

ROADMAP

Title of the initiative: Alignment to the New Legislative Framework (Decision 768/2008)
Lead DG: DG ENTR/ C1
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Initial IA screening & planning of further work

A. Context and problem definition

What is the political context of the initiative? How does this initiative relate to past and possible future initiatives, and to other EU policies?

In **August 2008** Council and European Parliament adopted the “**goods package**”, a set of horizontal measures aimed at enhancing the functioning of the internal market in goods. For the “harmonised area” (industrial sectors for which EU wide harmonised rules exist) a core aspect was to increase the safety of products on the market. The EU has over the years established strict requirements for a vast range of products like machinery, automobiles, toys, electrical products, lifts, etc in its harmonisation directives which guarantee a high level of safety for citizens. However these requirements are not always respected in practice and a considerable number of products which are not compliant have been found on the market.

To remedy this situation the “**New Legislative Framework**” was adopted. Its objective is to strengthen and complete the existing rules and to improve the way how the requirements are actually applied and enforced in practice by business and authorities. The New Legislative Framework consists of two complementary instruments, **Regulation 765/2008/EC on accreditation and market surveillance** and **Decision 768/2008/EC** establishing a **common framework for the marketing of products**.

The **Regulation** contains rules for the European policy on **accreditation** (control of the competence of laboratories and certification/inspection bodies delivering certificates in the EU) and for the policy in the field of **market surveillance** and controls of products from third countries (for safe products whatever their origin). The Regulation has become applicable on 1 January 2010.

The **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, safeguard clause, etc). These common provisions have been **reinforced** to ensure that the directives work more effectively in practice. **New elements**, like obligations for importers, have been introduced which are crucial to improve the safety of products on the market. The **Decision** is the complement to the Regulation. While the latter basically contains the obligations for Member States and their authorities to ensure that products on their market are safe and comply with the legal requirements, the Decision contains the relevant obligations to be respected by economic operators like manufacturers, importers, distributors as well as the bodies testing and certifying products.

Apart from giving more clout to EU legislation the Decision also has the objective of bringing more consistency into the whole EU regulatory framework for products. It is designed as a toolbox that contains the elements commonly used in technical harmonisation legislation in a

standardised format. These elements should be used as consistently as possible in future legislation on products. In this way the regulatory environment will become **more coherent and user-friendly** for economic operators and national authorities.

However, due to its “**sui generis**” nature the Decision does not have legal effects for economic operators, individuals or Member States. To give practical effect to its provisions they need to be integrated into the existing product legislation. The Commission is hence in the process of bringing the existing legislation up to the new standards set by the Decision. The proposal of the Commission will aim at transposing the solutions introduced in the Decision in a number of sectors covered by product harmonisation directives. The alignment of this legislation will render directly applicable to these sectors the improvements introduced by the "goods package". The **alignment to the new regulatory standards** set out in the Decision **concerns 10 directives**. The ten directives are the following:

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

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

Non-automatic Weighing Instruments Directive: Council Directive 90/384/EEC on the harmonisation of the laws of the Member States relating to non-automatic weighing instruments

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

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

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

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

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

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

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

Pyrotechnic articles Directive 2007/23/EC on the placing on the market of pyrotechnic articles

The majority of these directives aim to ensure a high level of safety of the products covered by their scope. The directive on electromagnetic compatibility protects against electromagnetic disturbance and the metrology directives guarantee the accuracy of measurements performed by measuring instruments. Apart from protecting these public interests all directives also ensure the free movement of products throughout the EU. To this end the directives have established requirements which the products must meet in order to be placed on the EU market. They also set out the procedures that manufacturers must undergo to demonstrate that their products fulfil the requirements (conformity assessment procedures). As a visible sign that the products are complying with the requirements the CE marking has to be affixed to them.

What are the main problems identified?

Reports from market surveillance authorities, conclusions drawn from joint actions or the constantly growing number of notifications received by the EU RAPEX system show that there are a significant number of products on the market, which do not fulfil the requirements set out by these directives. Certain manufactures or other actors in the distribution chain simply affix the CE marking to their products although these products do not fulfil the conditions for being CE marked. Importers and distributors are often not sufficiently aware of the applicable legislation and do not carry out the necessary verifications to ensure that they are not supplying non-compliant products.

