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COMMISSION STAFF WORKING DOCUMENT

Accompanying document to the

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL SETTING OUT THE REQUIREMENTS FOR ACCREDITATION AND MARKET SURVEILLANCE RELATING TO THE MARKETING OF PRODUCTS AND A DECISION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL ON A COMMON FRAMEWORK FOR THE MARKETING OF PRODUCTS

IMPACT ASSESSMENT

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SETTING OUT THE REQUIREMENTS FOR ACCREDITATION AND MARKET SURVEILLANCE RELATING TO THE MARKETING OF PRODUCTS

IMPACT ASSESSMENT

BACKGROUND

The proposal for a Regulation and for a complementary Decision for the marketing of products comes under item 2006/ENTR/001 of the Commission Legislative and Work Programme 2006. Stakeholders and other Commission Services concerned by the proposal have been closely involved in the preparatory process from an early stage.

In 2002, the Commission carried out an on-line consultation in order to identify elements of the New Approach which could be further improved[1]. The Commission used the results of this consultation for input to the Communication "Enhancing the Implementation of the New Approach Directives"[2] which was adopted in 2003. This Communication contained recommendations to improve the operational efficiency of the Internal Market, and therefore the competitiveness of European industry. The Communication was endorsed by the Council Resolution of 10 November 2003[3] which invited the Commission to come up with appropriate initiatives. At the Conference on the 20th Anniversary of the New Approach, in November 2005, the Commission confirmed its intention to present a proposal on the extension and review of the New Approach.

Between December 2004 and February 2006, 16 working documents covering in detail the recommendations included in the Communication, were been prepared for discussion with Member States' experts represented in SOGS[4] (Senior Officials' Group on Standardisation and Conformity Assessment Policy). These documents have also been published on the "New Approach" website of DG Enterprise[5] and were widely distributed to stakeholders. On the basis of the feedback received, a working document outlining the possible content of a

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1 http://ec.europa.eu/yourvoice/results/4/index_en.htm gives the results of the consultation Review of the New Approach.

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

3 Council Resolution of 10 November 2003 on the Communication of the European Commission Enhancing the Implementation of the New Approach Directives OJ C 282, 25.11.2003.

4 This is an informal group of experts who come together to assist the Commission in the development of policy in the areas of standardisation and conformity assessment.

5 http://ec.europa.eu/enterprise/newapproach/review_en.htm

proposal was published in May 2006 for public consultation period of 3 months.[6] This document discussed the elements for a horizontal legislative approach to technical harmonisation, and the feedback received[7] showed broad support for the measures envisaged under this initiative.

This document presents an impact assessment of the various policy options available for improving the functioning of the internal market for industrial products. The document has been prepared on the basis of data gathered from two internet consultations, four targeted questionnaires, an SME test panel[8], sector specific studies, individual case studies, literature reviews and ongoing consultations. The various problems with the functioning of the system are firstly identified, then the objectives are defined, the basic policy options are discussed with an impact analysis of each option and finally a comparison of options is made with recommendations for consideration.

1. INTRODUCTION

1.1. Harmonisation of legislation plays a key role in realising the Single Market

The realisation of the Single Market is a major driver for competitiveness and economic growth in the EU and hence constitutes a core activity of the European institutions. Since the foundation of the EU, impressive progress has been made in ensuring the free movement of goods throughout the Community. This has been achieved by different means: The jurisprudence of the Court of Justice on Article 28 EC and the mutual recognition principle, directive 98/34 preventing the introduction of new national laws which could constitute a barrier to trade and last but not least the harmonisation of technical regulation at EU level to address common legitimate environment, safety or health concerns.

The harmonisation activity has been a key priority for the Commission since the end of the 1960s which has led to the adoption of some 600 legislative texts for harmonisation covering industrial products. It is estimated that today approximately 80% of industrial production and approximately 74% of intra-EU manufacturing trade is covered by harmonisation legislation.

This process has proved to be the most effective way of eliminating technical barriers to trade, in spite of the lengthy decision making procedures. In the early days of the European Community unanimity in the Council of Ministers was necessary for decisions to be taken; however following the Single European Act in 1986, qualified majority voting was introduced which simplified things. Nevertheless, progress was perceived as being slow and so the Commission looked for other means to complete the internal market.

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6 http://ec.europa.eu/enterprise/newapproach/pdf/draft_certif_2005_16_rev2_foreword.pdf

7 Results of the consultation are available at http://ec.europa.eu/enterprise/newapproach/review_en.htm

8 The EU SME panel summarises the answers of the small and medium enterprises respondent to the wide consultation launched by the Commission via the Euro Info Centres (EICs) on CE marking, common framework for accreditation, market surveillance, traceability, obligations of economic operators, conformity assessment procedures, and notified bodies.

Inspired by the "Cassis de Dijon" judgement of the European Court of Justice, the Commission proposed a fundamentally revised new approach to harmonisation by reducing the content of legislation to cover only the essential protection requirements which the Court had indicated were the only valid reasons for a national authority to block a product from another Member State.

1.2. The "New Approach"

1.2.1. The New Approach is a flexible legislative technique.

Hence, the so called "New Approach" was born on 7 May 1985, which limited legislation to cover only essential health and safety requirements of products. This simplification was a step forward in the legislative provisions which allowed all the technical elements for product specification to be covered in harmonised European standards, not the legislation itself. Thus providing a flexible, technology neutral and non-prescriptive means of regulation. A manufacturer therefore has the flexibility in how to conform to the requirements and to demonstrate compliance. The final step being that the manufacturer applies the CE marking to identify that the product complies with the law.

Parallel to its legislative programme, the Community it also developed a policy to reinforce European standardisation, such that voluntary harmonised European standards could be developed, the conformity to which gives presumption of conformity to the legislation. Figure 1 shows the interaction between the legislation and its requirements, standards and conformity assessment and the CE marking. A full explanation of the "New Approach" system is given in Annex I.

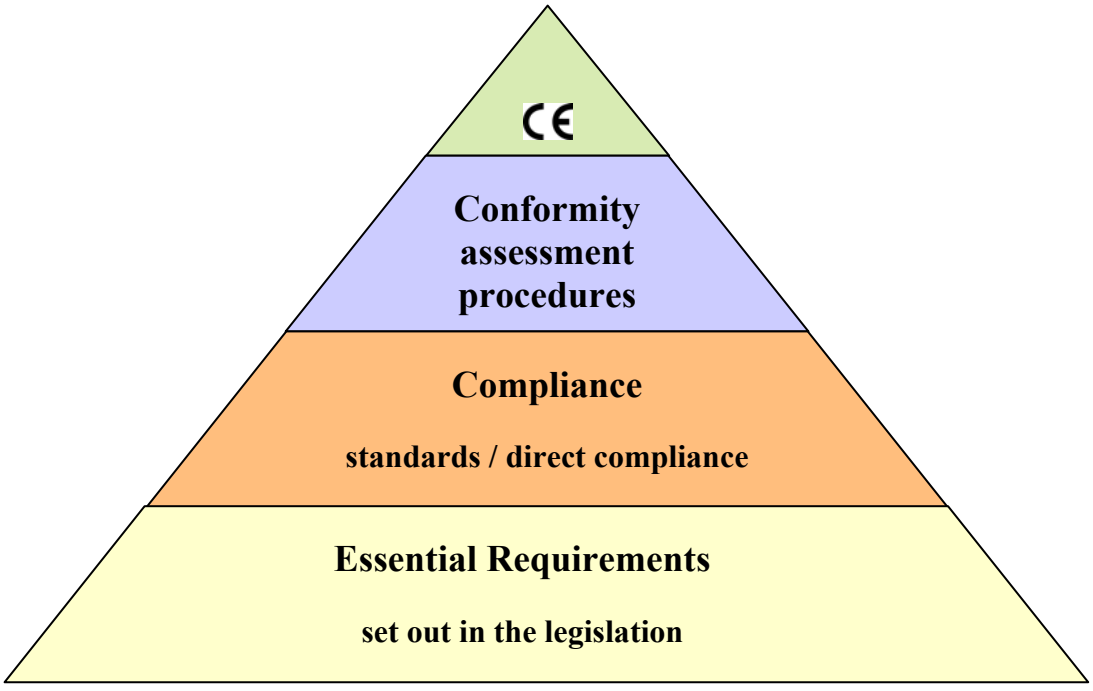

Figure 1: Schematic of New Approach concept.

Common elements covered in the legislation.

The New Approach is therefore a legislative technique used in the area of free movement of goods, particularly of industrial products. It moved away from the "Old Approach" of prescriptive detailed technical requirements written into the legislation, to providing only the essential public interest requirements to which products must comply. The result is a technology-neutral legal framework.

The New Approach was designed to be fully ***complementary*** to the old way of legislating and as such many common elements are covered but in a different way. Common elements include:

- Clear identification of scope;
- Use of common expressions, such as "placing on the market" or "manufacturer";
- Requirements which products must comply with in order to achieve the objectives of the legislation, expressed in terms of essential requirements or in detailed technical specifications included in the legislation;
- Determination of the technical means and procedures for demonstrating conformity with these requirements;
- Specific requirements for the labelling or marking of products;
- A "free movement clause", prohibiting any national measure to restrict the free movement of products which comply with the legislation, to ensure the free circulation of products throughout the EU;
- Very general market surveillance/enforcement requirements. These state Member States shall take appropriate measures to ensure that only conforming products are circulating on the market;
- A safeguard mechanism setting out the Community procedure in the case of the adoption of a national measure to restrict circulation.

1.2.2. What are the specificities of the New Approach?

As discussed above, instead of setting out detailed technical requirements in the legislation, New Approach directives limit themselves to defining essential requirements in relation to issues such as health, safety, consumer protection and the protection of the environment. The legislation fixes the level of safety which products must meet but does not pre-determine the technical solutions to achieve this level of safety. The choice of different solutions leading to the same result is therefore open to manufacturers.

Technical specifications, in the form of standards[9], coming under the framework of the New Approach directives, allow products to meet the essential requirements needed and are considered as an 'easy' way to meet compliance with the legislation (presumption of conformity). Use of standards guarantees the required level of safety of products, but use of harmonised standards is voluntary and a manufacturer may use any other technical solution which demonstrates that his product meets the essential requirements.

The directives also set out requirements for conformity assessment, which depending upon the product need to be done either by a third party testing, inspection or certification body or by the manufacturer himself. The different types of conformity assessment procedures were been identified by Decision 93/465/EEC and are set out in the form of "modules". Each directive has chosen the modules which are considered to be appropriate for demonstrating conformity, taking into account the type of risk related to the particular product.

Certain modules require the intervention of third party conformity assessment bodies, known as notified bodies. These bodies are chosen ("designated") by Member States on the basis of certain minimum criteria (competence, impartiality, integrity, etc) which are set out in the directives. They are then "notified" to the Commission, after which they are authorised to carry out conformity assessment activities according to the procedures set out in the directives.

In addition to this, the Commission has also supported the development at European level of a new evolution at national level: Accreditation. In the past, Member States public authorities approved products prior to them being placed on the market. However, national testing and certification resources were not always sufficient and the national authorities began to use the services of private conformity assessment bodies. In order to ensure that these private bodies were able to provide the correct level of service, they were submitted to the control of a national public authority body: the national accreditation body. This was devised in all Member States as a means to ensure an appropriate level of credibility for test results and product certification or inspection.

Last but not least the New Approach introduced a common marking of conformity, which has become its most visible and well known element. The CE marking is in effect a declaration by the manufacturer that the product conforms to all the essential requirements of the relevant legislation and that it has been subject to the applicable conformity assessment procedures. Since products bearing the CE marking are presumed to be in compliance with the applicable directives and hence benefit from free circulation, the CE marking operates as a "passport" to the whole EU market.

1.3. The New Approach is a good example of Better Regulation

Technical harmonisation has, in most cases, demonstrably achieved its objective of contributing to the effective completion the internal market. Today the New Approach is widely recognised as a good example of better regulation because due to

[9] Harmonised product standards are developed by the recognised European Standardisation Organisations (ESOs) CEN, CENELEC and ETSI in line with specific mandates from the Commission.

its lighter and more flexible legislative technique it has, through the adoption of only 25 directives[10], succeeded in freeing the circulation of vast industrial sectors which would probably have needed several hundreds of directives under the more traditional old approach. Today, New Approach directives cover more than 20 industrial sectors, including machinery, radio/telecoms equipment, toys, medical devices, building materials and even railway transport. The products covered represent a large proportion of products marketed in the EU, with an estimated value of more than €1500 billion per year.

