	42	54,55%	42,86%
The same product may be withdrawn from market or otherwise restricted in an EU country and supplied freely in another	36	46,75%	36,73%
When a safeguard clause procedure is launched, not all EU countries follow Commission opinion	10	12,99%	10,20%
Other	9	11,69%	9,18%

Table 14: Differences in approaches of national market surveillance authorities (AUT replies)

	Number of requested records	% of total number records (101)
MSA in different EU countries do not impose the same obligations on importers	33	32,7%
MSA in different EU countries do not impose the same obligations on distributors	30	29,7%
MSA in different EU countries do not impose the same	29	28,7%

obligations on manufacturers		
MSA in EU countries act differently when they deal with products presenting a risk (i.e. when they verify if products comply with legal requirements and when they address any risk found)	41	40,6%
The same product may be withdrawn from market or otherwise restricted in an EU country and supplied freely in another	31	30,7%
When a safeguard clause procedure is launched, not all EU countries follow Commission opinion	4	4%
Other	7	6,9%

12.1.2. Assessment of impacts

12.1.2.1.Internal Market

- Answer to EO consultation (questions B11.3 “Impact of the following elements of Action 1 on well-functioning of the internal market (i.e. creation of a level playing field within the EU where economic operators are subject to the same rules and the same market surveillance procedure regardless of the country they are active in”): The large majority of EO participating in the consultation (i.e. from 65% to 76% depending on the element of Action 1) considers that this policy action will have some positive impact on the well-functioning of the internal market. Furthermore, the majority of those having identified a positive impact evaluate the impact as significant. The % of those believing that the policy action will have no, or no significant, impact remains below 10% except for post-marketing obligations on manufacturers (19%).

Table 15: Impact of Action 1 on the well-functioning of the internal market (EO replies)

Obligations for importers/distributors	Number of requested records	Requested records (98)	% of total number records (98)	% of total number records (90)
No, or no significant improvement	9	(9.2%)	(9.2%)	(10%)
Moderate improvement	30	(30.6%)	(30.6%)	(33.3%)
Significant improvement	40	(40.8%)	(40.8%)	(44.4%)
Unable to evaluate impact	11	(11.2%)	(11.2%)	(12.2%)
N/A	8	(8.2%)	(8.2%)	-
Traceability obligations	**Number of requested records**	**Requested records (98)**	**% of total number records (98)**	**% of total number records (90)**
No, or no significant improvement	7	(7.1%)	(7.1%)	(7.8%)
Moderate improvement	38	(38.8%)	(38.8%)	(42.2%)
Significant improvement	37	(37.8%)	(37.8%)	(41.1%)
Unable to evaluate impact	8	(8.2%)	(8.2%)	(8.9%)
N/A	8	(8.2%)	(8.2%)	-
Post marketing obligations on manufacturers	**Number of requested records**	**Requested records (98)**	**% of total number records (98)**	**% of total number records (90)**
No, or no significant improvement	19	(19.4%)	(19.4%)	(21.1%)
Moderate improvement	30	(30.6%)	(30.6%)	(33.3%)
Significant improvement	34	(34.7%)	(34.7%)	(37.8%)
Unable to evaluate impact	7	(7.1%)	(7.1%)	(7.8%)
N/A	8	(8.2%)	(8.2%)	-
Common safeguard (market surveillance) procedures across the EU to deal with products presenting a risk	**Number of requested records**	**Requested records (98)**	**% of total number records (98)**	**% of total number records (90)**
No, or no significant improvement	6	(6.1%)	(6.1%)	(6.7%)
Moderate improvement	27	(27.6%)	(27.6%)	(30%)
Significant improvement	47	(48%)	(48%)	(52.2%)
Unable to evaluate impact	10	(10.2%)	(10.2%)	(11.1%)
N/A	8	(8.2%)	(8.2%)	-

- Answer to NB consultation (questions B11.3): As for EO, the large majority of NB participating in the consultation (i.e. from 71% to 77% depending on he element of Action 1) considers that this policy action will have some positive impact on the well-functioning of the internal market. Furthermore, the majority evaluate the impact as significant. The % of those believing that the policy action will have no, or no significant, impact remains below 10% for all elements of the policy action.

- Answer to authorities consultation (questions B11.3: As for EO and NB, the large majority of authorities participating in the consultation (i.e. from 60% to 72% depending on the element of Action 1) consider that this policy action will have some positive impact on the well-functioning of the internal market. As regards the scale of this positive impact, the answers are slightly more nuanced than for EO and NB: half or more of these authorities still evaluate the impact of obligations on imports/distributors, traceability obligations and common safeguard procedures as significant, while as regards post-marketing obligations the percentage is a bit lower (about 40%). The % of those believing that the policy action will have no, or no significant, impact remains below 10% except for post-marketing obligations on manufacturers (16.8%).

- Findings per sector: The fact that the majority of stakeholders consider that this action will improve to some extent the functioning of the internal market is broadly confirmed when looking at replies provided by all respondents (EO, NB and competent authorities) for each sector.

Table 16: Impact of Action 1 on the well-functioning of the internal market (EO replies per sector)

	Electrical & Electronic goods (88)	Lifts (28)	Pressure equip (44)	Measuring Instr. (69)	Civil explosives (10)	Pyrotech. Articles (12)	Equip. for use in explosive atmospheres (24)
Obligations for importers/distributors							
No, or no significant improvement	10%	7%	0%	7%	20%	0%	21%
Moderate improvement	43%	21%	32%	23%	30%	33%	21%
Significant improvement	35%	29%	50%	54%	20%	25%	38%
Unable to evaluate impact	1%	21%	9%	7%	0%	17%	17%
N/A	10%	21%	9%	9%	30%	25%	4%
Traceability obligations							
No, or no significant improvement	9%	4%	0%	4%	20%	0%	13%
Moderate improvement	43%	43%	43%	32%	20%	0%	38%

Significant improvement	34%	36%	39%	48%	30%	50%	25%
Unable to evaluate impact	2%	4%	9%	7%	0%	25%	13%
N/A	11%	14%	9%	9%	30%	25%	13%
Post marketing obligations on manufacturers							
No, or no significant improvement	26%	4%	5%	6%	50%	18%	25%
Moderate improvement	31%	54%	48%	35%	20%	18%	25%
Significant improvement	27%	25%	30%	41%	0%	27%	25%
Unable to evaluate impact	5%	4%	9%	9%	0%	18%	13%
N/A	11%	14%	9%	10%	30%	18%	13%
Common safeguard (market surveillance) procedures							
No, or no significant improvement	13%	7%	0%	1%	20%	0%	8%
Moderate improvement	34%	14%	25%	23%	20%	8%	67%
Significant improvement	38%	50%	50%	49%	30%	50%	4%
Unable to evaluate impact	5%	7%	11%	13%	0%	17%	8%
N/A	11%	21%	14%	13%	30%	25%	13%

12.1.2.2.Competitiveness of EU-firms

- Answer to EO consultation (questions B11.4: Impact of the following elements of Action 1 on the defence of the competitiveness of EU compliant firms against unfair competition of non-compliant firms): Three quarters of EO agree that action 1 will have a positive impact on the defence of the competitiveness of EU compliant firms against unfair competition of non-compliant firms. The percentage is slightly lower (62.3% for post-marketing obligations on manufacturers. Furthermore, the majority of them evaluate the impact as significant.

Table 17: Impact of Action 1 on the defence of competitiveness of EO (EO replies)

	Number of requested records	**Requested records (88)**	**% of total number records (98)**
Obligations for importers/distributors			
Moderate improvement	30	(30.6%)	(34.1%)
Significant improvement	45	(45.9%)	(51.1%)
Traceability obligations	**Number of requested records**	**Requested records (88)**	**% of total number records (98)**
Moderate improvement	32	(32.7%)	(36.4%)
Significant improvement	40	(40.8%)	(45.5%)
Post marketing obligations on manufacturers	**Number of requested records**	**Requested records (88)**	**% of total number records (98)**
Moderate improvement	19	(19.4%)	(21.8%)
Significant improvement	42	(42.9%)	(48.3%)
Common safeguard (market surveillance) procedures across the EU to deal with products presenting a risk	**Number of requested records**	**Requested records (88)**	**% of total number records (98)**
Moderate improvement	26	(26.5%)	(29.5%)
Significant improvement	46	(46.9%)	(52.3%)

- Answer to SME consultation (question 9: Do you think that the following elements of "Action 1" will give you any help in defending the competitiveness of your business against the unfair competition of non-compliant products?): very positive. From 68 to 73% of SME believe that this policy action will help them to defend the competitiveness of their business against unfair competition from non-compliant products.

Table 18: Impact of Action 1 on the defence of competitiveness of SME (SME replies)

Obligations for importers/distributors	Number of requested records	Requested records (597)	% of total number records (597)
some help	157	(26.3%)	(26.3%)
significant help	300	(50.3%)	(50.3%)
Traceability obligations	**Number of requested records**	**Requested records (597)**	**% of total number records (597)**
some help	152	(25.5%)	(25.5%)
significant help	260	(43.6%)	(43.6%)
Post marketing obligations on manufacturers	**Number of requested records**	**Requested records (597)**	**% of total number records (597)**
some help	144	(24.1%)	(24.1%)
significant help	264	(44.2%)	(44.2%)
Common safeguard (market surveillance) procedures across the EU to deal with products presenting a risk	**Number of requested records**	**Requested records (597)**	**% of total number records (597)**
some help	119	(19.9%)	(19.9%)
significant help	298	(49.9%)	(49.9%)

- Findings per sector (based on SME answers) confirm the overall analysis, despite slightly different percentages for pyrotechnic articles and equipment for use in potentially explosive atmospheres.