There are also difficulties with the effective enforcement of the directives. When non-compliant products are found, market surveillance authorities often find it difficult to trace them back to the economic operators who have supplied them, and to stop further supplies of such potentially dangerous products. This problem occurs in particular when the products originate in third countries. Member States are also imposing different obligations on importers and distributors when it comes to ensuring that products meet the applicable requirements. Furthermore non-compliant products have been discovered on the EU market, national authorities have not always treated in the same manner throughout the EU.

Non-compliant products are potentially dangerous for their end-users, like consumers, workers etc. This situation has also led to a lack of trust into the CE marking and into the effectiveness of the legislation behind it. Additionally non compliance has an important economic dimension: responsible manufacturers, who respect the law, lose out to unscrupulous competitors offering cheaper products due to savings on compliance costs.

Another problem has been identified as regards the quality of services delivered by the bodies (“**notified bodies**”) which are testing, inspecting and certifying products. Eight of the ten directives concerned require the certification of products by such bodies before they can be placed on the market. Most of the notified bodies carry out their tasks in a thorough and responsible manner. However reports from business and national authorities responsible for market surveillance or for controlling notified bodies have raised doubts about the competence of certain bodies and the credibility of certificates issued by them. The competence of notified bodies is controlled by the Member State who has notified them. The approach, level of rigor and regularity of such controls however differs from one MS to the other. National authorities have also voiced concerns about the competence of subsidiaries or subcontractors located outside the EU which are often carrying out conformity assessment activities on behalf of a European notified body. Improperly carried out conformity assessment does not only entail the risk that unsafe products get to the market. It also distorts competition within the manufacturing industry. A less rigorous implementation of the procedures means that certificates can be issued at significantly lower rates. A less rigorous assessment of conformity with the legal requirements also allows manufactures to make savings on compliance costs.

The third problem to be tackled is the inconsistency of the regulatory environment for products. Products are very often covered by more than one directive, and manufactures must comply with all their requirements. This sometimes proves difficult because the directives do not use the same terminology or because the procedures for demonstrating conformity differ from one directive to the other. Sometimes definitions or legal provisions are not sufficiently precise and leave room for diverging interpretations, which leads to incompatibilities, legal uncertainty and confusion. Differences in the conformity assessment procedures can entail extra costs and extra work for the manufacturer, as he might have to undergo different

procedures or have the product tested by different notified bodies.

Is EU action justified on grounds of subsidiarity?

This initiative concerns the internal market for goods. To a large extent the aspects addressed are already regulated by the ten directives. Partly, the problems are rooted in that EU legislation, e.g. the inconsistency of terminology. 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.

B. Objectives of EU initiative

What are the main policy objectives?

The overall objective is to ensure that products on the EU market are safe and fulfil all the requirements guaranteeing a high level of protection. Furthermore this initiative also aims at simplifying the regulatory environment for products.

Specific Objectives:

- Reduce the number of non-compliant products, in particular of unsafe products
- Ensure equal treatment of non-compliant products throughout the EU market and equal treatment of economic operators in the enforcement process
- Ensure the reliability and high quality of conformity assessment activities carried out by notified bodies
- Ensure more consistency of terminology and procedural requirements throughout the directives to facilitate their interpretation and implementation

Does the objective imply developing EU policy in new areas or in areas of strategic importance?

This initiative does not introduce a new policy. It aims at strengthening and further deepening the internal market in goods.

C. Options

What are the policy options? What legislative or 'soft law' instruments could be considered? Would any legislative initiatives go beyond routine up-date of existing legislation?

Option 1, the baseline scenario, consists of not introducing any changes to the existing situation. The directives would remain unchanged.

Option 2 foresees that the directives concerned take on board the solutions set out in Decision 768/2008 to address the problems relating to non-compliance, quality of notified bodies and inconsistency in the legal framework.