The asset of the New Approach is its flexibility. Keeping the directives free from detailed specifications has facilitated a flexible legal framework, which is technology-neutral and serves as a catalyst for innovation and growth. It has allowed keeping legislation slim and avoids the need for frequent adaptations to technical progress, an important factor in a business environment which is characterised by fast developing technologies. Manufacturers are given the freedom to choose any appropriate technical and innovative solution that meets the required safety level without being pressed in legal corset running behind technology evolutions. Leaving the technical details to the standardisers ensures standards can benefit from flexibility and state-of-the-art technical expertise to keep pace with technical progress, in a way which it is impossible to do in legislation. Moreover, extensive stakeholder involvement in the writing of standards makes the New Approach an early 'co-regulatory' model for the Commission's wider 'better regulation' drive.

It is for these advantages that enhanced recourse to the techniques of the New Approach is part of the Commission's strategy to simplify the regulatory environment. The New Approach has already proved to work successfully over a broad range of industrial sectors, including sensitive products such as medical devices and machinery. There are no reasons why it should not be successfully implemented in other areas, like environmental or worker protection legislation.

1.4. Harmonisation legislation and the New Approach can still be improved

While technical harmonisation, and in particular the New Approach directives, have successfully contributed to eliminating some barriers to trade, there are still weaknesses in the legislative framework, which prevent consumers and enterprises from fully exploiting the benefits of the Internal Market.

The existing rules are often criticised as burdensome or for being uncertain or inconsistent. Also within the 25 "New Approach" directives confusion has arisen due to inconsistencies in the requirements for these various elements making it increasingly difficult for all market players and national authorities to comply. There are also problems with uniform enforcement of the legislation in Member States, the image and value of CE marking and stakeholders express an increasing lack of confidence in conformity assessment bodies.

This has resulted in a lack of credibility and confidence in the system which then leads to suspicion. As a result there have been a multiplication of demands for proof

[10] Annex II gives a list of these directives. Some sectors are covered by more than one directive.

of safety or respect of the protection requirements, and hence to over-regulation and administrative burden.

The existing legal system thus needs to be revisited and strengthened in order to reinstall the confidence of stakeholders in internal market legislation for goods and ensure that it fully delivers the desired results.

2. WHAT ARE THE PROBLEMS TO TACKLE?

Experience with the implementation of Community legislation in the area of free movement of goods has highlighted certain weaknesses and shown that the effectiveness of the system can still be improved. In 2002, the Commission carried out a public consultation inviting stakeholders to comment on the functioning of the New Approach directives. On the basis of the feedback received, the Commission adopted a Communication in March 2003 entitled "Enhancing the implementation of the New Approach directives", which sets out the main elements on which a review should concentrate:

(1) Lack of confidence in notified bodies and in the whole notification process;

(2) Weaknesses in market surveillance and efficient and consistent enforcement of the directives;

(3) Inconsistencies between different directives;

(4) Misunderstanding of the value and role of CE marking.

Most of these issues, in particular the inconsistency of the legal framework and the weaknesses in its enforcement, are not specific to the New Approach directives and also concern other harmonisation instruments. Consequently all these issues have been examined within a broader perspective going beyond simply the New Approach areas.

2.1. Performance of notified bodies and weaknesses in the notification process

Certain conformity assessment procedures require that a product is tested, inspected or certified by an independent third party, a "notified body", before it is placed on the market. Notified bodies hence play an important role within the New Approach system to guarantee the safety of products on the market. Therefore, it is crucial to ensure that they have the necessary competence and capacity to carry out their tasks correctly. Furthermore, confidence in their competence is crucial to ensure EU wide recognition of certificates issued by these bodies.

Most notified bodies do a professional and complete job. However, sometimes certain notified bodies apply practices which can undermine the confidence of this type of work in the whole sector.

2.1.1. *Uneven level of conformity assessment services provided by notified bodies*

Feedback received from targeted surveys and studies[11] indicates that notified bodies often take different approaches in assessing the conformity of products with the legislation. Manufacturers have reported that the interpretation of safety requirements as well as procedural requirements vary significantly from body to body. Manufacturers can therefore shop around for the lowest price which is not always linked to the consistency of service.

Notified bodies provide their services as a commercial activity and are in competition with each other. This has, in principle, positive effects for their customers, i.e. the manufacturers. Manufacturers are free to choose which body they would like to employ on the basis of the one offering the best service at the most competitive price. However, there is also a negative side; as notified bodies are under continuous pressure to offer competitive services, some of them may resort to unfair practices in order to attract or to keep their customers.

Evidence of unfair competition is obviously difficult to obtain, and information relies mainly on feedback and complaints received from industry and other notified bodies. 55% of respondents replying to the questionnaire addressed to notified bodies have experienced cases of unfair competition for different reasons:

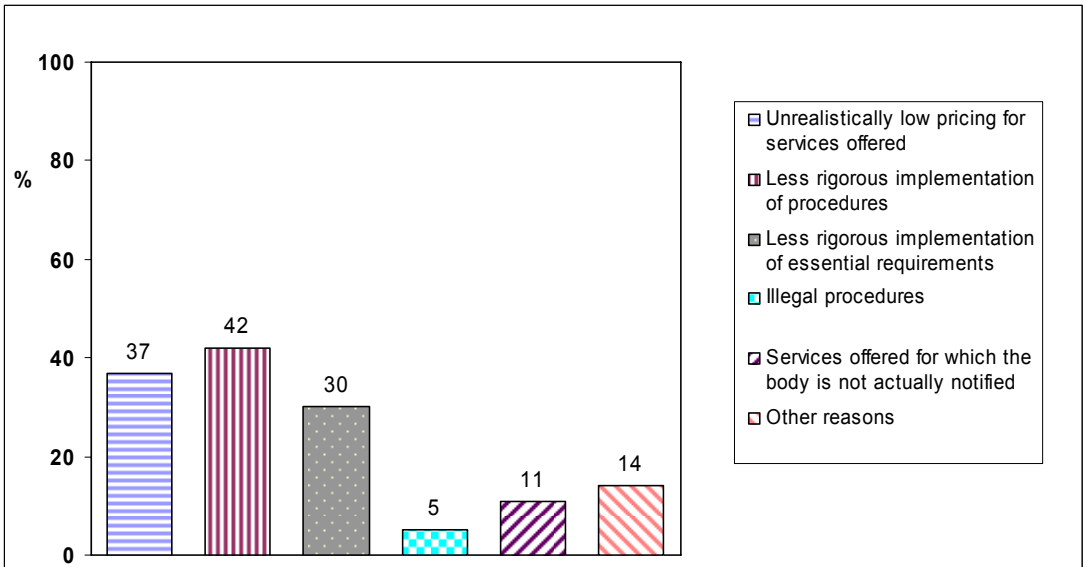

Figure 2: Reason for unfair competition

The most frequently quoted reason for unfair competition is the less rigorous implementation of procedures by some notified bodies, see figure 2. For example, the elimination or reduction of on site controls[12] or relaxed requirements for frequency of periodic audits/inspections can reduce the costs of assessments quite considerably.

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11 E.g. Medical Devices: Report on the functioning of the medical devices directive, 2002

12 The problem of reducing on-site inspections has also been highlighted in the Impact Assessment on the Proposal for a directive on common rules and standards for ship inspection and survey organizations and for the relevant activities of maritime administrations http://ec.europa.eu/governance/impact/docs/ia_2005/sec_2005_1498_fr.pdf

This enables a notified body to issue certificates at significantly lower prices. Lower prices are not per se an indicator of lower quality of the conformity assessment undertaken, however, information received from stakeholders indicates that, in some case, prices for assessment of similar products vary so much that it is difficult to believe that the assessments have been carried out correctly. While a variation in price of up to 15% is usually considered as a standard competition situation, notified bodies reported cases of between 30% and 75% lower prices, whereas SMEs report a an average variation of 48%.[13] Where a normal price for conformity assessment was approximately €2500-3000, the same services were offered by other bodies at €500. Hence there are strong indications that "dumping rates" or unrealistically low prices for services offered are frequently linked to a less stringent approach applied during the assessment. This could apply to fewer inspections or controls, cases of lax or incomplete testing, acceptance of test results from the manufacturer himself or acceptance of test results from another third party which itself does not adequately apply conformity assessment procedures.

Information from the responses to the questionnaire also inform us that notified bodies frequently lose projects or clients due to such unfair practices. They are, therefore, put under market pressure to cut their costs. This results in a downward spiral in terms of both their turnover and their quality of service. Apart from the obvious economic loss, this situation has an overarching effect of damaging the general image of notified bodies and their work, and risks undermining the overall quality of conformity assessment services.[14]

Divergences in the application of conformity assessment by the notified bodies also have a distorting influence on competition within the manufacturing industry. This is to some extent due to differences in the fees, but much more important is the fact that different notified bodies interpret the applicable material and procedural requirements in vastly different ways. As already indicated, a less rigorous approach to the certification process can significantly reduce compliance costs for manufacturers giving them a competitive advantage vis-à-vis those manufacturers who undertake correct conformity assessment work.

To date, the negative impact of such procedures has been limited to economic effects for notified bodies and manufacturers alike and has not yet reached a level where the health and safety of consumers, workers or end-users is routinely endangered, although there have been cases. For example, there have been safeguard clause procedures related to products certified by a notified body in almost all industrial sectors, see Annex II table 3. In some cases this has led to accidents with products which have been certified by a notified body but which were nevertheless not in compliance with the applicable requirements.[15]

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13 Several SMEs replying to the SME test panel indicated that rates charged by notified bodies for comparable services vary throughout EU.

14 The same conclusion has also been drawn in other studies, e.g. PWC study on economic aspects of product testing: a study for the Dutch Ministry of economic affairs, May 2002.

15 A recent Court case dealt with the accident of worker with a machine: The machine had been certified by a notified body although it was not in compliance with the requirements of the machinery directive C-Yonemoto Case C-40/04 OJ C271 29.10.2005 p7

Problems experienced with Notified Bodies are also relevant in an environmental context, as a few directives address environmental aspects and foresee the intervention of notified bodies in the conformity assessment process. This mainly concerns the legislation related to the energy efficiency of energy using products and the maritime transport sector. The intervention of notified bodies in conformity assessment procedures under these directives constitutes an important element in ensuring that the products do not constitute a danger for the environment, in the same was as in New Approach directives for health and safety. Consequently, the downgrading of quality in the service delivered by notified bodies can seriously hamper the effective functioning of this control mechanism and result in products on the market which are harmful to the environment.

2.1.2. Lack of transparency and different approaches in the competence assessment and monitoring of notified bodies

Industry, public authorities and notified bodies themselves have expressed doubts that all notified bodies actually possess the required competence to carry out the tasks for which they are notified.[16] 60% of participants in the public consultation considered that notified bodies are not sufficiently monitored. For example, there are bodies which have been notified to the Commission, but which are not carrying out any conformity assessment activities for which they have been notified. It is highly questionable whether, after a certain period of inactivity, a notified body still has the necessary competence to carry out the tasks for which it has been notified. In some industrial sectors this has led to a proliferation of notified bodies, which does not correspond to the size of the market.[17.] Figure 3 shows the responses to the question asking if competence of notified bodies is the same in all Member States. Clearly there is a perception that it is not, which highlights a weakness in the system which undermines its credibility.

16 Evaluation of the application of the Lifts Directive, Final Report for DG Enterprise, 2004; Report on the functioning of the medical devices directive 20002; Impact assessment on the proposal for a Directive on common rules and standards for ship inspection and survey organisations and for the relevant activities of maritime administrations http://ec.europa.eu/governance/impact/docs/ia_2005/sec_2005_1498_fr.pdf,

17 This problem is particularly present in the lifts sector or in the sector of weighing instruments. Annex II gives an overview on the number of bodies notified per country and per directive

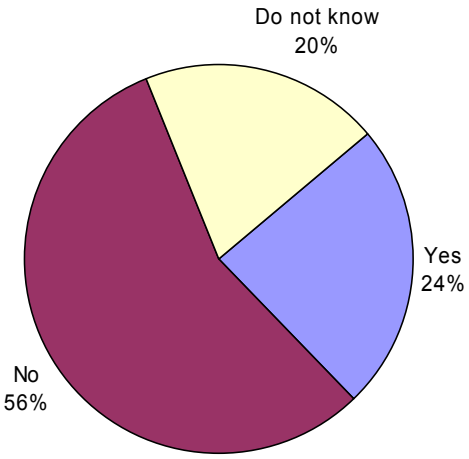

Figure 3: Is the competence of Notified Bodies consistent in Member States?