Table 19: Impact of Action 1 on the defence of competitiveness of SME (SME replies by sector)

	Electrical & Electronic goods (336)	Lifts (63)	Pressure equip (78)	Measuring Instr. (67)	Civil explosive. (8)	Pyrotechnic articles (24)	Equip. for use in explosive atmospheres (25)
Obligations for importers/distributors							
some help	27.1%	34.9%	28.2%	22.1%	25%	20%	8%
significant help	51.8%	34.9%	57.7%	50%	37.5%	56%	48%
Traceability obligations							
some help	25.9%	31.7%	17.9%	27.9%	50%	20%	16%
significant help	44.6%	36.5%	59%	41.2%	25%	28%	32%
Post marketing obligations on manufacturers							
some help	25.6%	28.6%	23.1%	22.1%	25%	16%	8%
significant help	41.7%	47.6%	56.4%	48.5%	37.5%	32%	40%

Common safeguard (market surveillance) procedures							
some help	17.6%	19%	24.4%	22.1%	25%	40%	12%
significant help	52.1%	54%	56.4%	41.2%	25%	36%	36%

12.1.2.3. Operating costs and administrative burden

- Answer to EO consultation (question B11.5: Impact of each element of "Action 1' on operating costs and/or administrative burden for economic operators; question B13.1 & 2 & 3 "If you answered that one or more of the elements of Action 1 may give rise to a significant increase in operating costs/administrative burden, please explain why" and "please provide an indicative estimate of the increase you expect" and " please explain how do you regard this increase in operating costs and/or administrative burden in relation to the objective of reducing non-compliance").

Overall findings: depending on the various elements of Action 1 from 11 to 42% of respondents consider there will be no, or no significant, increase in operating costs and/or administrative burden, from 32-55 % consider there will be a moderate increase, 1-5% consider that there will be a reduction, 16-26% either did not answer the question or declared themselves unable to evaluate the impact, while only the remaining 5-9% (virtually 5 to 9 respondents out of 98 EO[95]) believed that action 1 would give rise to a significant increase in operating costs and/or administrative burden.

Table 20: Impact of Action 1 on operating costs and/or administrative burden for EO (replies by general EO)

Obligations for importers/distributors	Number of requested records	Requested records (98)	% of total number records (98)	% of total number records (90)
Reduction of operating costs and/or administrative burden	1	(1%)	(1%)	(1.1%)
No, or no significant increase in operating costs and/or adm. burden	11	(11.2%)	(11.2%)	(12.2%)
Moderate increase in operating costs and/or adm. burden	54	(55.1%)	(55.1%)	(60%)
Significant increase in operating costs and/or adm. burden	6	(6.1%)	(6.1%)	(6.7%)
Unable to evaluate impact	18	(18.4%)	(18.4%)	(20%)
N/A	8	(8.2%)	(8.2%)	-

Traceability obligations	Number of requested records	Requested records (98)	% of total number records (98)	% of total number records (89)
Reduction of operating costs and/or administrative burden	2	(2%)	(2%)	(2.2%)

[95] 8 of them in the electric and electronic good sectors and 1 for the measuring instrument sectors.

No, or no significant increase in operating costs and/or adm. burden	12	(12.2%)	(12.2%)	(13.5%)
Moderate increase in operating costs and/or adm. burden	53	(54.1%)	(54.1%)	(59.6%)
Significant increase in operating costs and/or adm. burden	9	(9.2%)	(9.2%)	(10.1%)
Unable to evaluate impact	13	(13.3%)	(13.3%)	(14.6%)
N/A	9	(9.2%)	(9.2%)	-

Post marketing obligations on manufacturers	**Number of requested records**	**Requested records (98)**	**% of total number records (98)**	**% of total number records (90)**
Reduction of operating costs and/or administrative burden	4	(4.1%)	(4.1%)	(4.4%)
No, or no significant increase in operating costs and/or adm. burden	41	(41.8%)	(41.8%)	(45.6%)
Moderate increase in operating costs and/or adm. burden	31	(31.6%)	(31.6%)	(34.4%)
Significant increase in operating costs and/or adm. burden	6	(6.1%)	(6.1%)	(6.7%)
Unable to evaluate impact	8	(8.2%)	(8.2%)	(8.9%)
N/A	8	(8.2%)	(8.2%)	-

Common safeguard (market surveillance) procedures	**Number of requested records**	**Requested records (98)**	**% of total number records (98)**	**% of total number records (90)**
Reduction of operating costs and/or administrative burden	5	(5.1%)	(5.1%)	(5.6%)
No, or no significant increase in operating costs and/or adm. burden	23	(23.5%)	(23.5%)	(25.6%)
Moderate increase in operating costs and/or adm. burden	41	(41.8%)	(41.8%)	(45.6%)
Significant increase in operating costs and/or adm. burden	5	(5.1%)	(5.1%)	(5.6%)
Unable to evaluate impact	16	(16.3%)	(16.3%)	(17.8%)
N/A	8	(8.2%)	(8.2%)	-

The groups of obligations that will give rise to some additional costs, according to the majority of respondents, are obligations for importers/distributors and traceability obligations. However, among the same respondents, an overwhelming majority believed that the cost increase would be moderate.

Only a minority of respondents (17%) provided indicative estimates of the magnitude of cost increases expected: the large majority (65%) estimated the increase in cost between 0.3% and 5% of current operating costs; as to the rest, half of them (17%) provided an estimate of 10% and the other half provided estimates between 20 and 25%.

Furthermore 38% of EO participating in the consultation considered the possible cost increase quite reasonable in relation to the objective of reducing non-compliance.

This figure should be compared to the 14% of respondents considering the increase unreasonable.

Table 21: Overview of EO replies to the question "Please explain how do you regard this increase in operating costs and/or administrative burden in relation to the objective of reducing non-compliance"

	Number of requested records	Requested records (98)	% of total number records (98)	% of total number records (56)
Very reasonable	7	(7.1%)	(7.1%)	(12.5%)
Quite reasonable	30	(30.6%)	(30.6%)	(53.6%)
Quite unreasonable	9	(9.2%)	(9.2%)	(16.1%)
Not reasonable at all	5	(5.1%)	(5.1%)	(8.9%)
I don't know	5	(5.1%)	(5.1%)	(8.9%)
N/A	42	(42.9%)	(42.9%)	-

Looking at the answers of the group of EO (19 respondents) believing that at least one of the elements of action 1 would give rise to a significant increase in operating costs and/or administrative burden:

- Two thirds (13 respondents, including 4 business organisations[96]) of economic operators expecting a significant increase in costs are in the sector of electrical and electronic products; 3 respondents, including 1 small regional business organisation are in the measuring instruments sector.

- The category of economic operators most concerned appear to be manufacturers (10 respondents)

- Traceability obligations are mentioned most often (9 times) as giving rise to significant cost increases; the other groups of obligations were mentioned only 5 or 6 times.

- As regards the reasons for allegedly significant cost increases, the reason most often mentioned (16 times) is the cost of paperwork (e.g. checking documentation accompanying products, filing and storing information on products), 8 operators mentioned costs of testing and physical inspection of products, 6 respondents considered that the specific reasons for cost increases would be the translation of technical documentation (including test reports) and declaration of conformity (DoC) in all EU languages. Furthermore 1 manufacturer and a business organisation explained that a major source of costs would be the logistics involved in adding importer contact details on products shipped from third countries and suggested as an alternative indicating on products details of the EU authorised representative or the EU based manufacturer when available. However, the contact details of the EU authorised representative would not have the same value as those of the importer since the former is often only a legal consultant of the manufacturer and not involved in the commercialisation of the product; on the other hand when the EU based manufacturer is available then no imports into the EU take place and there are no importers that would be obliged to make their contacts known.

[96] Two of which representing a specific product segment in one MS, one representing a specific product segment at European level and the last one representing EO located in a third country..

- Only 5 respondents were able to provide indicative estimates of the magnitude of the increase expected. The average estimate provided is 9%.

- Slightly less than half of these respondents (42%) considered the possible new costs reasonable with respect to the desired objective, most of the rest (47%) considered them unreasonable, while the remainder took no position on this issue.

- Answer to SME consultation (question 10: "What effects do you think that the following elements of Action 1 will have on operating costs and/or administrative burden?"; question 11.a) and b): If you answered that one or more of the elements of Action 1 may give rise to a significant increase in operating costs and/or administrative burden, please explain why and please provide an indicative estimate of the increase you expect either as a percentage of current operating costs or in terms additional time spent (hours/month)

    - Overall findings: depending on the various elements of Action 1, about 21-27% of respondents considered there would be no, or no significant, increase, 21-27% considered there would be a moderate increase, 4-6% considered that would be a reduction, 15% declared themselves unable to evaluate impact, while the remaining 12-18% (from 72 to 106 respondents) believed that action 1 would give rise to a significant increase in operating costs and/or administrative burden.

    - None of the specific elements of Action 1 is expected to give rise to cost increases according to the majority or respondents.

    - Only a subgroup of respondents (134, i.e. 22%) provided indicative estimates of the magnitude of cost increases expected: 40% of them estimated the increase in cost between 1% and 5% of current operating costs; a further 30% provided estimates between 6% and 10%; a further 18% provided estimates up to 20%; the small remaining groups provided disparate estimates ranging from 25% to 60%.