Measures foreseen to address the problem of non-compliance:

- Introduction of clear obligation for importers and distributors regarding product compliance
- Introduction of traceability requirements for manufacturers, importers and distributors
- Reinforcement of the existing safeguard clause mechanism ensuring an exchange of information on non-compliant products and consistent action against such products throughout the EU

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

- Reinforcement of the notification requirements for notified bodies
- Introduction of clear requirements for subcontractors and subsidiaries
- Revised notification process including an exchange of information on the evaluation of competence of the notified body and promoting recourse to accreditation
- Introduction of the possibility for Member States to object to a notification
- Introduction of a requirement to de-notify incompetent or inactive notified bodies

Measures foreseen to ensure more consistency amongst the directives

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

Option 3 consists of a set of non regulatory instruments to address the problems relating to the presence of non-compliant product on the market and to the performance of certain notified bodies:

- Awareness campaigns for importers and distributors explaining the main elements of European legislation and the importance of ensuring compliance at all levels of the distribution chain.
- Voluntary agreement to ensure traceability throughout the distribution chain
- Voluntary agreement for notified bodies to become accredited

The problem of inconsistencies in terminology and procedures throughout the directives cannot be addressed by non-regulatory options.

Does the action proposed in the options cut across several policy areas or impact on action taken/planned by other Commission departments?

No

Explain how the options respect the proportionality principle

The options will not go beyond what is necessary to achieve the objectives.

D. Initial assessment of impacts

What are the significant impacts likely to result from each policy option (cf. list of impacts in the impact assessment guidelines), even if these impacts would materialise only after subsequent Commission initiatives?

Option 1 (Baseline scenario) - No changes

Economic impacts:

The current situation has a negative effect on the **competitive situation** of companies respecting the rules. They lose out to unscrupulous or careless competitors. The latter can get away with not observing the rules and make savings on compliance costs.

The situation is similar in the certification industry. Notified bodies delivering proper quality work are facing unfair competition from bodies which can offer their services at lower prices at the cost of the quality of the conformity assessment.

The current situation also distorts the **internal market in goods**. Different approaches taken

by national market surveillance authorities with regard to non-compliant products and to the obligations of importers and distributors leads to a different treatment of these operators. The disparities in the quality of conformity assessment bodies risk undermining the confidence in certificates and their EU wide recognition. National market surveillance authorities will feel the need to more and more question certificates which ultimately might give rise to new barriers to trade in goods.

The inconsistencies amongst the directives as regards conformity assessment procedures create **additional costs** for enterprises. Part of these costs is generated through the increased efforts to analyse the complex legal legislation, be this additional staff or working hours or the costs for external legal consultancy. More important however are the costs resulting from different procedures, which all have to be complied with and lead to additional compliance and conformity assessment costs.

Social impacts

The presence of non-compliant products on the market can seriously endanger the health and safety of their users, consumers, workers and professionals. In general however the number of accidents report in the various sectors is relatively low.

Option 2 – Aligning the directives to the new horizontal framework

Economic impacts

Option 2 will strengthen the **competitiveness** of companies which have been respecting the applicable legislation. The enhanced control obligations will lead importers and distributors to purchase their goods from reliable sources only. Unfair playing operators making savings on compliance costs will find it more difficult to sell their products. Improved traceability will render market surveillance more effective and help to find operators not respecting the rules. This will increase the deterrent effect and limit the number of illegal traders. Likewise the reinforced control of notified bodies should limit unfair competition.

This option will also have a positive impact on the **internal market** since it will ensure that economic operators, in particular importers and distributors, active in different Member States are treated equally by the national enforcement authorities. The revised safeguard clause mechanism will lead to a uniform approach throughout Member States on actions taken against non compliant products. Notified bodies should also benefit from more equal conditions regarding the assessment of their competence.

Enhanced traceability requirements and obligations for importers and distributors may lead to slight increases in the **operating costs** for companies. These costs should however be relatively insignificant in relation to the overall costs of businesses and will mainly be felt by operators who have so far not complied with the legislation.

The requirements for notified bodies may imply additional costs, in particular for non-accredited bodies which would seek accreditation in view of the new legal situation that facilitates the notification process when accreditation is used. Most notified bodies are however already accredited.

Bringing more consistency into the legislative framework should lead to a slight reduction of operating costs in particular for companies which are concerned by several directives.

The enhanced requirements for notifying conformity assessment bodies might entail budgetary consequences for **public authorities**, in particular when they are not using accreditation to assess the competence of their notified bodies.

Social impacts

Option 2 will reduce the number of non-compliant products and thereby reduce the potential

risk to the health and safety of consumers and other end-users.