Under the current legislation the assessment and monitoring of notified bodies is the responsibility of the Member States. Figure 4 shows the assessment chain, whereby it is the Member State that assesses Notified Bodies who in turn assess products/manufacturing sites on behalf of manufacturers. EU legislation has fixed the criteria for notification, but the Commission and other Member States receive no information on the details of the assessment process. The criteria vary and are not up-to date to developments on the market place in all directives (i.e. the respect of IPR rights or the sub-contracting of certain activities to bodies outside the EU or consultancy services provided by the bodies).[18]

Figure 4: Assessment chain

National authorities take divergent approaches in the interpretation and application of the criteria laid down in the directives. Most Member States use accreditation for evaluating the competence of a notified body and consider it as a useful qualification element[19] for granting notification. However, accreditation is not a pre-condition for notification in all Member States. Furthermore, since accreditation has been regulated up till now at national level, different approaches and differing systems exist throughout the Community causing an uneven level of rigour throughout

[18] For more details see chapter 2.2 of working document Drat CERTIF 2005-3: Designation of notified bodies (Part1) – common requirements for notified bodies. http://ec.europa.eu/enterprise/newapproach/pdf/draft_certif_2005_3.pdf

[19] When notified bodies subcontract parts of their tasks related to conformity assessment (or some specialised tasks), they very often use accreditation as the means to ensure that the subcontracted bodies meet the necessary requirements of competence, impartiality and independence.

Member States[20]. There are also different arrangements in the relationship between accreditation and the notification process: in some Member States the accreditation body is also the notifying authority for some New Approach directives (in one case even for all of them) or it takes part in a committee or a team deciding on notifications, whilst in other Member States no formal relationship exists between the notifying authority and the accreditation body.[21] In some Member States, especially where regional authorities take the first step in decisions leading to the notification, the notified bodies complained about a lack of co-ordination of those regional authorities and consequently differences in approach towards the bodies to be notified.

Divergences also exist in the ex-post evaluation (monitoring) of the notified bodies which is not carried out systematically or not with the same frequency in all Member States.

Due to different designation, accreditation and monitoring policies, notified bodies are operating under uneven conditions inside the EU. Bodies evaluated to stricter approaches bear additional costs in relation to their competitors, which are subject to less stringent criteria. For example, the fact that accreditation is a precondition for notification in some Member States, but not in others, or that in some countries the re-assessment of accreditation can be done at a 4-year interval, whilst in others an annual assessment is required. Hence, notified bodies are submitted to different level of rigour which undermines the aim of mutual recognition and equal conditions within the Internal Market.

2.1.3. Unnecessary burdensome requirements in the notification procedure

Until recently the notification procedure was a rather burdensome and time-consuming process, because notifications had to be sent from the notifying Member State via its Permanent Representation to the Commission and, at the same time, to the other Member States using a complicated bureaucratic paper process. This procedure has now been significantly simplified and accelerated due to the introduction of "NANDO-Input"[22], a web-based application designed for the direct notification of conformity assessment bodies, which has been operational since April 2006. Using the NANDO-Input tool, the act of notification now takes place electronically and enables the bodies to be notified much more quickly than before using the old paper-based system.

However, the current legal framework obliges the Commission to publish a list of notified bodies in the Official Journal of the European Communities, for information purposes. The lists were typically published once per year and, therefore, there could be a significant time period between the notification of a body and the publication of a new list. Almost as soon as the list was published it became out of date. Publication in the Official Journal was once the only way to make information available to the public, but with introduction of the internet it is time to modernise. Publication itself is not a condition for becoming an official notified body, although in terms of

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20 Accreditation of testing and certification bodies, KAN report 30e, June 2003.

21 The different involvement of accreditation bodies in the notification process is given in Annex IV

22 NANDO = New Approach Notified and Designated Organisations

transparency it is important for manufacturers, market surveillance authorities and notified bodies themselves that this information is made publicly available.

Use of NANDO also allows the Commission to publish details of notified bodies on its web site, which is a much easier and quicker way to provide information which is always current and up to date. The list in the Official Journal has, therefore, become obsolete, however the current legal framework still obliges this publication; replacing the requirement for paper publication with electronic publication would reduce bureaucracy and provide a better service to the public.

When asked whether electronic publication of the list of notified bodies on the Commission website would be an improvement, 94% of notified bodies replying to the questionnaire indicated that, yes, they thought electronic notification was an improvement. Figure 4 shows the breakdown in reasoning.

2.1.4. Current measures taken to tackle the problem

There have been different attempts to tackle the problems using non-legislative measures. One example is exchange of information and co-ordination in sector specific notified body groups. There are 17 different groups, working mainly via internet, covering sectors where there is new approach legislation, for example the pressure group which covers both the pressure equipment directive and the simple pressure vessels directive. Notified bodies work together in these groups to co-ordinate information and discuss issues of implementation. However, these groups are purely voluntary and there is no obligation to participate, consequently not all notified bodies do.

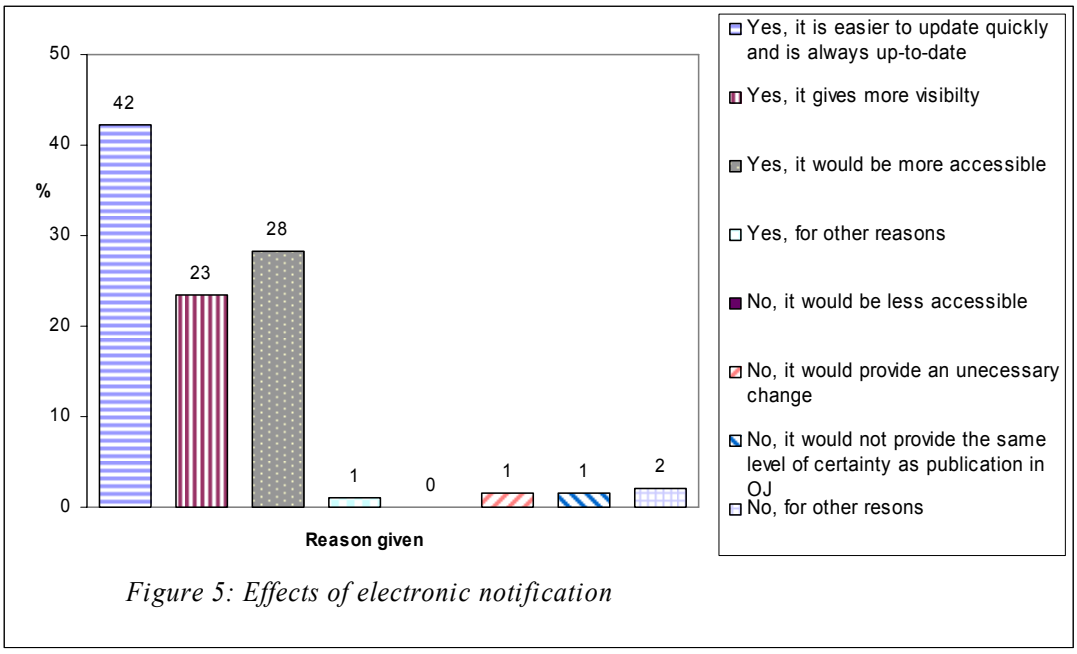

Figure 5: Effects of electronic notification

The evaluation of notified bodies and designation policy has been regularly discussed with national experts in SOGS[23]. A consensus document has been established laying

[23] SOGS: Senior Officials' Group on Standardisation and Conformity Assessment Policy

out the general principles of accreditation and sector-related guidance documents have further specified the requirements for notification.

Member States co-ordinate their accreditation activities through the framework created by a pan-European organisation known as EA, the European co-operation for Accreditation[24]. EA has been operational since 1997 and is a network of nationally recognised accreditation bodies based in Europe. Its main objectives are to ensure transparency of operations (including assessments) and results of its members, to support and promote mutual recognition and acceptance of accredited conformity assessment services and results, and to manage a peer evaluation system intended to provide mutual confidence in the competence of its members.

The peer evaluation system managed by EA is currently the only tool at European level which allows a comparison of the performance of accreditation bodies. The EA is widely recognised as being beneficial in the establishment of common working methodologies for the evaluation of conformity assessment bodies.

However, the position and influence of EA is limited by its legal status and its recognition by public authorities varies from Member State to Member State, usually depending on the degree of co-operation between the accreditation body and the public authorities in charge of notification (see also Annex IV). The development of policies within EA (e.g. cross frontier policy on accreditation) is also limited by the fact that its members, i.e. the national accreditation bodies, are bound by different national legislation in the field of accreditation. The implementation of certain rules or decisions taken within EA can be supported by national laws and regulations in some Member States, whilst in others this is not the case and problems may be experienced. One example is the absence of reaction from some Member States in cases of negative EA evaluations.

Due to the existing lack of common legal basis and of regulation of accreditation at EU level, a harmonised accreditation policy cannot be completely and successfully developed and integrated into the European model. The only Community wide recognition is via a Memorandum of Understanding between the Commission and EA, but this is not sufficient to overcome the current difficulties.

2.2. Weaknesses and difficulties in the enforcement of the directives

Legislation will only achieve its objectives if it is effectively enforced.

It is generally noted that the enforcement of EU product legislation is unsatisfactory and a considerable number of non-compliant (and potentially dangerous) products reach the market. The share of non-compliant products can only be estimated and the situation differs very much from sector to sector and from Member State to Member State. Nevertheless, the available information[25] indicates that a significant proportion

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[24] EA is a non-profit association established in November 1997 and registered as an association under Dutch law in June 2000. EA results from the merger of EAC, European Accreditation of Certification, and EAL, European co-operation for Accreditation of Laboratories.

[25] In some sectors which are strongly concerned by this problem industry has carried out its own research, e.g. results of CELMA market surveillance forum, April 2006 – federation of luminaire manufacturers: http://www.celma.org/pages/CELMA%20Market%20Surveillance%20Forum%20L+B%202006.asp

of the products on the market do not comply with the legal requirements. As many as In 2004, in Germany as many as 33% industrial products were found not to be in conformity with the legislation and the market surveillance authority were unable to identify the country of origin of 35% of these products.[26] Table 1 summarises responses from various sources.

Table1: Indications from stakeholders on the share of non-compliant products on the market.

Source	Share of non-complaint products on the market
SME Test panel	The majority of SMEs could not provide figures. Where figures where given, they differed considerably from sector to sector as well as between Member States. The figures ranged from 4%-51%, the average being 24%.
Enterprise questionnaire	Most respondents could not provide figures but indicated that the problem was important. However, below is an overview of the estimates provided: Electro-technical sector: 10-30% (up to 50 % in the luminaires sector) Mechanical sector: 5-7 % Medical devices: 10-30% Construction products: 10-30%
Market surveillance authorities	Electro-technical 10-70 % Medical Devices 2-20 %, Construction products 2-30 % Recreational Craft 1 %

2.2.1. Deficiencies in the current organisation of market surveillance

Currently, market surveillance does not operate effectively throughout the Community and 96% of respondents to the public consultation[27] considered that market surveillance is insufficiently rigorous.

Market surveillance is organised differently in Member States and can also vary from sector to sector, as demonstrated in a recent survey[28] of national market surveillance

[26] Tchnische Uberwachung Bd.47 (2006) Jan/febr.
[27] Results given at: http://ec.europa.eu/enterprise/newapproach/review_en.htm
[28] http://ec.europa.eu/enterprise/newapproach/review_en.htm

authorities. 94% of respondents felt that levels of market surveillance level differ significantly between Member States. The following areas were identified having the biggest differences: Number, frequency and efficiency of checks performed (82% of respondents), resources allocated (75%), degree of detail of checks (63%). In addition, 66% of respondents responded that the level of sanctions differ throughout the Community.

Member States were asked about the effectiveness of existing market surveillance systems and whether reinforcing certain elements would have an improvement on the situation. Figure 6 shows that in all areas, harmonisation of procedures, common requirements, enhanced controls, stronger traceability, co-ordinated actions, enhanced co-operation and better sanctions there is significant room for improvement.

These differences in national organisation of market surveillance cause problems when viewed in the framework of the European single market which no longer has internal borders where controls at national borders have practically disappeared. For this reason it can no longer be considered that a single Member State controls all products entering its market. To ensure that only compliant products circulate on the market, every Member State depends on the market surveillance of its neighbours. Consequently, weaknesses in the organisation of market surveillance in one single Member State can seriously undermine the efforts taken by other Member States to keep non-compliant from the market; this creates a weak link in the chain.