Table 22: Impact of Action 1 on operating costs and/or administrative burden for SME (replies by SME)

Obligations for importers/distributors	Number of requested records	Requested records (597)	% of total number records (597)
reduction of operating costs and/or administrative burden	35	(5.9%)	(5.9%)
no or no significant increase in operating costs and/or administrative burden	160	(26.8%)	(26.8%)
moderate increase in operating costs and/or administrative burden	196	(32.8%)	(32.8%)
significant increase in operating costs and/or adm. burden	73	(12.2%)	(12.2%)
unable to evaluate impact	87	(14.6%)	(14.6%)
Traceability obligations	**Number of requested records**	**Requested records (597)**	**% of total number records (597)**
reduction of operating costs and/or administrative burden	25	(4.2%)	(4.2%)

no or no significant increase in operating costs and/or administrative burden	162	(27.1%)	(27.1%)
moderate increase in operating costs and/or administrative burden	182	(30.5%)	(30.5%)
significant increase in operating costs and/or adm. burden	90	(15.1%)	(15.1%)
unable to evaluate impact	86	(14.4%)	(14.4%)

Post marketing obligations on manufacturers	Number of requested records	Requested records (597)	% of total number records (597)
reduction of operating costs and/or administrative burden	25	(4.2%)	(4.2%)
no or no significant increase in operating costs and/or administrative burden	140	(23.5%)	(23.5%)
moderate increase in operating costs and/or administrative burden	177	(29.6%)	(29.6%)
significant increase in operating costs and/or adm. burden	106	(17.8%)	(17.8%)
unable to evaluate impact	93	(15.6%)	(15.6%)

Common safeguard (market surveillance) procedures	Number of requested records	Requested records (597)	% of total number records (597)
reduction of operating costs and/or administrative burden	36	(6%)	(6%)
no or no significant increase in operating costs and/or administrative burden	124	(20.8%)	(20.8%)
moderate increase in operating costs and/or administrative burden	141	(23.6%)	(23.6%)
significant increase in operating costs and/or adm. burden	72	(12.1%)	(12.1%)
unable to evaluate impact	166	(27.8%)	(27.8%)

- Findings per sector: Looking at the answers of the group of SME (175) believing that at least one of the elements of action 1 would give rise to a significant increase in operating costs and/or administrative burden: 57% of respondents belong to the electrical and electronic goods sector, about 12% respectively to those of measuring instruments and pressure equipment, while 9% to pyrotechnic articles. It should be noted that these figures more or less mirror the proportion of overall respondents from those sectors. SME in pyrotechnic articles sector appear more concerned about cost increases, related obligations for importers and distributors and to traceability obligations.

12.1.2.4.Comparison between costs and benefits for EO and SME

In order to facilitate comparison between costs and benefits for EO and to better demonstrate that the burdens for SME would not be disproportionate, the following tables show the views expressed by shareholders as regards the extent of the possible positive and negative impacts of the alignment.

Table 23: Comparisons of perceived costs and benefits for general Economic Operators (EO)

	Benefits (B)	**Costs (C)**	**C/B Comparison**	**View of EO on overall C /B balance**[97]
	Defence of competitiveness (i.e. Reduction in losses due to unfair competition identified in Figure 1, p.19)	Increase in operating costs and/or adm. burden		
Obligations on importers and distributors	Significant improvement (46% EO) Moderate improvement (31%)	Significant increase (6% EO) Moderate increase (55%)	1) More respondents pointing to benefits than respondents pointing to cost increase 2) Most frequent view: significant improvement vs moderate costs	Reasonable (38%) Unreasonable (14%)
Traceability	Significant improvement (41% EO) Moderate improvement (33%)	Significant increase (10% EO) Moderate increase (54%)	Same as above	
Post-marketing obligation on manufacturers	Significant improvement (43% EO) Moderate improvement (19%)	Significant increase (6% EO) Moderate increase (32%)	Same as above	
Common safeguard (market surveillance) procedures	Significant improvement (47% EO) Moderate improvement (27%)	Significant increase (5% EO) Moderate increase (42%)	Same as above	

[97] Answers to question: "Please explain how do you regard this increase in operating costs and/or adm. burden in relation to the objective of reduction non-compliance". The question was not asked to SME who received a shorter questionnaire.

Table 24: Comparisons of perceived costs and benefits for SME

	Benefit (B)	Costs (C)	C/B Comparison
	Defence of competitiveness (i.e. Reduction in losses due to unfair competition identified in Figure 1, p.19)	Increase in operating costs and/or adm. burden	
Obligations on Importers and Distributors	Significant help (50% SME) Some help (25%)	Significant increase (12% EO) Moderate increase (33%)	1) More respondents pointing to benefits than respondents pointing to cost increase 2) Most frequent view: significant improvement vs moderate costs
Traceability	Significant help (44%) Some help (26%)	Significant increase (15% EO) Moderate increase (30%)	Same as above. 3) Less than the majority of SME identifies possible cost increase
Post-marketing obligation on manufacturers	Significant help (44%) Some help (24%)	Significant increase (18% EO) Moderate increase (30%)	Same as above.
Common safeguard (market surveillance) procedures	Significant help (50%) Some help (20%)	Significant increase (12% EO) Moderate increase (24%)	Same as above.

The burden of the proposed measures will not be disproportionate either on EO in general or on SME. As regards the proportionality of the proposed measures, it is perhaps also useful to recall that the new obligations normally build on principles already presented via guidance (good practices for responsible operators) or clarify/expand the content of existing obligations. Therefore compliance with the aligned rules is not expected to require economic operators (including SME) to set-up significant new procedures. Furthermore, the alignment does not modify any of the currently applicable technical product requirements. The fact that a remarkable share of SME does not expect cost increases (and certainly not significant ones) supports this conclusion.

Furthermore the new obligations already incorporate a strong element of proportionality, as they have been designed to make economic operators at different levels of the value chain (e.g. an SME distributing a product vs a big manufacturer) only accountable for aspects linked to their actual scope of action (e.g. a distributor will basically only verify if the product bears the conformity marking and that it is accompanied by the required documentation and instructions, while the manufacturer will remain responsible for showing compliance).

12.1.2.5.Public authorities

- Answer to EO consultation (question B11.1: "Impact of the following elements of Action 1 on the level of non-compliance"): between 67% and 71% of EO participating in the public consultation consider that this policy action will have a positive impact on the level of non-compliance (proxy for increase in effectiveness of enforcement activities). Between 9 and 15% of respondents believed this would not be the case. The majority of EO having identified a positive improvement evaluated the contribution given by traceability obligations as significant, while evaluating the contribution given by the other elements as being more moderate.

Table 25: Impact of Action 1 on level of non-compliance (replies by EO)

Obligations for importers/distributors	Number of requested records	Requested records (98)	% of total number records (98)	% of total number records (90)
No, or no significant improvement	15	(15.3%)	(15.3%)	(16.7%)
Moderate improvement	45	(45.9%)	(45.9%)	(50%)
Significant improvement	23	(23.5%)	(23.5%)	(25.6%)
Unable to evaluate impact	7	(7.1%)	(7.1%)	(7.8%)
N/A	8	(8.2%)	(8.2%)	-

Traceability obligations	Number of requested records	Requested records (98)	% of total number records (98)	% of total number records (91)
No, or no significant improvement	16	(16.3%)	(16.3%)	(17.6%)
Moderate improvement	27	(27.6%)	(27.6%)	(29.7%)
Significant improvement	39	(39.8%)	(39.8%)	(42.9%)
Unable to evaluate impact	9	(9.2%)	(9.2%)	(9.9%)
N/A	7	(7.1%)	(7.1%)	-

Post marketing obligations on manufacturers	Number of requested records	Requested records (98)	% of total number records (98)	% of total number records (90)
No, or no significant improvement	14	(14.3%)	(14.3%)	(15.6%)
Moderate improvement	39	(39.8%)	(39.8%)	(43.3%)
Significant improvement	28	(28.6%)	(28.6%)	(31.1%)
Unable to evaluate impact	9	(9.2%)	(9.2%)	(10%)
N/A	8	(8.2%)	(8.2%)	-

Common safeguard (market surveillance) procedures to deal with products presenting a risk across the EU	Number of requested records	Requested records (98)	% of total number records (98)	% of total number records (90)
No, or no significant improvement	9	(9.2%)	(9.2%)	(10%)
Moderate improvement	43	(43.9%)	(43.9%)	(47.8%)
Significant improvement	27	(27.6%)	(27.6%)	(30%)
Unable to evaluate impact	11	(11.2%)	(11.2%)	(12.2%)
N/A	8	(8.2%)	(8.2%)	-

- Answer to NB consultation (question B11.1: "Impact of the following elements of Action 1 on the level of non-compliance): between 66% and 83% of NB participating in the public consultation considered that this policy action would have a positive impact on the level of non-compliance (proxy for increase in effectiveness of enforcement activities). Between 6% and 13% of respondents believed this would not be the case (except for post-marketing obligations for which this percentage is 21%). As regards the extent to which the alignment may improve the current situation, the views of authorities having identified a positive impact were more or less equally shared between significant and moderate impact.

- Answer to authorities consultation (question B11.1: " Impact of the following elements of Action 1 on the level of non-compliance): between 57% and 71% of authorities participating in the public consultation considered that this policy action would have a positive impact on the level of non-compliance (proxy for increase in effectiveness of enforcement activities) Between 6 and 14% of respondents believed this would not be the case. As regards the extent to which the alignment may improve current situation, the majority of NB having identified a positive impact considered the impact as significant (except for traceability obligations, the views of these NB are almost equally distributed between 'moderate' and 'significant').