Option 3 – Non regulatory instruments: Campaigns and voluntary actions on behalf of economic operators

Economic impacts

Option 3 will also have a positive effect on the competitiveness as described under option 2, however to a significantly lesser extent. Improved awareness will reduce the number of operators who have been supplying non compliant products due to ignorance of the legal situation. However the actions envisaged will not be sufficient to dissuade those operators who are deliberately playing on the ineffectiveness of market surveillance in cases with a cross border dimension

The effects on operating costs of economic operators trading goods and notified bodies linked to traceability requirements and the use of accreditation will be the same as under option 2.

Social impacts

Option 3 will reduce the number of non-compliant products and thereby reduce the potential risk to the health and safety of consumers and other end-users, however to a lesser extent than option 2.

Could the options have impacts on the EU-Budget (above 5 Mio €) and/or should the IA also serve as the ex-ante evaluation, required by the Financial Regulation?

No

Could the options have significant impacts on simplification/administrative burden or on relations with third countries?

Simplification impacts: Under the current situation (option 1) there are a number of inconsistencies amongst the ten directives concerned which make it more complex and difficult for authorities and economic operators to apply the directives, in particular when they have several directives apply to one single product.

Option 2 is expected to have a simplification effect on the regulatory environment for the European manufacturing industry. The legislation will get clearer and therefore easier to apply. Furthermore bringing more consistency into these directives will make it easier and cheaper for those manufacturers who have to comply with several of these directives.

Option 3 does not have a simplification effect, as it would not change the legislation.

Administrative burden: No significant impacts are expected under any of the options. An increase of burdens will only be felt by those economic operators who have until today not taken the necessary precautions for ensuring that they only supply compliant products and will now comply in the future under Options 2 and 3.

Relations with third countries: Option 1 will not have any implications on the relation with third countries. Options 2 and 3 will not introduce new technical rules, which could potentially be barriers to trade, but reinforces the means to ensure compliance with the existing technical rules. Under both options specific obligations for importers would be introduced (either through the law or by adhering to the voluntary agreement), which have so far not been explicitly foreseen in the directives. To varying degrees they did however exist at national level in the laws transposing the directives. Responsible importers are well informed about the applicable EU legislation and take the necessary precautions to ensure that the products they are importing are respecting the requirements. The obligations would not entail any significant

extra costs or extra burdens. An increase of burdens will only be felt by those importers who have until today not taken the necessary precautions for ensuring that they only supply compliant products and some of them might refrain from importing. This is however not expected to have an impact on trade figures.

Who is affected?

Manufacturing industry, retailers and distributors, consumers, professional users, national authorities, certification bodies and laboratories

E. Planning of further impact assessment work

What information and data is already available? What further information needs to be gathered? How will this be done (e.g. internally or by an external contractor) and by when? What type and level of analysis will be carried out (cf. principle of proportionate analysis)?

This initiative is the follow up to the adoption of the New Legislative Framework. Hence, this impact assessment can draw to a large extent on the impact assessment carried out on the revision of the horizontal framework. The objective of horizontal review was to address problems perceived globally throughout the various sectors, including the ones in question now, and to provide solutions that can work across all sectors. In this context a number of possible solutions and their impacts have already been analysed.

This impact assessment will revisit these problems and in particular the solutions suggested by the NLF from the specific perspective of every industrial sector concerned. This analysis will include a detailed description of the economic situation of every sector concerned and particular attention will be paid to the situation of SMEs.

Certain data is available internally (RAPEX statistics, reports from joint actions of administrative cooperation's groups, NANDO database..). Additional data will be gathered from stakeholder associations, through the public consultation. If necessary, recourse will be made to an external contractor.

Which stakeholders & experts have been/will be consulted, how and at what stage?

A public consultation (Your voice in Europe) will take place in the first half of 2010. To get a clear picture on the situation of SMEs, a SME business test panel will be carried out.

Furthermore there will be exchange of views with Member States experts represented in the Senior Officials Group on Standardisation and Conformity Assessment Policy (SOGS) as well as in the individual expert groups for the concerned directives

Industry and consumer associations and representatives of the certification industry, which are represented in sector specific expert groups, have already been informed about the initiative.