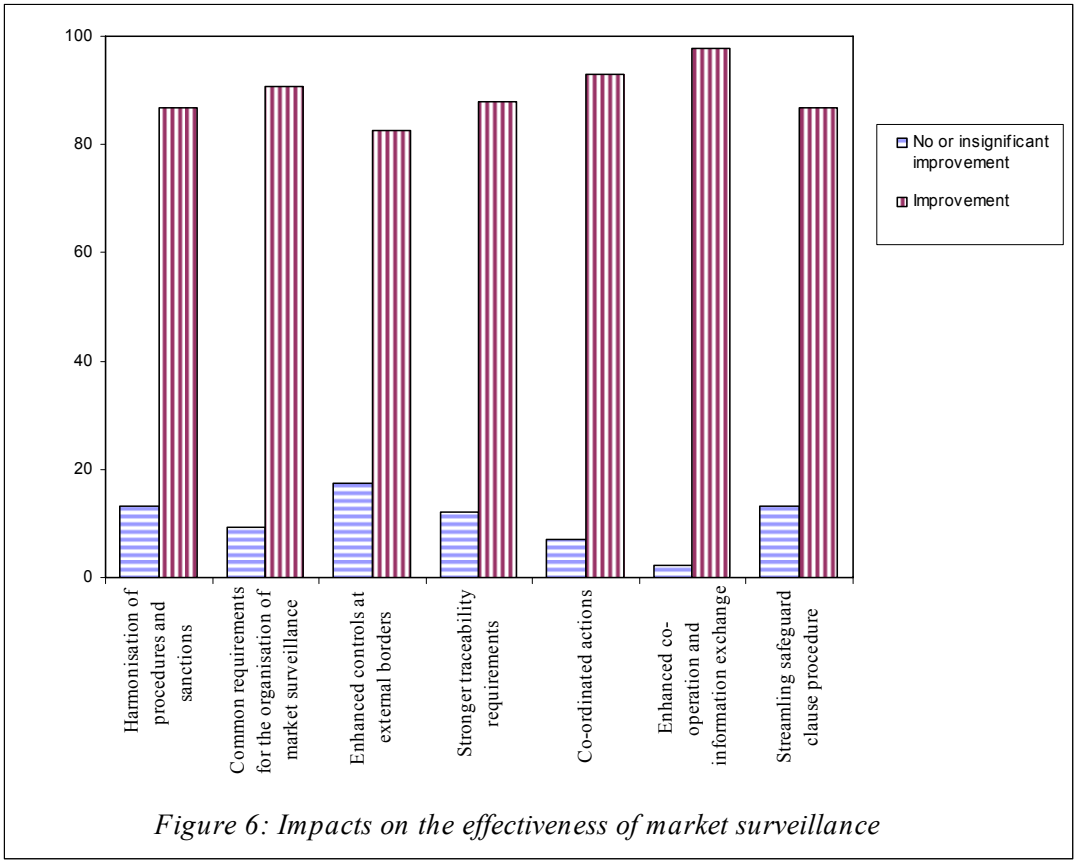

Figure 6: Impacts on the effectiveness of market surveillance

This interdependence is reinforced by the fact that the competence of market surveillance authorities is limited to the national territory. Where action is needed

beyond the border, authorities must rely on their colleagues in the other Member State. However, as there is not a sufficiently broad legal basis, cross-border co-operation in the EU does not currently work effectively. The results of the questionnaire show that only 34 % of respondents indicated that they have ever taken any action due to information provided by another Member State. An important step to improve cross-border cooperation has been achieved with the implementation of the General Product Safety Directive. However, outside the scope of this directive co-operation activities between enforcement authorities only take place in some sectors and between some Member States not all, for example toys, machinery, electrical equipment, personal protective equipment, pressure equipment, and only on a voluntary basis. This hampers the efficiency of market surveillance activities.

We should also remember that imports from third countries are growing faster than domestic production. The EU is faced with an increasing number of non-conforming products arriving from third countries. For example, in the electro-technical sector, the share of imported products in the total of non-compliant products detected by market surveillance authorities is between 70% and 99%. A recent survey on the safety of imported toys in new Member States[29] indicated that 55% of the sample of imported products were noncompliant, and of those 12% had no indication of origin. The absence of internal border controls reinforces the importance of controls at external borders. External borders are the best place to detect non-conforming products from third countries as they are the entry point for imported goods. However, resources are not always sufficient and have not kept pace with the increase in imports; therefore, external borders are not always sufficiently controlled. The differences in effectiveness of border controls between entry points once again creates a problem for the whole Community. Experience has shown that where a shipment of non-compliant products is detected and destroyed at one entry point, importers will often look for another entry point into the Community which has less stringent controls for import of his product.

2.2.2. Insufficient controls by actors in the distribution chain

Often, distributors do not sufficiently check the conformity of the products which they are supplying and rely on the fact that this, is in principle, the task of the manufacturer. This is a particular problem in relation to imports from third countries. Manufacturers outside the EU are often less aware of the European legal requirements than European manufacturers. Furthermore, products manufactured outside the EU may not necessarily be intended for the European market and hence need not comply with European regulations. Therefore, it cannot be assumed that conformity to European legislation has already been guaranteed during the manufacturing process. Consequently importers must ensure that the manufacturer has actually complied with the European legislation. Importers and distributors are not sufficiently aware of their obligations. Reasons for this include the complexity of the legal situation and the fact that New Approach directives only address the manufacturer or the authorised representative. There are also unscrupulous operators who benefit from the current weaknesses in market surveillance by introducing cheap non-compliant products on the market.

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[29] Safety of imported toys in the Czech Republic, Slovakia and Hungary. General inspectorate for consumer protection, Hungary, July 2006.

2.2.3. *Difficulties to trace products and economic operators*

Globalisation makes it difficult to determine how and by whom a product is manufactured or who has placed it on the market. For market surveillance to be efficient, collaboration with manufacturers is essential in order to rectify compliance, prevent the placing on the market, and, as a last resort, to withdraw non-compliant products. In practice market surveillance authorities often experience difficulties in identifying the person who has actually manufactured and/or supplied the products, in particular when the manufacturer is located outside the EU and has not appointed an authorised representative. They often cannot find a contact person who could provide them with the necessary information to evaluate the conformity of the product and who could help them to ensure that dangerous products are withdrawn from the market[30].

Currently traceability is not ensured throughout the whole supply distribution chain. The directives require only that the manufacturer is identified on the product, but there are currently no legal means to identify the other operators (such as importers and distributors) in the distribution chain. These operators are, however, important contact and information points for market surveillance authorities, in particular when the manufacturer is not established inside the EU.

2.2.4. *Inefficient safeguard clause mechanism*

The safeguard clause mechanism is not operating efficiently: the number of safeguard clause notifications received by the Commission in recent years is steadily increasing, see Annex II Table 3. The Commission procedure to establish whether a national measure is justified is lengthy.

There are various reasons for the current inefficiency of the procedure. Firstly the Commission does not have the necessary technical competence to evaluate the conformity of a product and must often use external expertise. Secondly, in a majority of cases notifications do not contain sufficient information to allow an immediate assessment of the case. In addition, the manufacturer has not always been contacted by the notifying Member State and has not had the possibility to submit further documentation. Gathering this information leads to considerable delays in the procedure.[31] In very complex cases it can take more than a year. Member States also have a tendency to notify every restrictive measure without a prior assessment as to whether the product really poses a risk to health and safety. This has lead to an increase of safeguard clauses making it more and more difficult for the Commission to manage these cases within a reasonable time period.

2.2.5. *Effects of the problem*

The inefficiency of the current enforcement mechanisms creates an unfair competitive advantage for operators not adhering to the rules, especially in price-sensitive areas. They can make significant savings on compliance costs by not doing

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30 See RAPEX statistics (1 January – 30 September 2006) http://ec.europa.eu/consumers/cons_safe/prod_safe/gpsd/stats01-09-2006.pdf, page 6

31 Table 3, Annex III gives an overview on the number of safeguard clauses received and the average time to complete such a procedure.

all that is necessary and can consequently offer their products at lower prices than their competitors who respect the law.[32] 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". It might even activate a downward spiral, since operators could be tempted to follow the negative example of their illegally behaving competitors.

This problem can ultimately undermine the objectives of Community legislation, no matter whether it aims at protecting the health and safety of citizens or the environment[33]. Although there is currently no general safety risk, non-compliant products coming to the market can endanger the health and safety of consumers, workers or users or cause damage to the environment. The number of consumer goods with serious non-compliances notified to the Commission through the RAPEX database[34] is increasing.

The situation undermines confidence in the CE marking and the credibility of EU legislation as an effective means to protect citizens or the environment.

2.2.6. Current measures taken to tackle the problem

Being the responsibility (and a prerogative) of Member States, enforcement has, until recently, only had an ancillary role in EU harmonisation legislation. The existing harmonisation legislation does not in general address market surveillance. Most instruments contain a very general clause obliging Member States to ensure that only products in compliance with the requirements of the directive are placed on the market. In the New Approach directives the safeguard clause procedure obliges national authorities to notify the Commission whenever they take a measure restricting the free circulation of a potentially dangerous product. The Commission has to issue an opinion whether the measure is justified or not.

In respect of consumer goods these general provisions in the sectoral directives are completed by the provisions of the General Product Safety Directive (2001/95/EC) (GPSD). The GPSD has created a horizontal framework ensuring the safety of consumer products. To this end it sets out a number of post-market obligations for manufacturers, importers and distributors as well as certain obligations for Member States as regards the organisation of market surveillance. Apart from that it established a co-operation network of competent authorities, which inter alia operates a European rapid alert system for dangerous non-food products system for exchange of information and rapid intervention (RAPEX). It ensures information about

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

[33] In the area of environmental law, where industry constantly laments the high compliance costs, this problem can be even more drastic. First, the existing environmental liability regime is less rigid than the liability regime provided for damages caused by defective products. Second, manufacturers usually have a manifest business interest in guaranteeing the safety of the product, as accidents are damaging their reputation. Environmental responsibility has not (yet) reached the same level of importance for the market. Hence there are fewer incentives for industry to comply with environmental needs

[34] Annual Report on the Operation of the Rapid Alert System for non-food consumer products (RAPEX) 2005; http://ec.europa.eu/consumers/reports/report_rapex_05_en.pdf

dangerous products identified in the Member States is quickly circulated between the Member States and the Commission. It applies in the harmonised sectors like toys, cosmetics, etc, in so far as the relevant harmonisation directives have themselves not provided for specific rules.

The GPSD and in particular the RAPEX system have brought considerable progress of cooperation in the area of consumer goods. Since the creation of RAPEX the number of notifications received has increased significantly allowing Member States to take rapid action on dangerous consumer products throughout the Community.

However, the mechanisms established by the GPSD are not sufficient to ensure a coherent level of enforcement of Community harmonisation legislation throughout the EU. While harmonisation legislation covers both consumer and non-consumer products, the GPSD focuses on consumer protection. Therefore, its mechanisms are not applicable to whole range of products covered by Community harmonisation legislation. Hence RAPEX does not include information on dangerous industrial products like machinery or lifts, which present a risk for workers or users. Furthermore only health and safety aspects are covered by this system, environmental risks are not taken into consideration.

While the GPSD contains an obligation for Member States to take part in the cooperation mechanism, the obligations it imposes on Member States to organise and perform market surveillance are rather general. For this reason differences in the various Member States still continue to persist, leading to a different level of protection and enforcement within the EU.

2.3. Misunderstanding of CE marking and lack of credibility

2.3.1. Misunderstanding of the CE marking

By affixing the CE marking to the product the manufacturer declares that the product is in conformity with all applicable directives. A product bearing CE marking, benefits from free circulation inside the Community.

The CE marking is well known in the marketplace but its meaning is often unclear. Studies have demonstrated that consumers in particular have a poor understanding of the role of CE marking.[35] It is often perceived as an indication of origin or another incorrect perception is that CE marked products have been tested and approved by some kind of authority.[36] Furthermore, consumers do not know which products should bear the CE marking and which should not and they do not seek it when making a purchasing decision.

There are different reasons for the confusion on the meaning of the CE marking:

The significance of CE marking is complicated and not clearly evident for consumers who are unfamiliar with the whole system supporting the affixing of the marking.

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35 Europeans and the EC logo, INRA (Europe), Eurobarometer 52.1, Report drawn up for DG SANCO, 2000; http://europa.eu.int/comm/dgs/health_consumer/library/surveys/sur16_study_en.pdf

36 CE - A study of consumers' and retailers' knowledge of the CE mark, The Swedish Research institute of Trade, 2004

Even amongst professionals and legislators the meaning is not always clear. The marking was introduced into European legislation in order to provide information for national authorities on the compliance of the product to guarantee its free movement within the Community. It was not designed to provide information to consumers. However, as it is increasingly used more and more on consumer products, its visibility for the public has increased giving rise to confused and erroneous interpretations as to its meaning.

Another reason behind this confusion is that products often bear a number of other legal and voluntary marks. In most cases the significance of these markings is equally unknown to consumers. Furthermore a number of these markings have a similar meaning, which makes the distinction of the CE marking even more difficult. Consumers are confused by the multitude of different markings and often do not use the informative value of the CE marking as a basis for their choice.

Consumers who do not know the value of CE marking do not verify whether products actually bear the CE marking or not and hence may buy non-compliant and potentially dangerous products. Those who have an incorrect perception of the CE marking might be misled in their product choice. They may purchase a product which they wrongfully presume to be manufactured in Europe or tested and approved by an independent third party or authority.

The limited knowledge amongst professionals in the distribution chain also has negative impacts on the safety of products offered to end-users and consumers.