Table 26: Impact of Action 1 on level of non-compliance (replies by authorities)

Obligations for importers/distributors	Number of requested records	Requested records (101)	% of total number records (101)	% of total number records (82)
No. or no significant improvement	12	11.9%	11.9%	14.6%
Moderate improvement	34	33.7%	33.7%	41.5%
Significant improvement	32	31.7%	31.7%	39.0%
Unable to evaluate impact	4	4.0%	4.0%	4.9%
N/A	-	-	18.8%	-
Traceability obligations	Number of requested records	Requested records (101)	% of total number records (101)	% of total number records (82)
No. or no significant improvement	6	5.9%	5.9%	7.2%
Moderate improvement	36	35.6%	35.6%	43.4%

Significant improvement	36	35.6%	35.6%	43.4%
Unable to evaluate impact	5	5.0%	5.0%	6.0%
N/A	-	-	17.8%	-
Post marketing obligations on manufacturers	**Number of requested records**	**Requested records (101)**	**% of total number records (101)**	**% of total number records (82)**
No. or no significant improvement	14	13.9%	13.9%	16.7%
Moderate improvement	41	40.6%	40.6%	48.8%
Significant improvement	17	16.8%	16.8%	20.2%
Unable to evaluate impact	12	11.9%	11.9%	14.3%
N/A	-	-	16.8%	-
Common safeguard (market surveillance) procedures to deal with products presenting a risk across the EU	**Number of requested records**	**Requested records (101)**	**% of total number records (101)**	**% of total number records (82)**
No. or no significant improvement	10	9.9%	9.9%	12.8%
Moderate improvement	30	29.7%	29.7%	38.5%
Significant improvement	28	27.7%	27.7%	35.9%
Unable to evaluate impact	10	9.9%	9.9%	12.8%
N/A	-	-	22.8%	-

- Answer to user consultation (question B11.1: " Impact of the following elements of Action 1 on the level of non-compliance): 73% to 80% of users participating in the public consultation consider that the different elements of this policy action will have a positive impact on the level of non-compliance As regards the extent to which the alignment may improve current situation, the majority of users having identified a positive impact considered the impact as significant, except for traceability obligations.

12.1.2.6.Consumers and households; professional users

- Answer to users consultation: (question B 6 "Do you think that this sector is affected by non-compliance?"; question B5.1: "do you think that the problem of non-compliance affects negatively end-users in this sector?"; question B11.1:"impact of Action 1 on the level of non-compliance")

  The large majority of users (64%) indicated that they consider the relevant sectors to be affected by the problem of non-compliance; only 12% considered that this was not the case. Furthermore, 60% considered that non-compliance is damaging users to some extent and estimated the seriousness of the damage as either significant (a third of them) or moderate (two thirds); only 3% considered that non-compliance was not negatively affecting users; the remaining users did not reply to this question.

Specific examples of damages provided by respondents (quotations):

Electrical and electronic good sector: 3 to 5 % of the primary costs are necessary to balance non-compliance (professional user).

Measuring instruments: if the product does not pass the control prescribed, then the users cannot rely on the claimed quality and duration (professional user organisation). Estimates unknown, but it is quite clear that non-compliance can allow fraudulent weightings, implying bad prices and economical damage for users (professional users).

Lifts: lack of accessibility [e.g. for disabled and old people] and safety (consumer organisation).

Pressure equipment:

- Increased safety risk from catastrophic failure if materials used are prone to brittle fracture. Reduced service life for equipment if materials used have reduced corrosion resistance. Production loss resulting from need to repair non-compliant equipment during service (professional user organisation).

- Non compliant products may lead to: i) delayed putting into operation ii) interrupted chemical production (professional user).

- Project delays; replacement costs and often interim temporary measures put in place to resume production; increased hydrocarbon leaks leading to higher risks (professional user). Relationship with authorities, final users must prove that products are in accordance with law and standard regulations in Europe; potential injuries or fatalities when such products are in production with toxic or inflammable liquid or gas (professional user).

ATEX: more expensive spare parts. Manufacturers only allow maintenance by the manufacturer's personnel. Equipment that does not fall under the guidelines was sold at a higher price (more than 50%). Discussions with supplier over the conformity cost a lot of money (professional user).

12.1.2.7.Public health and safety

- Replies provided by stakeholders of all sectors, except measuring instruments to question B11.2 "Impact of the following elements of Action 1 on health and safety conditions for consumers and workers dealing with products in this sector [this question does not apply to the measuring instruments sector]".

Table 27: Impact of Action 1 on health and safety (replies by EO)

Obligations for importers/distributors	Number of requested records	Requested records (36)	% of total number records (98)
No, or no significant improvement	8	(22.2%)	(8.2%)
Moderate improvement	19	(52.8%)	(19.4%)
Significant improvement	2	(5.6%)	(2%)
Unable to evaluate impact	7	(19.4%)	(7.1%)
Traceability obligations	**Number of requested records**	**Requested records (36)**	**% of total number records (98)**
	9	(25%)	(9.2%)
	19	(52.8%)	(19.4%)
Significant improvement	5	(13.9%)	(5.1%)
Unable to evaluate impact	3	(8.3%)	(3.1%)
Post marketing obligations on manufacturers	**Number of requested records**	**Requested records (36)**	**% of total number records (98)**
No, or no significant improvement	13	(36.1%)	(13.3%)
Moderate improvement	15	(41.7%)	(15.3%)
Significant improvement	6	(16.7%)	(6.1%)
Unable to evaluate impact	2	(5.6%)	(2%)
Common safeguard (market surveillance) procedures to deal with products presenting a risk across the EU	**Number of requested records**	**Requested records (36)**	**% of total number records (98)**
No, or no significant improvement	6	(16.7%)	(6.1%)
Moderate improvement	14	(38.9%)	(14.3%)
Significant improvement	14	(38.9%)	(14.3%)
Unable to evaluate impact	2	(5.6%)	(2%)

Table 28: Impact of Action 1 on health and safety (replies by NB)

Obligations for importers/distributors	Number of requested records	Requested records (60)	% of total number records (76)
No, or no significant improvement	5	(8.3%)	(6.6%)
Moderate improvement	21	(35%)	(27.6%)
Significant improvement	25	(41.7%)	(32.9%)
Unable to evaluate impact	5	(8.3%)	(6.6%)
Traceability obligations	**Number of requested records**	**Requested records (60)**	**% of total number records (76)**
No, or no significant improvement	4	(6.7%)	(5.3%)
Moderate improvement	24	(40%)	(31.6%)
Significant improvement	23	(38.3%)	(30.3%)
Unable to evaluate impact	5	(8.3%)	(6.6%)
Post marketing obligations on manufacturers	**Number of requested records**	**Requested records (60)**	**% of total number records (76)**
No, or no significant improvement	8	(13.3%)	(10.5%)
Moderate improvement	19	(31.7%)	(25%)
Significant improvement	24	(40%)	(31.6%)
Unable to evaluate impact	5	(8.3%)	(6.6%)
Common safeguard (market surveillance) procedures to deal with products presenting a risk across the EU	Number of requested records	Requested records (60)	% of total number records (76)
No, or no significant improvement	2	(3.3%)	(2.6%)
Moderate improvement	19	(31.7%)	(25%)
Significant improvement	27	(45%)	(35.5%)
Unable to evaluate impact	8	(13.3%)	(10.5%)

Table 29: Impact of Action 1 on health and safety (replies by authorities)

Obligations for importers/distributors	Number of requested records	Requested records (66)	% of total number records (101)
No, or no significant improvement	12	(18.2%)	(11.9%)
Moderate improvement	17	(25.8%)	(16.8%)

Significant improvement	21	(31.8%)	(20.8%)
Unable to evaluate impact	6	(9.1%)	(5.9%)

Traceability obligations	Number of requested records	Requested records (66)	% of total number records (101)
No, or no significant improvement	12	(18.2%)	(11.9%)
Moderate improvement	22	(33.3%)	(21.8%)
Significant improvement	19	(28.8%)	(18.8%)
Unable to evaluate impact	5	(7.6%)	(5%)

Post marketing obligations on manufacturers	Number of requested records	Requested records (66)	% of total number records (101)
No, or no significant improvement	10	(15.2%)	(9.9%)
Moderate improvement	24	(36.4%)	(23.8%)
Significant improvement	17	(25.8%)	(16.8%)
Unable to evaluate impact	6	(9.1%)	(5.9%)

Common safeguard (market surveillance) procedures to deal with products presenting a risk across the EU	Number of requested records	Requested records (66)	% of total number records (101)
No, or no significant improvement	10	(15.2%)	(9.9%)
Moderate improvement	24	(36.4%)	(23.8%)
Significant improvement	16	(24.2%)	(15.8%)
Unable to evaluate impact	6	(9.1%)	(5.9%)

12.2. Performance of Notified Bodies

12.2.1. Assessment of impacts

12.2.1.1.Internal Market

Replies to public consultation, question C25.3: "Impact of the following elements of Action 2 on well-functioning of the internal market (i.e. creation of a level playing field within the EU where economic operators are subject to conformity assessment carried out according to the same level of quality regardless of the country in which they are active and of the specific Notified Bodies providing the service)".

- Answer to EO consultation: Two thirds (64%) of EO that have recourse to the services of NB considered that action 2 would have a positive impact on internal market. Only 7-8% of respondents believed action 2 would have no or no significant impact. The strongest positive impact was attributed to the reinforcement of notification requirements for NB for which 41% of respondents expected a significant improvement.

Table 30: Impact of Action 2 on the well-functioning of the internal market

Reinforcement of notification requirements for NB	Number of requested records	Requested records (87[98])
No or no significant improvement	6	(6.9%)
Moderate improvement	20	(23%)
Significant improvement	36	(41.4%)
Unable to evaluate impact	5	(5.7%)
Revised procedures for notification	**Number of requested records**	**Requested records (87)**
No or no significant improvement	6	(6.9%)
Moderate improvement	37	(42.5%)
Significant improvement	18	(20.7%)
Unable to evaluate impact	6	(6.9%)
Information obligations on NB	**Number of requested records**	**Requested records (87)**
No or no significant improvement	7	(8%)
Moderate improvement	43	(49.4%)
Significant improvement	13	(14.9%)
Unable to evaluate impact	4	(4.6%)

- Answer to NB consultation: from 65 to 78% of NB considered that these three elements of action 2 wouldl contribute to the creation of a level playing field within the EU where economic operators are subject to conformity assessment carried out according to the same level of quality regardless of the country in which they are active and of the specific NB providing the service. Between 12 and 22% of NB participating in the consultation believed this would not be the case. Among the respondents having identified a positive impact, the majority qualified the extent of the positive impact as 'moderate' (as opposed to 'significant').