2.3.2. Lack of credibility of the CE marking

CE marking is often criticised for its lack of credibility. Although CE marking is a visible declaration by the manufacturer that the product is in conformity with the requirements of all applicable legislation, sometimes products bearing the CE marking are not in compliance with the legislation. (see chapter 2.2). The results of the public consultation showed that the CE marking has a positive image in international trade, whilst internal confidence in the CE marking is significantly lower.

CE marking represents the whole system of product conformity under the New Approach, and therefore weaknesses in the functioning of the system undermine the confidence in the CE marking. The credibility of the CE marking is thus intrinsically linked to the lack of effective market surveillance as product compliance with legislation is not effectively policed, and as a result CE marking often appears on products which are not in compliance which undermines the credibility of the whole legislation. Lack of confidence in the CE marking also has negative repercussions on industry. Manufacturers need to have enhanced recourse to additional marking/testing to ensure the confidence of the market place in their products.

Finally, the CE marking is not protected by intellectual property rights, meaning that prosecution of its misuse must be based upon some other grounds. Market surveillance authorities base their actions regarding corrective measures, such as withdrawal of products etc. on the breach of product safety legislation. There is currently no effective means to proceed against the misuse of the CE marking as such, i.e. to take action based on the CE marking as a right in itself. In other words,

when the CE marking is misused for e.g. commercial purposes on the web or in leaflets without being linked to a specific product, there is no case of non-compliance which could be prosecuted and neither Member States nor the Commission can take any action against this misuse. This commercial use further contributes to confusion amongst consumers.

2.3.3. Current measures taken to tackle the problems

The existing legal texts do not give a definition or explain the meaning of the CE marking. The meaning of the CE marking is explained in great detail in the Blue Guide.[37] However, the Blue Guide does not reach the broader public, although some Member States (e.g. Sweden[38], Denmark) have organised information campaigns and in 1995 an EU wide information campaign was carried out through the European Info Centre network.

2.4. Inconsistencies and legal uncertainty in the current regulatory framework

2.4.1. What is the problem?

The current legal framework contains a number of inconsistencies and legal uncertainties which cause problems in the interpretation and implementation of the directives. Products are very often subject to several legal instruments, which treat common elements, such as definitions or the procedures for demonstrating conformity, differently. This leads to incompatibilities, difficulties in practical application, legal uncertainty and unnecessary duplications.

Over the years the legislation applying to products has become more and more complex and voluminous, and the requirements to be considered in the production process are spread over a multitude of different legal instruments: This can be illustrated by the example of a manufacturer of an electrical product. Electrical products are (usually) covered by the Low Voltage Directive[39]. As his product will produce electromagnetic fields, he will also have to respect the requirements of the directive on electro magnetic compatibility[40]. The product must also comply with the environmental requirements set out in the "ROHS"[41] and "WEEE"[42] directives, and in addition energy labelling provisions[43] may also apply to the product. As you can see in this example the requirements for even a simple product can be complicated, and inconsistencies in terminology, requirements and procedures can prove very difficult and burdensome for manufactures to deal with to ensure legal compliance.

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37 http://ec.europa.eu/enterprise/newapproach/legislation/guide/index.htm

38 CE marking campaign 2003: collaboration between between SWEDAC, the Swedish Work Environment Authority, the National Electrical Safety Board, the Swedish Consumer Agency, the Confederation of Swedish Enterprise, the Swedish Federation of Trade and the Swedish government http://www.swedac.se/CE/eng/pdf/Background_CE-Campaign.pdf

39 http://ec.europa.eu/enterprise/electr_equipment/lv/index.htm

40 http://ec.europa.eu/enterprise/electr_equipment/emc/index.htm

41 Directive 2002/95/EC on the restriction of the use of certain hazardous substances in electrical and electronic equipment; see http://ec.europa.eu/environment/waste/weee_index.htm

42 Directive 2002/96/EC on waste electrical and electronic equipment, see http://ec.europa.eu/environment/waste/weee_index.htm

43 http://ec.europa.eu/energy/demand/legislation/domestic_en.htm

Problems are often experienced with simple expressions used in the legislation, such as "manufacturer" or "placing on the market"[44]. Numerous pieces of legislation use these terms without defining them, others contain definitions, but these definitions differ from one legal instrument to the other. The current discussions about the interpretation of "placing on the market" in the context of the Restrictions of Hazardous Substances (ROHS) or the recent phthalates directive[45] illustrate the importance of this issue. Moreover there have been evolutions in the marketplace and the economic reality has become more complex. The existing definitions and concepts do not always take account of these developments. Sometimes definitions or are not sufficiently precise and leave room for diverging interpretations.

Another issue to be tackled in this context is the discrepancy of conformity assessment procedures. For the New Approach directives, decision 93/465/EEC contains 8 different "modules" (conformity assessment procedures) which can be used for demonstrating compliance with the legal requirements. The individual directives have not always stuck to the text of the decision, and some have slightly modified these standard procedures by changing details or the inclusion of additional elements. Furthermore the directives do not all use the same modules or same combination of modules. A product may be covered by several different directives and therefore a manufacturer may have to apply several different procedures to demonstrate that his product is in compliance with the legislation.[46] This is confusing, burdensome and can be expensive for manufacturers. Differences also exist regarding the information which has to be contained in the declaration of conformity, adding to the confusion.

Other issues are also unclear in the legal texts, for example the procedure for the objection against a harmonised standard. The standard article used in the directives establishes a certain procedure which may lead to the "withdrawal" of the harmonised standard; however it is unclear as to whether this procedure also applies to standards which have not yet been published in the Official Journal, since the legal text only refers to a withdrawal but not to the non-publication.

2.4.2. What are the effects of the problem?

Legal uncertainty and inconsistencies negatively affect industry. As discussed above, the legal situation for enterprises is rather complex. Manufacturers have to ensure compliance not only with one piece of legislation, but often with a variety of legal instruments. Due to different wording and concepts it gets more and more difficult for companies to understand their legal obligations. They are increasingly forced to seek legal advice to help them to comply with the law.

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44 Make it simple make it better; UK better regulation task force, December 2004. Recommendation for clarity and common definitions.

45 Directive 2005/84/EC on the approximation of the laws, regulations and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations (phthalates in toys and childcare articles).

46 For example, outdoor machinery is covered by four different directives: the machinery directive, the directive on electromagnetic compatibility, the directive on emission from non-road machinery and the directive on noise emissions from outdoor equipment.

In addition, these inconsistencies and legal uncertainties also make it difficult and more complicated for national authorities to properly implement and enforce the law. This leads to different interpretations by Member States which jeopardises the free movement of goods in the Community.

Incompatible conformity assessment procedures for one and the same product increase compliance and certification costs. In some cases manufactures are forced to go to two different notified bodies to have their products certified under the different directives. Even when they find a notified body which is notified under both directives, they may incur additional costs as the procedures may be different and they have to pay for two different certificates.

2.4.3. Current measures taken to tackle the problem

In various areas the Commission has issued guidance documents with the objective of interpreting the legal texts, for example the Blue Guide explains in detail the concept of placing on the market in addition to other terms. These explanations are completed by sector specific guidance documents, nevertheless these guidance documents do not provide solutions for every case and as they are not legal documents and therefore are non-binding there is no obligation for authorities or notified bodies to follow them.

2.5. Does the EU have the right to act?

Article 95 EC provides the legal basis for measures having as their objective the functioning of the internal market.

Subsidiarity test: Inconsistencies and weaknesses in the existing legislation can only be eliminated by Community legal action. As regards market surveillance and accreditation, it has become evident that measures taken at national level are not sufficient to solve the existing problems. The measures envisaged to tackle the problems will also be examined in the light of ensuring that intervention at EU level does not go beyond what is strictly necessary to achieve the objectives.

3. OBJECTIVES

3.1. General objectives

A functioning Internal Market is fundamental for fostering competitiveness, growth, economic and social progress within the EU. Harmonising the conditions for the marketing of products at EU level has played and will continue to play an essential role for realising the internal market for goods. To ensure that the internal market in goods fully operates to the benefit of all groups of society, two conditions must be met: First, harmonisation legislation must guarantee a high level of protection of the public interests at stake and second the legal framework must create favourable conditions to foster innovation and the competitiveness of European businesses.

This initiative conforms to the general objectives as set out in the Treaties[47] and in the Community Lisbon programme by tackling the problems identified in Chapter 2. To this end economic operators should be provided with a clear and consistent legal framework which ensures better overall coherence of EU legislation and thereby simplifies its implementation. At the same time the deficiencies in market surveillance and in the monitoring of notified bodies must be remedied in order to guarantee a high level of protection of public interests and a level playing field amongst economic operators.

In line with the Commission strategy for simplification of the regulatory environment[48], this initiative further aims to encourage use of the legislative concepts of the New Approach, since it is a proven example of Better Regulation. Filling the gaps and simplifying its implementation will reinforce its capacity to ensure a high level of protection and the free movement of goods throughout the EU within a flexible and innovation-friendly legal framework.

These general objectives shall be achieved by realising the following more specific and operational objectives:

3.2. Specific Objectives

3.2.1. Notified bodies and notification procedure

It is clear that notified bodies must deliver coherent and high quality conformity assessment services, regardless of where they are physically located in Europe. The rules relating to the operation of notified bodies must ensure equal conditions and avoid unfair competition which undermines the quality of conformity assessments.

3.2.2. Effective and efficient enforcement of the legislation

The objective is to increase the effectiveness of enforcement of legislation and to reduce the number of non-compliant products circulating on the market in order to guarantee that all market players compete under equal conditions as well guaranteeing a high level of protection for the public.

The control of the market must be reinforced; Member States must have efficient, well functioning market surveillance systems in place and the necessary tools to allow to work effectively across national borders. To this end, co-operation and co-ordination between national authorities must be strengthened and systems must be in place to ensure product traceability throughout the whole Community market.

The roles and obligations of all operators intervening in the supply and distribution chain must also be clarified.

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47 See Article 2 EU Treaty, Articles 2, 3 and 95 of the EC Treaty

48 Implementing the Community Lisbon programme: A strategy for the simplification to the environment, COM (2005) 535 http://ec.europa.eu/growthandjobs/pdf/COM2005_330_en.pdf

3.2.3. A clear meaning and enhanced credibility for CE marking

The meaning of the CE marking should give a clear message to all, not only to manufacturers, experts or market surveillance authorities but also to consumers, importers and distributors. Furthermore the credibility of the CE marking needs to be reinforced.

4. POLICY OPTIONS

4.1. Basic options

This chapter identifies and examines different ways to tackle the problems outlined in chapter 2 and to achieve the objectives defined in chapter 3.

There are three different options for consideration:

(1) The first option ("the baseline-scenario") consists of keeping the current situation unchanged;

(2) The second option is to take non-regulatory measures which do not necessitate a change in existing legislation or the introduction of new legislation. There are however two limitations to the potential scope of this option:

   (a) Problems originating in the existing legal provisions can only be eliminated by a change in that legislation. Where the procedures are confusing, not efficient, inadequate or too burdensome, as is the case for the definitions, the safeguard clause procedures, certain conformity assessment procedures or the notification procedure, the legal texts need to be changed. Therefore, legal uncertainty created by the existing provisions cannot be addressed by non-regulatory measures. Guidance documents may serve as temporary instruments to overcome difficulties and differences in the interpretation and application but they cannot constitute long-term solutions to fill legal gaps or remedy deficiencies in legal drafting. Option 2 is therefore excluded for the problems outlined under section 2.4.

   (b) The Commission has already made extensive use of non-regulatory instruments, such as guidance papers, etc. While such instruments have been useful to some extent, they have so far been insufficient to effectively address the problems related to the uneven level of enforcement and to the evaluation and monitoring of notified bodies.

(3) The third option comprises measures requiring the intervention of the Community legislator.

In the following sections these basic options are further developed into specific (regulatory and non-regulatory) policy options which could provide solutions for each problem area identified in Chapter 2. A summary table of the options is given at the end of the section. The effectiveness and efficiency of these measures is discussed resulting in a short list of the most promising options.

4.2. Options related to notified bodies

4.2.1. Option A1: Creating a network of notified bodies and a horizontal group of notified bodies

To improve the co-ordination of conformity assessment activities in the different directives all notified bodies could be interlinked through a formal network. The presidents of the sectoral notified body groups could also be grouped into a horizontal co-ordination group under the chairmanship of the Commission, to address horizontal issues to ensure coherence and a consistently high quality of conformity assessment activities across all directives.[49] The advantages of doing this are flexibility of approach, low cost and minimal resourcing needed for its implementation. There is, however, one important impediment to the effectiveness of this option. Participation in the notified body groups is, at present, not compulsory as a legal requirement, participation is purely voluntary. The idea would be to oblige participation of all notified bodies in their relative sector group (even in a 'virtual' way using web-based applications, to reduce costs for SMEs). For this reason, this option standing alone may not be sufficient to overcome the current problems.

4.2.2. Option A2: Regulating the activities of notified bodies

The current system of self-regulation could be replaced by a regulatory framework covering the activities of notified bodies, which would elaborate in more detail the tasks to be carried out in the context of the different conformity assessment procedures. On the one hand a legal framework would set clear rules thereby ensuring a more consistent approach to conformity assessment and it would make recourse to unfair practices more difficult. On the other hand, there are substantial arguments against this option. To achieve a discernable degree of consistency, the legal texts would need to give explicit technical details. Fixing technical details in the legislation would deprive the conformity assessment policy under the New Approach from its most important asset, its flexibility. The system would become rigid making application of flexible solutions adapted to specific situations, for example, small series production, SMEs, innovative products, etc, impossible or very difficult. Therefore, this option would result in more disadvantages than benefits and should be excluded from further consideration.

4.2.3. Option A3: Centralising the competence assessment and monitoring of notified bodies at EU level (Commission or creation of a specific agency.

One way of ensuring a coherent and transparent assessment and monitoring of notified bodies would be to centralise such activities at Community. In this scenario several sub-options could be envisaged:

(a) competence assessment and monitoring carried out by the Commission itself;

(b) creation of a specialised Community agency.

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[49] See Draft CERTIF 2005-8: Creating a network of Notified Bodies http://ec.europa.eu/enterprise/newapproach/pdf/draft_certif_2005_8.pdf

Option a) can be immediately excluded; the assessment of technical competence of notified bodies requires very specific knowledge and in depth expertise in technically complex areas, which does not exist inside the Commission. The Commission would have to outsource the tasks, which may lead to a problem of independence, or it would have to create a specific agency (option b). In order to cover the whole range of sectors in which notified bodies are active, the agency would have to be of considerable size.

This solution will need a critical examination from the subsidiarity point of view. Member States and accreditation bodies would completely lose their responsibilities and competencies in the field of accreditation, whilst the formal notification of the conformity assessment bodies would still remain the responsibility of the Member States. Another important aspect is the risk of incoherence between the harmonised and the voluntary/non-harmonised area that would most likely occur if a separate system for assessment and monitoring of notified bodies was created.

4.2.4. Option A4: Competence assessment and monitoring of notified bodies performed at national level based on a common EU legal framework and supported by a European infrastructure

This option would build upon the current system (decentralised competence assessment and monitoring carried out under the responsibility of each Member State) and complete it with a common legal framework for accreditation and a co-ordination infrastructure at Community level.

Regulation at EU level will bring the current diverging national systems closer and provide the necessary framework for a more coherent and uniform implementation of accreditation at national level and its use in support of notification. As the non-regulatory measures taken so far have been insufficient to overcome the national differences, it is indispensable to opt for the regulatory solution. A common legal framework would harmonise the general rules for accreditation, such as the principle of non-competition, the public authority nature of accreditation, the rules on cross-frontier accreditation policy and oblige co-operation between the different Member States' accreditation bodies.

In order to ensure the coherent application of the accreditation framework, this option foresees a European infrastructure for accreditation that would steer and govern its implementation. This role could be taken over by the existing European Co-operation for Accreditation (EA). As indicated in 3.1.4?, EA operates at EU level, promotes mutual recognition and acceptance of accreditation certificates thus contributing to the free movement of goods. Its system of peer evaluation provides greater coherence between accreditation bodies' practices and increases mutual confidence. The option would provide EA with public recognition and reinforce its structure and operation. As EA brings together representatives of national public authority organisations, it would therefore be in a position to guarantee the level of independence and technical capabilities required.

4.2.5. Option A5: Electronic notification procedure

This option foresees the introduction of a legal basis for electronic notification on the website which would replace the obligation to publish the list of notified bodies in

the Official Journal. The logical conclusion of this is, therefore, to abolish the publication in the Official Journal as a web based publication is quicker and more easily updateable.

4.3. Options to improve the enforcement of directives

4.3.1. Option B1: Enhance co-operation of market surveillance authorities by extending the existing co-operation mechanisms

The existing co-operation mechanisms and information exchange tools could be extended without any need to change the existing framework. More than ten sectoral specific ADCO groups do presently exist, covering directives such as toys, personal protective equipment, machinery and construction products, etc. These groups provide a mechanism for Member States' market surveillance enforcement authorities to come together to exchange information regarding surveillance for a particular sector. This concept could be extended to cover all directives and their organisation and the working methods could be improved to exploit the existing the opportunities more efficiently.

The Commission could also establish an overarching horizontal group, complementary to the sector specific groups. Such a group could ensure that there is better coherence, co-ordination and co-operation across directives. However, to avoid duplication such a group should limit its operation to cover only horizontal aspects related to market surveillance, exchange of best practice from sector to sector and the identification of priority actions and specific fields for inter-sectoral co-operation. There could also be opportunities to share resources.

The big advantage of these measures is that they can be implemented using the existing legal and operational framework, with limited additional resource costs. However, the success of these groups depends on the active involvement and support from all Member States based upon what is currently a voluntary system. Participation in these activities does require resource allocation from member States which does incur a cost for them. In sectors where there is currently little or no market surveillance, measures such as ADCOs will not be sufficient to overcome the general problem that the legislation is not enforced.

4.3.2. Option B2: Raising the awareness of economic operators as to their obligations

Given the multiple obligations (GPSD, national law, liability regime, etc) the existing guidance documents[50] do not contain very detailed explanations on the obligations of economic operators, and in particular of importers and distributors. *Horizontal guidance* developed with the full co-operation of national enforcement authorities could outline the existence of such obligations and certain minimum requirements that should be respected by these actors.

The legal situation varies significantly from Member State to Member State, as well as from sector to sector. It is difficult or even impossible to define common minimum obligations. This bottom line can by definition not reflect the full extent of

[50] For example, the blue guide and sectoral specific guidance papers

the obligations economic operators will have to respect in a specific situation and there is a risk that it could even be misleading. In addition, a guidance document will not provide sufficient incentives for operators who intentionally exploit legal gaps or weaknesses in market surveillance in order to place non-compliant products on the EU market.

For these reasons this option has not been examined further.

4.3.3. Option B3: More effective controls of the market place

Within this option, there are two basic approaches which could achieve a better level of compliance. One is to tighten up the control requirements before a product is made available on the market (pre-market controls) and the second consists of more effective control of products, which are already on the market (post-market controls).

(1) More stringent pre-market control:

A better level of compliance could be achieved by systematic or more stringent controls at the pre-market stage. Legislation could, for example, systematically require the intervention of a notified body in the conformity assessment process.

At first glance, this option appears to be quite effective as it requires every product to be tested by a third party *before* it is placed on the market which would therefore constitute an additional control on the manufacturer/manufacturing process. However, the main problem we are trying to solve is how to catch manufacturers who do not apply the rules and the introduction of strict pre-market controls will not solve this unless it is backed up by an efficient mechanism for post-market control; meaning that so post-market control would needed in addition.

(2) More effective post-market control mechanism:

This option comprises of improving the organisation of market surveillance activities at the European level, to promote more coherency and efficiency of action. Reinforced co-operation and co-ordination mechanisms would be introduced, both at the national level and cross-border, in order for market surveillance to operate effectively throughout the whole Community.

In this context, the centralisation of certain activities or the setting up of an Agency could *a priori* be seen as options, given that there are already examples in certain sectors (eg. European Agency for Aviation Safety (EASA), European Maritime Safety Agency (EMSA), European Railway Agency (ERA) and the Food Veterinary office (FVO)). Whilst, there may be a case for a central organisation of market surveillance activities at the EU level in certain sectors, this option is unfeasible and unrealistic in the true horizontal context, due to the vast range of products to be covered and the organisation and vast expertise that would be necessary.

Similarly the complete harmonisation of market surveillance operation and requirements written into the legislation raises some questions with regard to subsidiarity, proportionality and the effectiveness point of view. Whilst such harmonisation would, without doubt, have a positive impact in aligning the level and

rigour of market surveillance throughout the Community[51] it would also lead to difficulties in maintaining flexibility for sector specific problems, flexibility to cope with different Member States' market structures and could, therefore, lead either to overkill of requirements or to gaps in the system. Furthermore, complete harmonisation would result in considerable costs for the adaptation of what are often well established and well functioning national structures and procedures.

4.3.4. Option B4: Common EU framework on market surveillance setting out minimum requirements

This option consists of the creation of an EU legal framework which would set out minimum requirements for the organisation and operation of the national market surveillance system, combined with co-ordination mechanisms (as proposed in option B1). The framework requires the establishment of an effective and efficient organisation for national market surveillance, including, for example, sufficient resources, necessary powers, effective communication between authorities, etc. It also sets out certain obligations including the withdrawal of non-compliant products from the market, requirements to perform checks on products, to follow up complaints, to monitor accidents, to co-operate with economic operators etc.[52] Furthermore, it establishes an obligation to participate in horizontal EU co-operation activities and to provide mutual assistance, when necessary.

This option would also create a legal basis for enhancing the existing co-operation and co-ordination mechanisms, to build upon and improve what we already have in place. This would, therefore, ensure exchange of information and best practices, common projects and the sharing of resources. It would also provide for a single electronic information exchange system by extending the use of the current RAPEX system[53] to products for professional use.

Under this option, the existing safeguard clause procedure would be rationalised. The idea is to split the safeguard procedure into an information exchange phase taking place at national level and a second phase taking place at Community level. In the first phase, Member States would inform each other of national measures taken to restricting the free movement of a product. The procedure would then be completed unless there were objections from other Member States. Only in the case of disagreement between Member States on the justification of the measure, would a decision be taken at the Community level.

4.3.5. Option B5: Reinforcing traceability and the introduction of specific obligations for importers

This option would ensure that that market surveillance authorities can identify a responsible person in the EU and obtain the necessary information. The legislation would be amended to ensure traceability of a product and its supplier throughout the

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51 83 % of public authorities deem that a harmonisation of market surveillance, i.e. a harmonisation of procedures and sanctions, would lead to an improvement of the situation; 33 % even anticipate a significant improvement . http://ec.europa.eu/enterprise/newapproach/review_en.htm.

52 See CERTIF Document: http://ec.europa.eu/enterprise/newapproach/pdf/draft_certif_2005_7.pdf

53 RAPEX is an information exchange system designed to handle urgent cases related to products which present a serious risk for health and safety. It is currently limited to consumer products only

whole supply and distribution chain. The legislation would also specify the obligation of importers and distributors in more detail.

Traceability could be ensured by:

- Introducing a general obligation to appoint an authorised representative for products imported from third countries;
- Establishment of a registration system for manufacturers and importers;
- An obligation to identify the manufacturer and the importer of a product and an obligation on them to identify products they purchased and supplied on (except supplies to final users/consumers).

Specific obligations for importers and distributors could be introduced in the legal framework, clarifying that these operators must check whether the manufacturer has fulfilled his obligations. These obligations would take account of the role of these operators and would be minimum obligations applying in addition to those arising from national law.[54]

4.4. Options to improve the understanding of the CE marking

4.4.1. Option C1: Information and awareness raising campaign on the meaning of the CE marking

A visible EU wide information campaign which reaches a large number of consumers across Europe will improve consumers' understanding of the meaning of the CE marking and reduce the misperceptions which might mislead them in their purchasing decisions. Consumers would have a clearer picture of what CE marking does and does not stand. They would look for CE marked products and avoid those which are not CE marked but should be so.

An information campaign would have more visibility than changes in the legal text. In the survey, some respondents mentioned that an information campaign would be the most appropriate way to improve the knowledge of consumers on the CE marking. One impediment might however be the complex system behind the CE marking, which might make it difficult to communicate a clear and easily understandable message.

4.4.2. Option C2: Abolition of CE marking

Since the meaning of CE marking is very often not known or misunderstood and there is a lack of proper policing which affects its credibility the abolition of CE marking could be envisaged.[55] However, CE marking indicates conformity of a product and is the visible sign that the whole process including conformity assessment has been completed. It gives a clear indication for customs and market

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[54] A more detailed explanations is provide by chapter 3 of Draft CERTIF 2005-15 http://ec.europa.eu/enterprise/newapproach/pdf/draft_certif_2005_15.pdf

[55] See discussion document Draft CERTIF 2005-11: The role and significance of the CE marking http://ec.europa.eu/enterprise/newapproach/pdf/draft_certif_2005_11.pdf

surveillance authorities that the product to which it is affixed complies with all the applicable requirements and may therefore circulate freely throughout the Community. Therefore, CE marking provides a first means for authorities to assess the compliance of products. Abandoning CE marking without substituting it by another mechanism, would deprive those authorities responsible for the release of products for free circulation and their monitoring, of a clear and visible indication of compliance. This could impair the free movement of products. For this reason, the vast majority of stakeholders objected to the abolition of the CE marking. Only a slight minority (less than 9 %) of stakeholders opted for abolition.