- Answer to authorities' consultation: from 59 to 66% of authorities believed in a positive impact on the internal market; from 9 to 16% did not. Among the respondents having identified a positive impact, the majority qualified the extent of the positive impact as 'significant' (as opposed to 'moderate').

12.2.1.2.Competitiveness of EU-firms

- Answer to EO consultation (Replies to question C25.4: "Impact of the following elements of Action 2 on the defence of the competitiveness of EU compliant firms against unfair competition of non-compliant firms): 60-62% of EO participating in the consultation believed this policy action would help defend the competiveness of EU business vis-à-vis unfair competition from non-compliant products; only 6-9% believed this would not be the case. The remainder did not take a position on this issue

[98] Only the replies of EO that declared to make use of NB's services have been taken into account.

Table 31: Impact of Action 2 on the defence of competitiveness

Reinforcement of notification requirements for NB	Number of requested records	Requested records (87)
No or no significant improvement	6	(6.9%)
Moderate improvement	17	(19.5%)
Significant improvement	37	(42.5%)
Unable to evaluate impact	4	(4.6%)
N/A	23	(26%)
Revised procedures for notification	**Number of requested records**	**Requested records (87)**
No or no significant improvement	5	(5.7%)
Moderate improvement	34	(39.1%)
Significant improvement	20	(23%)
Unable to evaluate impact	6	(6.9%)
N/A	22	(25%)
Information obligations on NB	**Number of requested records**	**Requested records (87)**
No or no significant improvement	8	(9.2%)
Moderate improvement	35	(40.2%)
Significant improvement	17	(19.5%)
Unable to evaluate impact	4	(4.6%)
N/A	23	(26%)

- Answer to NB consultation (replies to question C20): 64% of NB participating in the consultation believed that they were affected to some extent by unfair competition from other NB which did not assess correctly the conformity of products with legal requirements; 20% believed this was not the case; 16% did not express a view.

12.2.1.3.Operating costs and administrative burden for NB

- Answer to NB consultation (replies to question C25.5 "Impact of the following elements of Action 2 on operating costs and/or administrative burden for Notified Bodies" ; question C27.1 & 2 & 3 " If you answered that one or more of the elements of Action 1 may give rise to a significant increase in operating costs/administrative burden, please explain why" & "please provide an indicative estimate of the increase you expect" & " please explain how do you regard this increase in operating costs and/or administrative burden in relation to the objective of ensuring the quality of services provided by notified bodies")

- Overall findings: depending on the various elements of Action 2 about 30-42% of respondents considered there would be no or no significant increase in operating costs and/or administrative burden, 32-37% considered that there would be a moderate increase, 1-4% considered that there would be a reduction, 5% either did not answer the question or declared themselves unable to evaluate impact, while only the remaining 14-24% (11 to 18 respondents out of 76 NB) believed that action 2 would give rise to a significant increase in operating costs and/or administrative burden.

Table 32: Impact of Action 2 on operating costs and/or administrative burden for NB

Reinforcement of notification requirements for NB	Number of requested records	Requested records (76)	% of total number records (76)	% of total number records (72)
Reduction of operating costs and/or administrative burden	3	(3.9%)	(3.9%)	(4.2%)
No or no significant increase in operating costs and/or adm. burden	23	(30.3%)	(30.3%)	(31.9%)
Moderate increase in operating costs and/or adm. burden	28	(36.8%)	(36.8%)	(38.9%)
Significant increase in operating costs and/or adm. burden	18	(23.7%)	(23.7%)	(25%)
N/A	4	(5.3%)	(5.3%)	-

Revised procedures for notification	Number of requested records	Requested records (76)	% of total number records (76)	% of total number records (72)
Reduction of operating costs and/or administrative burden	1	(1.3%)	(1.3%)	(1.4%)
No or no significant increase in operating costs and/or adm. burden	31	(40.8%)	(40.8%)	(43.1%)
Moderate increase in operating costs and/or adm. burden	24	(31.6%)	(31.6%)	(33.3%)
Significant increase in operating costs and/or adm. burden	16	(21.1%)	(21.1%)	(22.2%)
N/A	4	(5.3%)	(5.3%)	-

Information obligations on NB	Number of requested records	Requested records (76)	% of total number records (76)	% of total number records (72)
Reduction of operating costs and/or administrative burden	3	(3.9%)	(3.9%)	(4.2%)
No or no significant increase in operating costs and/or adm. burden	32	(42.1%)	(42.1%)	(44.4%)
Moderate increase in operating costs and/or adm. burden	26	(34.2%)	(34.2%)	(36.1%)
Significant increase in operating costs and/or adm. burden	11	(14.5%)	(14.5%)	(15.3%)
N/A	4	(5.3%)	(5.3%)	-

As regards the specific elements of Action 2, the reinforcement of notification requirements for NB and the revised procedure of notification appear to raise slightly more concerns than information obligations. Among those respondents expecting cost increases, the majority believed that the increase would be moderate.

Only some respondents (21%) provided indicative estimates of the magnitude of the cost increases expected. The average estimate provided was 28%, which however should be interpreted with caution since it does not seem to reflect the view expressed by the majority of respondents and because the estimates provided for specific cost items are very disparate (see below for accreditation costs).

As regards the specific reasons for cost increases, 57% of respondents did not provide any indication, 30% of respondents indicated accreditation, other respondents cited:

– Need for notification

– Increased testing and documentation

– Employment or contracting of qualified personnel

– Possible additional equipment and personnel costs due to fewer tests performed at subcontractors

– Administrative burden

– Administrative and legal costs due to the fact that EO will complain more often

From these responses it appears that NB have attributed to this policy some effects that relate more generally to technical legislation already in place that will not change with the alignment of these provisions with the NLF Decision. For instance alignment does not introduce the need for notification (which is an existing legal obligation), nor increased testing and documentation; the employment of qualified personnel will increase existing costs of NB only if they do not already employ qualified personnel; alignment does not prevent subcontracting (it only requires that NB take responsibility for work carried out by subcontractors); lastly, alignment does not increase the likelihood of complaints from EO.

As regards accreditation costs, only 5 NB provided estimates of the percentage increase in operating costs that ranged widely from 1% to 70%; while 5 more NB provided estimates of the additional time spent per month which was estimated at between 7% and 16%.

Furthermore, 37% of NB participating in the consultation considered the possible cost increase quite reasonable in relation to the objective of enhancing the quality of conformity assessment services provided, while only 16% of respondents considered the increase unreasonable.

Table 33: Overview of NB replies to question C27.3 "Please explain how you regard this increase in operating costs and/or administrative burden in relation to the objective of ensuring the quality of services provided by notified bodies in this sector"-

	Number of requested records	Requested records (76)	% of total number records (76)	% of total number records (48)
Very reasonable	3	(3.9%)	(3.9%)	(6.2%)
Quite reasonable	25	(32.9%)	(32.9%)	(52.1%)
Quite unreasonable	8	(10.5%)	(10.5%)	(16.7%)
Not reasonable at all	3	(3.9%)	(3.9%)	(6.2%)
I don't know	9	(11.8%)	(11.8%)	(18.8%)
N/A	28	(36.8%)	(36.8%)	-

- Findings per sector: the analysis of sectoral data suggests that respondents from the Lift sector are most concerned about cost increases due to revised requirements for NB and those from the measuring instruments are concerned both about NB requirements and revision of the notification process. However due to the limited data in these sectors, these results should be treated with caution.

Table 34: Overview of NB replies to question C27.3 "Please explain how you regard this increase in operating costs and/or administrative burden in relation to the objective of ensuring the quality of services provided by notified bodies in this sector" per sector

	Electrical & Electronical goods (16)	Lifts (9)	Pressure equip (23)	Measuring Instr. (13)	Civil explosive (4).	Pyrotechnic articles (2)	Equip. for use in explosive atmospheres (9)
Reinforcement of notification requirements for NB							
Reduction of operating costs and/or administrative burden	0	0	4.3	7.7	0	0	11.1
No or no significant increase in operating costs and/or adm. burden	18.8	11.1	39.1	30.8	75	50	22.2
Moderate increase in operating costs and/or adm. burden	56.2	44.4	34.8	23.1	25	0	33.3
Significant increase in operating costs and/or adm. burden	18.8	33.3	17.4	30.8	0	50	33.3
N/A							
Revised procedures for notification							
Reduction of operating costs and/or administrative burden	0	0	0	0	0	0	11.1
No or no significant increase in operating costs and/or adm. burden	31.2	33.3	43.5	38.5	75	50	44.4
Moderate increase in operating costs and/or adm. burden	43.8	44.4	34.8	23.1	25	0	11.1
Significant increase in operating costs and/or adm. burden	18.8	11.1	17.4	30.8	0	50	33.3
N/A							
Information obligations on NB							
Reduction of operating costs and/or administrative burden	0	11.1	0	0	50	0	0
No or no significant increase in operating costs and/or adm. burden	18.8	33.3	43.5	61.5	25	50	66.7
Moderate increase in operating costs and/or adm. burden	56.2	33.3	34.8	23.1	25	0	22.2
Significant increase in operating costs and/or adm. burden	18.8	11.1	17.4	7.7	0	50	11.1

- Estimates of accreditation costs

The cost basis for accreditation within the regulated sector, for instance for a conformity assessment body (CAB) wishing to be accredited in order to become a NB, is no different to that applied to those seeking accreditation in the voluntary sector. However, even for accreditation costs in the voluntary sector, it is not possible to provide a general estimate. This is because national accreditation bodies (NAB) have different fee structures based on their individual circumstances and they charge for their work at different man-day rates. Furthermore, the economic situation varies from Member State to Member State, and this will impact on the cost of accreditation through factors such as overhead costs, salary levels, travel costs, etc., in each NAB. Whether or not NAB receive government funding for accreditation activities also has a direct bearing on the man-day rate that they use, and so on the overall cost of the accreditation.

In the light of these constraints, the following table shows the analysis of accreditation fees that have been charged to its customers (laboratories, inspection bodies and certification bodies) by one specific European NAB in the last financial year. Although an accurate comparison with other NAB is not possible, it can be reasonably assumed that the fees charged by this specific NAB constitute at least a rough estimate for average accreditation fees in the EU.

The fees shown include all costs (e.g. assessment costs, annual fees, travel and subsistence of assessment staff, etc) and therefore represent the full cost to the accredited organisation for the full scope of their accredited activity. For general information, the data is based on over 2 000 among laboratories, inspection bodies, and certification bodies.

Table 35: Accreditation fees charged by one European NAB in 2010 (EUR)

Analysis of Fees paid by all Laboratories			
Indicative range of fees: from 0 to 90 000	Fees	% charged	
		More	Less
Mean Fees charged	7 213	28%	72%
Median Fees Charged	4 863	50%	50%

Analysis of Fees paid by Inspection Bodies			
Indicative range of fees: from 0 to 52 000	Fees	% charged	
	Fees	More	Less
Mean Fees charged	5 286	30%	70%
Median Fees Charged	3 839	50%	50%

Analysis of Fees paid by Certification Bodies			
Indicative range of fees: from 0 to 170 000	Fees	% charged	
		More	Less
Mean Fees charged	17 700	29%	71%
Median Fees Charged	11 168	50%	50%

Source: EA

As different CAB may ask for substantially different scopes of accreditation, the range of fees applied to a single CAB is very wide. A small CAB requesting accreditation for simple conformity assessment procedures for a limited range of products will be charged much smaller fees than a big multi-site CAB requesting accreditation for complex conformity assessment procedures over a large range of products.
However, even with those constraints, it is very useful to see what is the mean of the fees that have been charged in each conformity assessment sector, and what percentage of the bodies in

each sector is actually charged below this mean. In the most common situations the accreditation costs will have a limited impact on each of the conformity assessment certificates granted by a CAB. Furthermore, as regards the cost of accreditation, the EA stresses that conformity assessment bodies apply for accreditation the scope of which is considerably wider than that required for the NB activity. It follows that these cost are spread on a basis that is much wider and this further reduces their impact on the costs of specific services. On the other hand, it also follows that it is very difficult to identify precisely the share of accreditation costs possibly induced by the alignment of each directive to the NLF Decision.

12.2.1.4.Public authorities: benefits

- Answer to EO consultation (questions C25.1 "Impact on the level of services provided by NB"): between 62% and 83% of EO participating in the public consultation consider that this policy action will have a positive impact on the level of quality of conformity assessment services provided by NB (proxy for increase in effectiveness of notifying activities). Between 5 and 8% of respondents believed this would not be the case. The strongest positive impact was attributed to reinforcement of the notification criteria.

Table 36: Impact of Action 2 on the level of services provided by NB (replies by EO)

Reinforcement of notification requirements for NB	Number of requested records	% Requested records(87)
No or no significant improvement	6	7%
Moderate improvement	24	28%
Significant improvement	40	46%
Unable to evaluate impact	7	8%

Revised procedures for notification	Number of requested records	% Requested records(87)
No or no significant improvement	4	5%
Moderate improvement	44	51%
Significant improvement	21	24%
Unable to evaluate impact	7	8%

Information obligations on NB	Number of requested records	% Requested records(87)
No or no significant improvement	7	8%
Moderate improvement	47	54%
Significant improvement	14	16%
Unable to evaluate impact	6	7%

- Answer to NB consultation (questions C25.1 "Impact on the level of services provided by NB"): between 60% and 84% of NB participating in the public consultation consider that this policy action will have a positive impact on the level of quality of NB services proxy for increase in effectiveness of notifying activities). Between 9 and 14% of respondents believed this would not be the case (except for information obligations for which this percentage was 32%)

Table 37: Impact of Action 2 on the level of services provided by NB (replies by NB)

Reinforcement of notification requirements for NB	Number of requested records	% Requested records(76)	% of total number records(72)
No or no significant improvement	7	9%	10%
Moderate improvement	36	47%	50%
Significant improvement	28	37%	39%
Unable to evaluate impact	1	1%	1%
N/A	-	5%	-

Revised procedures for notification	Number of requested records	% Requested records(76)	% of total number records(72)
No or no significant improvement	11	14%	15%
Moderate improvement	34	45%	47%
Significant improvement	24	32%	33%
Unable to evaluate impact	3	4%	4%
N/A	-	5%	-

Information obligations on NB	Number of requested records	% Requested records(76)	% of total number records(72)
No or no significant improvement	24	32%	33%
Moderate improvement	36	47%	50%
Significant improvement	10	13%	14%
Unable to evaluate impact	2	3%	3%
N/A	-	5%	-

- Authorities consultation (questions C25.1 "Impact on the level of services provided by NBs"): between 65% and 72% of authorities participating in the public consultation considered that this policy action would have a positive impact on the level of quality of NB services (proxy for increase in effectiveness of notification activities) Between 5 and 15% of respondents believed this would not be the case. The strongest positive impact was attributed to the reinforcement of notification criteria.

Table 38: Impact of Action 2 on the level of services provided by NB (replies by authorities)

Reinforcement of notification requirements for NB	Number of requested records	% Requested records(101)	% of total number records(87)
No or no significant improvement	9	8.91%	10.34%
Moderate improvement	31	30.69%	35.63%
Significant improvement	42	41.58%	48.28%
Unable to evaluate impact	5	4.95%	5.75%
N/A	14	14%	-

Revised procedures for notification	Number of requested records	% Requested records(101)	% of total number records(86)
No or no significant improvement	5	4.95%	5.81%
Moderate improvement	39	38.61%	45.35%

Significant improvement	32	31.68%	37.21%
Unable to evaluate impact	10	9.90%	11.63%
N/A	15	15%	-

Information obligations on NB	**Number of requested records**	**% Requested records(101)**	**% of total number records(87)**
No or no significant improvement	16	15.84%	18.39%
Moderate improvement	37	36.63%	42.53%
Significant improvement	29	28.71%	33.33%
Unable to evaluate impact	5	4.95%	5.75%
N/A	14	14%	-

- SME consultation (relevant question: "15.) Do you think that the following elements of "Action 2" will help improving the level of quality of services provided by Notified Bodies in this sector?"): between 46% and 51% of SME participating in the public consultation considered that this policy action would have a positive impact on the level of quality of NB services (proxy for increase in effectiveness of notification activities). Between 13 and 14% of respondents believed this would not be the case. Between 19 and 23% of respondents considered they were unable to evaluate this impact.

Table 39: Impact of Action 2 on the level of services provided by NB (replies by SME)

Reinforcement of notification requirements for NB	**Number of requested records**	**Requested records (597)**	**% of total number records (597)**
No or no significant improvement	81	(13.6%)	(13.6%)
Moderate improvement	151	(25.3%)	(25.3%)
Significant improvement	155	(26%)	(26%)
Unable to evaluate impact	113	(18.9%)	(18.9%)

Revised procedures for notification	**Number of requested records**	**Requested records (597)**	**% of total number records (597)**
No or no significant improvement	78	(13.1%)	(13.1%)
Moderate improvement	154	(25.8%)	(25.8%)
Significant improvement	120	(20.1%)	(20.1%)
Unable to evaluate impact	135	(22.6%)	(22.6%)

Information obligations on NB	**Number of requested records**	**Requested records (597)**	**% of total number records (597)**
No or no significant improvement	75	(12.6%)	(12.6%)
Moderate improvement	133	(22.3%)	(22.3%)
Significant improvement	161	(27%)	(27%)

Unable to evaluate impact	118	(19.8%)	(19.8%)

12.2.1.5.Public authorities: costs and administrative burden

- Answer to authorities consultation (question C29: "Impact of the following elements of Action 2 on administrative burdens and/or reorganisation costs for authorities"; question C30.1 & 2 " If you answered that one or more of the elements of Action 2 may give rise to a significant increase in costs/administrative burden, please explain why"; question C31.1 & 2 " If you answered that one or more of the elements of Action 2 may give rise to a significant increase in costs/administrative burden, please explain why" & "please provide an indicative estimate of the increase you expect"): depending on the various elements of Action 2 about 26-34% of respondents considered there would be no or no significant increase in costs and/or administrative burden, 25-36% considered that there would be a moderate increase, 3-5% considered that there would be a reduction, 32-38% either did not answer the question or declared themselves unable to evaluate impact, while almost none (0-2%) believed that action 2 would give rise to a significant increase in costs and/or administrative burden.

Table 40: Impact of Action 2 on operating costs and/or administrative burden for public authorities (replies by authorities)

Requirements for notifying authorities	**Number of requested records**	**% Requested records(101)**	**% of total number records(82)**
Reduction of costs / administrative burden	5	5%	6%
No or no significant increase in costs / administrative burden	26	26%	32%
Moderate increase in costs / administrative burden	36	36%	44%
Significant increase in costs / administrative burden	2	2%	2%
Unable to evaluate impact	13	13%	16%
N/A	-	19%	-

Revised procedures for notification	**Number of requested records**	**% Requested records(101)**	**% of total number records(82)**
Reduction of costs / administrative burden	4	4%	5%
No or no significant increase in costs / administrative burden	28	28%	34%
Moderate increase in costs / administrative burden	35	35%	43%
Significant increase in costs / administrative burden	0	0%	0%
Unable to evaluate impact	15	15%	18%
N/A	-	19%	-

Information obligation on NB	**Number of requested records**	**% Requested records(101)**	**% of total number records(82)**
Reduction of costs / administrative burden	3	3%	4%
No or no significant increase in costs / administrative burden	34	34%	41%

Moderate increase in costs / administrative burden	25	25%	30%
Significant increase in costs / administrative burden	1	1%	1%
Unable to evaluate impact	19	19%	23%
N/A	-	19%	-

Only five respondents (5%) provided indicative estimates of the magnitude of cost increases expected. The average estimate provided was 20%, which however should be interpreted with caution since it does not seem to reflect the view expressed by the majority of respondents.