As the abolition of the CE marking would create more problems than it solves this option has not been examined further.

4.4.3. Option C3: Change the current meaning of the CE marking

The concept behind CE marking is undoubtedly very complicated; it is affixed to products which have been certified by an independent third party as well as to products which have not undergone such a procedure. One option to consider is to simplify the meaning of the CE marking itself and to reserve it for use only in cases where products have been assessed by a third party. Another option could be to keep the CE marking as it stands for products based on manufacturer's declaration and in addition to create a different variant of CE marking (e.g. CE+) indicating that a third party has intervened in the conformity assessment process.

4.4.4. Option C4: Strengthen the legal protection of the CE marking

The CE marking could be registered and consequently protected as a Community collective trade mark. The regime governing its use would have to be clarified.

4.5. Options to eliminate inconsistencies of terminology and procedures in the legal framework

As already explained the only way to resolve the existing inconsistencies in the terminology as well as in the procedures is through a change in the legal texts, i.e. the various sector specific regulations and directives. In this respect, there are in principle only two options:

4.5.1. Option D1: Immediate modification of the existing legal texts

This option is the immediate modification of the existing legal texts. However, we must bear in mind that a considerable part of the internal market *acquis* is affected by this problem and therefore as such changes could have serious consequences, a detailed assessment of the impacts in every sector would be needed. Changes to each and every existing legal text are not really feasible in the context of this exercise.

4.5.2. Option D2: creation of a reference legal document

A better, more flexible solution is to establish a horizontal reference document containing standard terminology and procedures o which the individual legal instruments could be adapted in the future. Then, as sectoral texts are revised they can use this framework to include the harmonised elements appropriate for their sector.

Summary of Options

A: Options related to Notified Bodies	
A1	*Creating a network of notified bodies and a horizontal group of notified bodies*
A2	*Regulating the activities of notified bodies*
A3	*Centralising the competence assessment and monitoring of notified bodies at EU level (Commission or creation of a specific agency)*
A4	*Competence assessment and monitoring of notified bodies performed at national level based on a common EU legal framework and supported by a European infrastructure*
A5	*Electronic notification procedure*
B: Options to improve the enforcement of directives	
B1	*Enhance co-operation of market surveillance authorities by extending the existing co-operation mechanisms*
B2	*Raising the awareness of economic operators as to their obligations*
B3	*More effective controls of the market place* *(1) more stringent pre-market control* *(2) more effective post-market control mechanism*
B4	*Common EU framework on market surveillance setting out minimum requirements*
B5	*Reinforcing traceability and introduction of specific obligations for importers*
C: Options to improve the understanding of the CE marking	
C1	*Information and awareness raising campaign on the meaning of the CE marking*
C2	*Abolition of CE marking*
C3	*Change the current meaning of the CE marking*
C4	*Strengthen the legal protection of the CE marking*
D: Option eliminating inconsistencies of terminology and procedures in the legal framework	
D1	*Immediate modification of the existing legal texts*
D2	*Creation of a reference legal document*

5. ANALYSIS OF IMPACTS

5.1. Preliminary remarks

This initiative is a cross-cutting exercise, which affects directly or indirectly a vast range of industrial sectors with very different market conditions. The spectrum ranges from very homogenous product markets (e.g. lifts, cableways) to product groups with very heterogeneous market structures (toys, electrical products, machinery, personal protective equipment, etc). It should be born in mind that in the context of this exercise the impacts are assessed from a global, horizontal point of view and that the situation in certain sectors might be different from the global picture. Some of the problems generally experienced in a majority of sectors may not exist in particular sectors.[56]

Due to the cross-cutting scope of this initiative and the complexity of the issues treated, the description of the impacts will often remain qualitative, as it is practically impossible to quantify them across the whole range of sectors covered. In general relevant data, if available at all, is sector specific. Data exploring the global situation is rare. There is for example no general database on accidents with products caused by the non-compliance of the product concerned. For this reason recourse is made to sector-specific data which can be considered as representative for the general situation.

This analysis is based to a considerable extent on the feedback received from stakeholders. In order to back up existing indicators and to overcome the lack of data in certain areas, four different groups of stakeholders (enterprises and enterprise associations, public authorities, notified bodies and accreditation bodies) have been asked to provide certain information as well as to evaluate the possible impacts of the measures envisaged.

5.2. Identification of key impacts

This chapter examines the economic, social and environmental impacts to be expected from this initiative in order to identify key impacts which will be analysed in more detail in the following chapters.

5.2.1. Key impacts

This initiative will mainly have economic impacts. The issue of reinforcing controls on the market to ensure a better level of compliance is of major importance for the *competitiveness* of European manufacturing industry as well as for the *functioning of the internal market*. Ensuring a more coherent level of conformity assessment will equally contribute to this objective. A number of he measures will have significant impacts for *public administrations*. While the majority of measures aim at reducing

[56] One example is the problem related to the uneven performance of notified bodies. Some directives (e.g. the Low Voltage directive) do not provide at all for the intervention of a notified body in the conformity assessment procedure. Therefore this problem is of limited relevance in the electro-technical sector.

the *operating costs for business,* some measures might be linked with additional costs which will be assessed in further detail in the following chapters.

5.2.2. Social impacts

The measures examined in this context are also relevant to a number of social concerns, namely public health and safety, health and safety at the workplace, as well as consumer protection (understanding of CE marking).

There is no specific data which would allow to make a link between the an inappropriate testing by a notified body and accidents occurred with the certified products

The exposure of consumers, workers and users to health and safety risks emanating from products is influenced by various factors, and the quality of notified bodies intervening in the conformity assessment process is just one aspect of a more encompassing set of policy measures aiming to reduce this risk. Accidents with products are often not due to a defect in the product but to incorrect use. Statistics in the health at work sector do usually not make the distinction between the different causes.

5.2.3. Impacts on the environment

Chapters 2.1 and 2.2 have outlined the link between environmental concerns and of efficient enforcement mechanisms and the notified bodies.

Due to the fact that causal relationships for environmental damage are in general very complex and that the role of notified bodies is just one element in a more comprehensive set of measures aimed to reduce such harm, it is not possible to quantify the damage resulting from the lack of competence of notified bodies or improper quality of their conformity assessment. The same applies to the lack of efficient market surveillance. Both, the control by a notified body or by a market surveillance authority, can however prevent environmental damage. The potential benefits and costs savings due to prevention become obvious when looking at the example of accidents in the maritime sector, which had disastrous consequences[57].

The measures examined in the context of this initiative will not have per se a direct influence on the environmental resources. They may have indirect impacts on the environment in so far as they improve the functioning of environmental legislation by reinforcing enforcement mechanisms and the control of notified bodies. Consequently the environmental benefits will depend on the general *effectiveness* of every option to improve the current situation.

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[57] An overview on the environmental consequences of some major maritime accidents (Prestige, Erika) has been presented in the Impact Assessment on the proposal for a directive on common rules and standards for ship inspection and survey organizations and for the relevant activities of maritime administrations
http://ec.europa.eu/governance/impact/docs/ia_2005/sec_2005_1498_fr.pdf

5.3. Notified Bodies

5.3.1. Impacts of the "no change" scenario

Differences in Member States in the criteria and procedures relating to the assessment and the monitoring of competence of notified bodies distort competition between these bodies. Notified bodies submitted to stricter assessment and monitoring requirements are facing additional costs in comparison to competitors which do not have to comply with the same material or procedural aspects. However the majority of notified bodies could not quantify these additional costs. In Member States where accreditation is required for notification, notified bodies have to bear the accreditation fees. Prices for accreditation vary according to the size as well as to the activities of the notified body. The prices[58] indicated by the notified bodies range in general from €6,000 to €20,000. Fees for subsequent check-ups are generally lower. Due to the different review intervals (ranging in general between 1-4 years) these costs also vary. The major economic impact however results the investments needed to comply with the accreditation criteria.

Due to unfair practices, notified bodies incur losses in turnover and suffer from a damaging of their reputation. Put under pressure by the market they are forced to cut costs. This results in a downward spiral in terms of both their turnover as well as the quality of their service.

The distortion of competition between notified bodies has a spill-over effect on the competition between manufacturers. Differences in the conformity assessment policy applied by the notified bodies lead to the consequence that the manufacturing industry is also competing under unequal conditions. A less rigorous approach applied in the certification process can reduce the compliance costs of manufacturers significantly.

If the current situation remains unchanged the quality of services provided by notified bodies is put at stake. Inefficient monitoring of the competence of notified bodies and the economic pressure due to unfair practices undermines the quality and rigor of conformity assessment. This could lead to an increasing number of non-compliant and potentially dangerous or environmentally harmful products on the market. The situation undermines the confidence in Member States' notified bodies and may subsequently lead to the non-recognition of certificates and enhanced recourse to the safeguard clause. Industry will be faced with a reinforced demand for additional testing in order to facilitate access to certain national markets and hence incur additional costs.[59] In the long term these developments would undermine the functioning of the internal market and constitute a step backwards.

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[58] This range reflects the general trend of the replies. Some notified bodies communicated significantly higher rates, in some cases the rates were below the 6000€. In a study on economic aspects of product testing carried out in 2002 for the Dutch Ministry of Economic Affairs, the prices for an average accreditation (based on 7 days) were estimated at 14 636 €, a review at 10 823€ and a check up 6 773 €

[59] According to the results of the enterprise questionnaires the dominant reason for having recourse to additional marking is facilitated access to certain national markets.

5.3.2. *Impacts of option A1 (network of notified bodies)*

This option would not generate additional costs for notified bodies already participating in the Notified Body groups. For those which do not yet participate, this option would only involve additional costs for travelling to these meeting. As mentioned earlier it is however doubtful that this measure will be sufficient to solve the problems.

5.3.3. *Impacts of the creation of a EU legal framework on accreditation (A3 and A4)*

Both, options A3 and A4, will generalise the use of accreditation by creating an EU legal framework for accreditation. This will increase the coherence of the evaluation and monitoring regime throughout the EU and eliminate the current distortions of competition due to the inconsistent criteria and procedures.

The generalised use of accreditation has received vast support from all stakeholders.[60] Notified bodies showed themselves very convinced on the positive impacts of this measure. 88% believed that it will ensure a level playing field for notified bodies and 76 % expected a simplification effect. 95% think that it will have a positive effect on competitiveness and 79% of respondents did not expect considerable additional costs or additional administrative burden.

The notified bodies were asked to evaluate the impact of a more harmonised EU accreditation framework on their costs. 25% of respondents indicated a reduction of costs and 26 % of them expect no or insignificant change to their costs. Only 11% believed in an increase of costs of their operation. 35% were not able to assess and quantify the costs at all.

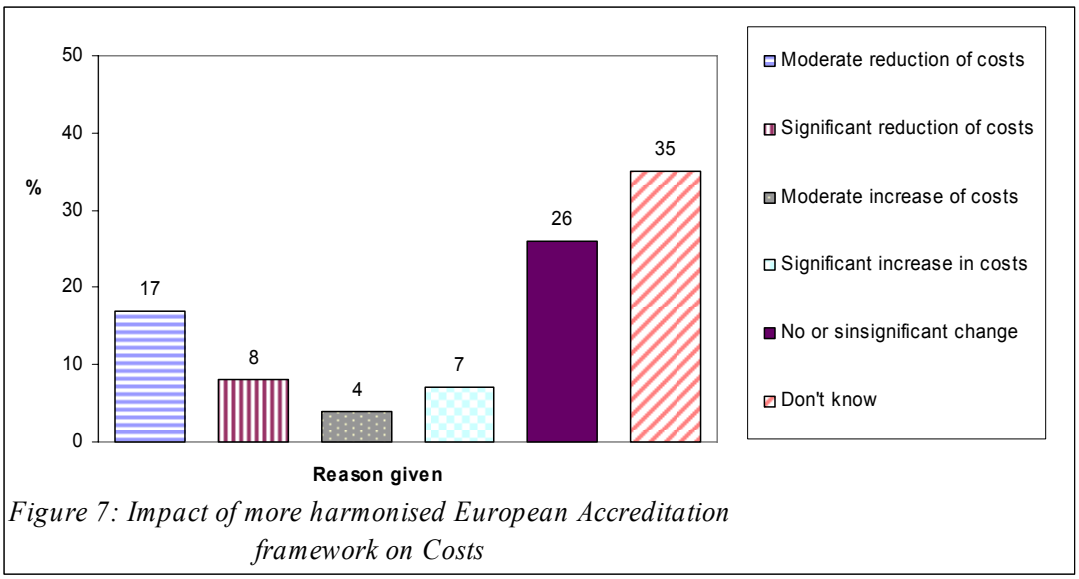

Figure 7: Impact of more harmonised European Accreditation framework on Costs

[60] In the IPM questionnaire 77,1% of respondents replied that accreditation would increase the credibility of conformity assessment services carried out by notified bodies.