As regards the specific reasons for cost increase, one respondent mentioned costs of translating documents for notifications and two mentioned the need for more detailed verification of documentation required by this policy intervention.

- Findings per sector:

Table 41: Impact of Action 2 on operating costs and administrative burden of authorities per sector (replies by authorities)

	Electrical & Electronical goods (28)	Lifts (11)	Pressure equip (15)	Measuring Instr. (21)	Civil explosive (6).	Pyrotechnic articles (9)	Equip. for use in explosive atmospheres (11)
Requirements for notifying authorities							
Reduction of costs / administrative burden	3.6	0	13.3	9.5	0	0	0
No or no significant increase in costs / administrative burden	21.4	36.4	20	38.1	16.7	11.1	27.3
Moderate increase in costs / administrative burden	28.6	36.4	53.3	9.5	66.7	55.6	45.5
Significant increase in costs / administrative burden	3.6[99]	0	0	4.8[100]	0	0	0
Unable to evaluate impact	14.3	18.2	6.7	14.3	16.7	11.1	9.1
N/A	28.5	9.0	6.7	23.8	0.0	22.2	18.1
Revised procedures for notification							
Reduction of costs / administrative burden	3.6	0	6.7	9.5	0	0	0

[99] Reply provided by one authority with the generic explanation that additional administrative burden will increase cost of personnel or reduce time for other tasks.

[100] Reply provided by one authority without specific explanations.

No or no significant increase in costs / administrative burden	17.9	27.3	26.7	42.9	16.7	11.1	45.5
Moderate increase in costs / administrative burden	32.1	45.5	53.3	4.8	66.7	55.6	27.3
Significant increase in costs / administrative burden	0	0	0	0	0	0	0
Unable to evaluate impact	17.9	18.2	6.7	19	16.7	11.1	9.1
N/A	28.5	9.0	6.6	23.8	0.0	22.2	18.1

Information obligation on NB

Reduction of costs / administrative burden	3.6	0	6.7	4.8	0	0	0
No or no significant increase in costs / administrative burden	28.6	45.5	20	47.6	16.7	11.1	54.5
Moderate increase in costs / administrative burden	14.3	18.2	53.3	4.8	66.7	44.4	18.2
Significant increase in costs / administrative burden	3.6[99]	0	0	0	0	0	0
Unable to evaluate impact	21.4	27.3	13.3	19	16.7	22.2	9.1
N/A	28.5	9.0	6.7	23.8	0.0	22.3	18.2

- Estimate of number of re-notifications needed per MS and per authority:

The table below shows the distribution of NB per MS and per relevant directive. Normally MS appoint different notification authorities by areas of competence; furthermore, when a MS appoints a single notification authority for all directives, the latter usually acts mainly as a contact point for the Commission, but the notifications are underpinned by the work of sectoral authorities. Since very often authorities are competent for groups of directives concerning similar products, some of the figures in the table have been aggregated to reflect the workload of authorities responsible for 2 or 3 related directives.

The table shows that for the large majority of MS and directives the estimated number of re-notifications necessary is very small and often negligible. Germany, Italy, Poland and UK can be faced with bigger - but overall very reasonable - numbers (e.g. from 35 to 60) in two or three sectors among electrical and electronic goods, pressure equipment, measuring instruments and lifts. Only Italy and UK may be faced in one sector (measuring instruments – NAWI) with a sizeable number of re-notifications (respectively 106 and 142).

In particular, by looking at specific directives:

– For the directives on pyrotechnic articles, civil explosives and ATEX, the estimates of possible re-notifications are (largely) below 12.

– For the lifts directive figures are normally well below 21 and only Italy could be faced with almost 60 re-notifications.

– For the two directives on electrical and electronic goods jointly (EMC and LVD), for the majority of MS the numbers of possible re-notifications are well below 16; only Germany France, Italy and UK could be faced with a higher number of re-notifications (between 33 and 46).

– For the two directives on measuring instruments jointly (MID and NAWI) the number for the majority of MS is well below 25; Germany and Poland could be faced with 2 re-notifications and only Italy and UK could be faced with more significant figures of respectively 106 and 142 re-notifications.

– For the two directives on pressure equipment jointly (SVPD and PED) for the majority of MS the numbers are well below 25; Germany, Italy and UK Poland could be faced respectively with 40, 48 and 35 re-notifications.

Table 42: Number of NB per Member States and per relevant directive

Countries of NB	Total NB	BE	BG	CZ	DK	DE	EE	IE	EL	ES	FR	IT	CY	LV	LT	LU	HU	MT	NL	AT	PL	PT	RO	SI	SK	FI	SE	UK
Pyrotechnic	10	1		1		1				2	1						1		1				1		1			
Civil Expl.	13	1	1	1		1				1	1						1				1		1		1	1	1	1
EMC	131	8	2	6	1	18	1		1	9	20			1			1		6	2	17	2		1	4	3	2	26
LVD	148	6	3	8	2	20	1		3	7	13	6		1	2		1		5	5	25	7	1	3	7	1	1	20
EMC+LVD		*14*	*5*	*14*	*3*	*38*	*2*	*0*	*4*	*16*	*33*	*6*	*0*	*2*	*2*	*0*	*2*	*0*	*11*	*7*	*42*	*9*	*1*	*4*	*11*	*4*	*3*	*46*
Atex	55	4	1	1	2	12				1	2	9				1	1		1	1	6		1	1	2	1	1	7
MID	140	1		1	4	18	1	1		7	4	9		1	1		1		5	1	22	7	1	2	3	1	1	48
NAWI	270	1	2	1	5	14	2	2	1	17	2	97		3	2	1	1		1	1	10	7	2	1	1	1	1	94
MID+NAWI		*2*	*2*	*2*	*9*	*32*	*3*	*3*	*1*	*24*	*6*	*106*	*0*	*4*	*3*	*1*	*2*	*0*	*6*	*2*	*32*	*14*	*3*	*3*	*4*	*2*	*2*	*142*
SPVD	95	4	4	3	1	9	1	1	10	7	3	14		3	1	1	3		1	3	4	2	2	1	6	1	1	9
PED	237	8	6	7	7	31	2	1	14	18	8	34		5	1	1	4		10	8	8	6	3	2	9	12	6	26
SPVD+PED		*12*	*10*	*10*	*8*	*40*	*3*	*2*	*24*	*25*	*11*	*48*	*0*	*8*	*2*	*2*	*7*	*0*	*11*	*11*	*12*	*8*	*5*	*3*	*15*	*13*	*7*	*35*
Lifts	192	8	5	5	2	9	1	1	12	15	21	58	1	4	3	3	3		4	2	2	5	2	4	4	4	7	7

12.2.1.6.Public health and safety

- Answer to EO consultation (questions C25.2 "Impact of the following elements of Action 2 on health and safety") 50-72% of EO participating in the consultation (excluding the measuring instrument sector) believed this policy action would help protect public health and safety; 17-25% believed this would not be the case. As for information obligations on NB, the impact was less clear. The majority of those who acknowledged a positive impact qualified it as moderate as far as notification procedures and information obligations were concerned. On the other hand, as regards NB requirements the number of EO qualifying the impact as moderate was equal to the number of EO qualifying it as significant.

Table 43: Impact of Action 2 on health and safety (replies by EO)

Reinforcement of notification requirements for NB	Number of requested records (36)	Requested records (36)
No or no significant improvement	6	(16.7%)
Moderate improvement	13	(36.1%)
Significant improvement	13	(36.1%)
Unable to evaluate impact	4	(11.1%)
Revised procedures for notification	**Number of requested records (36)**	**Requested records (36)**
No or no significant improvement	7	(19.4%)
Moderate improvement	13	(36.1%)
Significant improvement	12	(33.3%)
Unable to evaluate impact	4	(11.1%)
Information obligations on NB	**Number of requested records (36)**	**Requested records (36)**
No or no significant improvement	9	(25%)
Moderate improvement	13	(36.1%)
Significant improvement	5	(13.9%)
Unable to evaluate impact	9	(25%)

- Answer to NB consultation (question C25.2 "Impact of the following elements of Action 2 on health and safety") 73-85% of NB participating in the consultation (excluding the measuring instrument sector) believed this policy action would help protect public health and safety; 12-23% believed this would not be the case. The majority of those who acknowledged a positive impact qualified it as moderate.

Table 44: Impact of Action 2 on health and safety (replies by NB)

Reinforcement of notification requirements for NB	Number of requested records (60)	Requested records (60)
No or no significant improvement	7	(11.7%)
Moderate improvement	33	(55%)
Significant improvement	18	(30%)
Unable to evaluate impact	2	(3.3%)
Revised procedures for notification	**Number of requested records (60)**	**Requested records (60)**
No or no significant improvement	12	(20%)
Moderate improvement	27	(45%)

Significant improvement	17	(28.3%)
Unable to evaluate impact	4	(6.7%)
Information obligations on NB	**Number of requested records (60)**	**Requested records (60)**
No or no significant improvement	14	(23.3%)
Moderate improvement	29	(48.3%)
Significant improvement	15	(25%)
Unable to evaluate impact	2	(3.3%)

- Answer to authorities consultation (question C25.2 "Impact of the following elements of Action 2 on health and safety") 68-77% of authorities participating in the consultation (excluding the measuring instrument sector) believed this policy action would help protect public health and safety; 12-21% believed this would not be the case. The majority of those who acknowledged a positive impact qualified it as significant for the NB requirements and as moderate for notification procedures and information obligations.

Table 45: Impact of Action 2 on health and safety (replies by authorities)

Reinforcement of notification requirements for NB	**Number of requested records (66)**	**Requested records (66)**
No or no significant improvement	8	(12.1%)
Moderate improvement	25	(37.9%)
Significant improvement	26	(39.4%)
Unable to evaluate impact	7	(10.6%)
Revised procedures for notification	**Number of requested records (66)**	**Requested records (66)**
No or no significant improvement	10	(15.2%)
Moderate improvement	31	(47%)
Significant improvement	15	(22.7%)
Unable to evaluate impact	10	(15.2%)
Information obligations on NB	**Number of requested records (66)**	**Requested records (66)**
No or no significant improvement	14	(21.2%)
Moderate improvement	30	(45.5%)
Significant improvement	15	(22.7%)
Unable to evaluate impact	7	(10.6%)

12.3. Inconsistency of terminology

- Answers to question D38: "Which effects do you expect from clarifying and harmonising generally used notions like “placing on the market”, “manufacturer”, "importer", "distributor", etc.? (multiple choices possible)" and to question D34: "If you are applying simultaneously two or more of the ten directives concerned by this consultation, which impacts do you expect from aligning the texts of the conformity assessment procedures to the texts of the corresponding conformity assessment procedures set out in Annex II of Decision 768/2008? (multiple choices possible)".

Table 46: Impacts of Action 3 (replies by EO, NB, authorities and users- multiple choices possible)

- (a) Alignment of terminology in definitions (e.g. “placing on the market”, “manufacturer”, "importer", "distributor", etc.)

	EO	NB	Authorities
No or no significant changes	7%	10%	1%
It will make the relevant directives clearer	57%	70%	81%
It will avoid different interpretations by national authorities	80%	61%	79%
It will lead to difficulties since existing definitions by which I am concerned will be changed	3%	4%	2%
It will make the whole legal framework more confusing	5%	4%	1%
It will make the whole legal framework clearer	54%	52%	82%
It will allow more consistency throughout legislation	47%	65%	72%

- (b) Alignment of terminology in texts on conformity assessment procedures

	EO	NB	Authorities
No or no significant changes	33%	13%	16%
It will create difficulties as the conformity assessment procedures in the NLF Decision are not adequate for my sector	3%	7%	1%
It will lead to more coherence with other legislation	21%	44%	78%
It will or may reduce costs for EO	8%	27%	28%
It will or may increase costs for EO	14%	10%	10%
It will give rise to interpretation difficulties and differences in application by NB throughout the EU	4%	6%	3%
It will lead to more coherent conformity assessment carried out by NB throughout sectors	56%	48%	73%

12.4. Comparison of effectiveness of options 2 and 3

(a) Effectiveness in relation to the objective of reducing non-compliance

The formal alignment and the non legislative measures options differ only in relation to the way the measures in the NLF Decision are implemented. Therefore the categories of impacts identified for the alignment option are in principle also relevant to the non legislative measures option. However, whether the impact identified will materialise (at all or to a different degree) depends on the effectiveness of either option in relation to the objective of reducing the non-compliance of products marketed in the EU.

The option of non legislative measures is considered far less effective than the alignment option. This is because non legislative measures would not modify the current situation where responsible EO already *de facto* fulfil a number of obligations that are part of existing guidance provided to industry, while unscrupulous EO exploit the fact that this best practice is not legally binding.

This view is strongly supported by the results of the public consultation as almost three quarters of all stakeholders (EO, NB, authorities, users) having participated in it considered the option "Non legislative measures" ineffective overall.

The majority of all respondents (81%) considered the option of alignment of legal texts as quite (51%) or very (30%) effective, compared to the 17% of respondents recognising some degree of effectiveness (12% quite and 5% very effective) in the option of non-legislative measures.

Table 47: Comparison of effectiveness of the options 2 and 3 (replies by EO, NB, authorities and users)

Alignment of legal texts (option 3)

	EO	NB	Authorities	Users	Total	% over Total
Very effective	31	17	36	9	93	30%
Quite effective	46	52	43	15	156	51%
Quite ineffective	6	1	0	4	11	4%
Not effective at all	3	1	1	2	7	2%
I don't know	2	3	15	1	21	7%
N/A	10	2	6	2	20	6%
Total replies per type of respondents	98	76	101	33	308	

Non-legislative measures (option 2)

	EO	NB	Authorities	Users	Total	% over Total
Very effective	3	4	6	2	15	5%
Quite effective	6	8	19	3	36	12%
Quite ineffective	26	32	47	16	121	39%
Not effective at all	48	26	10	6	90	29%
I don't know	3	4	4	3	14	5%
N/A	12	2	15	3	32	10%
Total replies per type of respondents	98	76	101	33	308	

(b) Effectiveness in relation to strict and uniform control of NB across the EU

The alignment and the 'non legislative measures' options differ only in relation to the way they are implemented. However, whether the impact identified will manifest itself (at all or to a different degree) depends on the effectiveness of either option in relation to the objective of strict and uniform control of NB across the EU.

The Commission considers the option of non legislative measures far less effective than the alignment option. This is because national authorities would have to base their assessment of NB on non-binding requirements and it would be difficult for them to justify in a tribunal a decision not to notify a conformity assessment body that does not fulfil those requirements. Furthermore, when requesting NB to provide information on the validity of certificates provided by them or on negative conformity assessment results, national authorities would have to rely solely on NB willingness to cooperate with limited possibilities of enforcing their requests.

This view is strongly supported by the results of the public consultation, as two thirds of stakeholders (EO, NB, authorities) having participated in the consultation considered the option "Non legislative measures "as ineffective overall.

The majority of all respondents (83%) considered the option of alignment of legal texts as quite (51%) or very (32%) effective, as compared to the 21% of respondents recognising some degree of effectiveness (18% quite and 3% very effective) in the option of non-legislative measures.

Table 48: Comparison of effectiveness of options 2 and 3 (replies by EO, NB and authorities)

Alignment of legal texts (option 3)

	EO	NB	Authorities	Total	% over Total
Very effective	31	19	37	87	32%
Quite effective	41	50	48	139	51%
Quite ineffective	2	4	1	7	3%
Not effective at all	0	0	0	0	0%
I don't know	4	0	4	8	3%
N/A	20	3	11	34	12%
Total replies per type of respondents	98	76	101	275	

Non-legislative measures(option 2)

	EO	NB	Authorities	Total	% over Total
Very effective	4	3	2	9	3%
Quite effective	11	13	26	50	18%
Quite ineffective	41	36	45	122	44%
Not effective at all	18	21	12	51	19%
I don't know	4	1	5	10	4%
N/A	20	2	11	33	12%
Total replies per type of respondents	98	76	101	275	

(c) Effectiveness in relation to the problem of inconsistencies in current legislation

The Commission considers the option of non legislative measures far less effective than the alignment option for the simple reason that without formal alignment of the directives, current inconsistencies (identified in some definitions or in the terminology used for conformity assessment procedures) will not be addressed.

This view is strongly supported by the results of the public consultation, as two thirds of stakeholders (EO, NB, authorities) having participated in the consultation considered the option "Non legislative measures "as ineffective overall.

The majority of all respondents (81%) considered the option of alignment of legal texts as quite (44%) or very (37%) effective, as compared to the 27% of respondents recognising some degree of effectiveness (24% quite and 3% very effective) in the option of non-legislative measures.

Table 49: Comparison of effectiveness of options 2 and 3 (replies by EO, NB and authorities)

Alignment of legal texts (option 3)

	EO	NB	Authorities	Total	% over Total
Very effective	47	15	54	116	44%
Quite effective	29	33	35	97	37%
Quite ineffective	2	2	0	4	2%
Not effective at all	1	0	0	1	0%
I don't know	8	2	1	11	4%

N/A	11	24	11	34	13%
Total replies per type of respondents	98	76	101	263	

Non-legislative measures (option 2)

	EO	NB	Authorities	Total	**% over Total**
Very effective	3	0	6	9	3%
Quite effective	30	14	20	64	24%
Quite ineffective	40	24	51	115	44%
Not effective at all	6	12	9	27	10%
I don't know	8	2	4	14	5%
N/A	11	24	11	33	13%
Total replies per type of respondents	98	76	101	262	

13. ANNEX 5: SME TEST

(1) Consultation with SME representatives	SME were specifically consulted through the Enterprise Europe Network during the months of May and June 2010. A significant number of SME participated in the exercise. See section 1.3, as well as section 11.2 in Annex 3.
(2) Preliminary assessment of businesses likely to be affected	According to the findings of the consultation, SME are among the economic operators affected by the problems identified, i.e. non-compliance, inappropriate quality of the services provided by certain NB and inconsistent terminology of existing directives. See sections 3.1.2, 3.2.2 and 3.3.2.
(3) Measurement of the impact on SME	SME will be positively impacted by policies aiming at reducing the problems identified. In particular, this policy intervention will help defending the competiveness of compliant economic operators. The benefit of the selected option in this regards will be the same for both SME and other economic operators. As regards negative impacts, both SME and other economic operators believe that overall this policy action will not bring about significant costs increases. See sections, 6.4.2, 6.4.3.1, as well as Table 19, Table 22 and section 12.1.2.4 in Annex 3.

(4) Assess alternative options and mitigating measures	At the end of the impact assessment, there was no indication that the selected option might result in a disproportionate burden for SME. Consequently, there is no element showing the need for SME specific measures in order to ensure compliance with the proportionality principle.