This can be explained by the fact that today the vast majority of notified bodies are already accredited.[61] The harmonised framework will be based to a large extent on the existing system. Although adjustments of accreditation certificates may be needed in some cases, in general no significant additional costs or economic burden for notified bodies are expected. Costs will only occur to those notified bodies who have not yet been accredited. Where the organisation of these bodies already ensures an adequate level of quality, the costs for the adaptations necessary to fulfil the accreditation criteria will be moderate.

The manufacturing industry will benefit from more consistent conformity assessment services due to a more coherent and better surveillance of notified bodies.[62] This measure will not entail additional costs for the manufacturing industry, as no significant costs are expected for the notified bodies, which would be reflected in the increased prices of their services.

In general the establishment of a more coherent system of accreditation throughout the EU and the introduction of a common EU policy framework on accreditation are considered to have a positive impact on effectiveness of the EU economy.

5.3.4. Impacts of options A3 (Centralising accreditation at EU level – Creation of a European agency for accreditation)

This option would entail a restructuring of the currently decentralised accreditation system, as the national accreditation bodies would lose their tasks.

The setting up and operation of an agency would entail considerable costs. To give an indication on the operating costs we can make recourse to the example of the European Aviation Safety Agency (EASA)[63]. For its operation EASA uses the revenue from fees and charges of the services it offers. On top of that, it benefits from a subsidy of 24 million EUR per year (out of which 22 million come from the European Commission). Its staff amounts to about 300 employees, but the number should still be increased in order to cover all necessary fields.

We can expect that the potential agency for the assessment and monitoring of notified bodies would have similar aims and it would also collect financial resources from fees, however, the range of different sectors covered by notified bodies and the variety of products they assess is incomparably higher. Therefore, the number of staff and the amount of subsidy would need to be even higher than in EASA's case.

Moreover, an important part of accreditation procedure has to be performed in situ in order to reach convincing results. This would lead to important costs related to travel

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61 90% of the respondents stated that they were accredited. Out of them 93% indicated that the accreditation relates to their notification. The fact that the accreditation is not necessary for the notification was the most frequent reason given by the notified bodies for not being accredited.

62 The vast majority of enterprises consider that the accreditation will lead to a more coherent conformity assessment or to a better performance of notified bodies.

63 EASA develops common safety and environmental rules in civil aviation at the European level. It monitors the implementation of standards through inspections in the Member States and provides the necessary technical expertise, training and research. It is also responsible for type-certification, i.e. the certification of specific models of aircraft, engines or parts approved for operation in the European Union.

expenses, or to the creation of decentralised structures, branches or subsidiaries, thus resulting in de facto decentralisation.

National accreditation bodies naturally rejected this option in view of the effective use of existing structure, coherence of structures in regulated and non-regulated area and additional costs. More details about the results can be found in Annex V.

For those bodies which have already been accredited by their national accreditation body (i.e. the majority of notified bodies) this change to the new system would require certain adaptations in terms of procedures and will entail additional cost or administrative burden in the transitional phase.

5.3.5. Option A4 (Accreditation performed at national level underpinned by a European coordination infrastructure)

This option combines actions at national and EU level and can therefore make use of the positive aspects of both. The competence assessment and monitoring is carried out by national accreditation bodies, therefore closer to the notified bodies. This ensures effective use of resources and avoids additional costs.

EA is in a position to guarantee the level of independence and technical capabilities required. Apart from that, the asset of EA is that it is a structure already in place. It can build on the knowledge and experience acquired over the time by the competent national authorities. It operates a functioning system of peer evaluation and the accreditation bodies are acquainted with the procedures. Since staff of national accreditation bodies is familiar with the functioning of EA, it is expected that the implementation of EU accreditation policy would not entail a significant need for additional personnel at national level.

The central secretariat of EA would have to be reinforced to cover the coordination activities related to the tasks imposed on the EA. Currently, the operation of the administrative secretariat as well as the management of the peer evaluation system is financed from EA budget. The overall budget of the EA today is just under €500,000 and it consists exclusively from its membership fees.

The overall cost of contributing to the European accreditation activities in terms of staff, time, travel and infrastructures that incurs at present to national accreditation bodies, members of EA, amounts to some €2,500,000 (which includes the €500,000 EA budget). This sum represents around 2.5% of the overall budget for all the members of EA. Some accreditation bodies finance their European and international activities exclusively from the accreditation fees, but the majority of accreditation bodies benefit from public authority assistance that covers partly or entirely the costs of such activities.

The initial estimate of a contribution from the Community budget to the operation of EA can be figured as a sum of a contribution of 15% to the operational costs of EA (e.g. €75,000 per annum) and a budget to cover some other tasks imposed on EA, such as the development of sectoral accreditation programmes[64] and assistance to the

[64] The aim of the sectoral accreditation programmes is to compare the requirements for notified bodies stipulated by the Community legislation and the general requirements of the standards applicable to

Commission in the management of safeguard clause cases, estimated at €1 million per year, leading to a total of approximately €1,075,000 per year.

In some Member States it is presumed that an increased cooperation should be established between the accreditation body and other national authorities, especially in charge of notifications. Adjustments and changes to the existing accreditation structures are expected in a few Member States (Germany). Given the different situation and current structures in the Member States it is difficult to estimate the potential additional costs. It is however clear that the overall costs of this option are considerably lower than in the other option outlined above.

According to the Commission questionnaire this option resulted also as the best solution seen by the national accreditation bodies (see Annex V for more information).

5.3.6. Impacts of option A6: Electronic notification system

The introduction of a legal basis for the electronic notification and the replacement the publication of a list of notified bodies in the OJ by a publication in the Commission web-site will significantly simplify the notification process and eliminate the administrative burden of the paper based system for both national authorities and the Commission.

It will also eliminate the existing uncertainties amongst notified bodies relating to necessity of the publication for their authorisation to issue certificates under the directives for which they have been notified. As the notified body's details will automatically appear on the website at the moment the notification is accepted, the notified body can immediately become operational without any further delay.

5.4. Market surveillance

5.4.1. The no-change scenario

As already outlined under 2.2 the lack of efficient market surveillance mechanisms impairs the competitiveness of European industry. As it is difficult to estimate the share of non-compliant products on the market, it is equally difficult to estimate the loss of industry due to non-compliant products. For this reason most enterprises could not quantify these damages. Only a few enterprises actually indicated figures. These ranged in general between 4-25%[65] of the annual turnover. There is however widespread agreement amongst enterprises that the situation undermines their competitiveness compared to operators, which benefit from the current weaknesses in the enforcement and do not observe the rules.

The unhindered entry of non-compliant products on the market can seriously endanger the health and safety of their users, consumers, workers and professionals. Due to lack of an EU wide database linking accidents with their cause it is not

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accreditation to identify which additional criteria needs to be evaluated before the notification. They should serve as a support for accreditation to be fully and efficiently used as a uniform and comparable basis for notification by the public authorities.

65 Figures are taken from the SME panel and the enterprise questionnaire and reflect the general tendency.

possible to give figures on the accidents caused by non-compliances of a product. Apart from any attempt to allocate a certain proportion of such accidents to the lack of market surveillance would not make sense, since it forms part of a broader policy on accident prevention.[66] However, the fact that more and more products presenting serious non-compliances are found on the market[67] gives and indication on the potential danger arsing from the current situation.

Leaving the situation unchanged would also mean to accept obstacles for a real internal market. Despite the fact that EU law has harmonised the conditions for the marketing of products, markets will still remain fragmented due to national differences in the enforcement of the rules.

A system of technical harmonisation for products requires a well functioning control mechanism in order to ensure an even level of safety for all users and consumers and a level playing field for economic operators throughout the European Union (cf. chapter 2.2). Thereby, a choice has to be made concerning the allocation of tasks and therefore, burden, between economic operators and public authorities. It is obvious that a more stringent pre-market control system facilitates tasks for market surveillance authorities to a certain degree. It is however clear, that any role allocation must not jeopardize European industry's competitiveness. Therefore, a solution has to be found which balances burden between Member States and economic operators.

5.4.2. Impacts of option B1- enhancing the existing cooperation mechanisms

Enhanced cooperation between Member Sates' market surveillance authorities can make market surveillance more effective efficient. This is inter alia demonstrated by the results of the questionnaire sent to market surveillance authorities:

68 % of respondents believe that the enhanced cooperation mechanism would lead to a significant improvement, 30 % believe that there would be a moderate improvement and only 2 % are of the opinion that there would be no or only an insignificant improvement. All respondents agree that a cooperation mechanism as suggested would enable more effective controls and 91 % believe that it would lead to an efficient sharing of resources.

This option will entail costs for public authorities and the Commission budget. The costs for supporting the various types of coordination and cooperation activities foreseen in this context by the Community budget is estimated at 1 200 000 € per year. The additional costs for public authorities can hardly be quantified. Market surveillance authorities replying to the survey experienced difficulties in giving concrete estimates as to whether such cooperation mechanism would involve additional costs. Whilst some respondents anticipate an increase in term of human resources, most of them deem the additional costs to be insignificant compared to the

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66 While effective market surveillance is important for the functioning of the prevention policy as a whole it will as such not prevent accidents from happening. Vice versa the fact that market surveillance mechanisms fail in a certain case, need not automatically lead to an accident or a health problem

67 Rising number of RAPEX notifications. Annual Report on the Operation of the Rapid Alert System for non-food consumer products (RAPEX) 2005
http://ec.europa.eu/consumers/reports/report_rapex_05_en.pdf

objective to be achieved. Only 21 % expect significant additional costs whilst 60 % of respondents expect an overall reduction of costs due to cost savings by more targeted controls enabled by improved information flows etc.

5.4.3. Impacts – More stringent pre-market controls (option B3)

The systematic obligatory intervention of a notified body in the conformity assessment process (see 4.3.3), independent of product type and risk involved might contribute to detect unsafe products provided they are actually submitted to such procedure. It is, however, doubtful whether such systematic involvement of notified bodies contributes to getting hold of manufacturers not sticking to the rules and taking the risk of placing products on the market without having them certified.

Additional testing and certification requirements will be an obligation for all manufacturers, also for responsible ones which do already conform to the legislation. The consequence would be additional costs for the "good ones", the bad ones having a free ride.

Such approach would constitute an additional burden for enterprises. The influence of certification costs on the total production costs depends on the volume of production. For large production series manufactures have indicated a range between <1 % - 5%. For complex products or small series individual products, the costs can amount up to 20-30% of the total production costs. Figures provided by SMEs were naturally higher[68]. In a survey targeted to enterprises 75% of the respondents anticipate significant additional costs and 19% expect a moderate increase of costs linked to a compulsory involvement of a notified body. Furthermore additional costs would be expected from the delay of time to the market.

While this option would entail additional costs for business it is doubtful that it could actually lead to an improvement of the current situation. The absence of effective post-market controls will still be sufficient incentive for unfair playing operators to disregard the rules and bring non-compliant and non tested products onto the market.

5.4.4. Impacts - common framework on market surveillance+ obligations for operators + traceability (option B4)

The majority of enterprises are very much in favour of reinforcing market surveillance. Accordingly, 95 % of enterprises responding to a pertinent questionnaire think that reinforced market surveillance would contribute to ensuring a level playing field for companies. The vast majority of enterprises do not expect additional costs caused by a mechanism providing for reinforced market surveillance. Many enterprises stress the need for a common understanding of the severity of non-compliances in order to treat equal deficiencies equally throughout the EU.

A framework restricted to the setting of requirements which are necessary to ensure a uniform and sufficiently rigorous level of market surveillance would grant Member States the possibility to maintain their national structures, thus restricting adaptation costs. Furthermore, it would leave them a certain level of flexibility to adapt to

[68] In the SME questionnaire - % stated that their costs would increase significantly. The majority could not quantify this increase, but the average of the figures provided is 13,25%.

specific situations (e.g. Member State specifically exposed to third country imports etc.).

Market surveillance authorities positively evaluated the impacts of this option. The vast majority of respondents (84%) are of the opinion that it will improve the effectiveness of their work. 41% even anticipate that a system as suggested will bring a significant improvement.

Whilst 62% of responding authorities anticipate additional costs they recognise at the same time the utility of minimum requirements as such a system is deemed to be essential to ensure an equal level of market surveillance. As most authorities declare not to be able to specify the costs to be expected no estimate as to the concrete costs can be given. However these costs are expected to be significant only for those Member States which do not have efficiently functioning systems in place yet and therefore have not yet fully lived up to their responsibilities in this area.

5.4.4.1. Introduce an obligation to carry out border controls

Borders are the best place to detect deficiencies before products from third countries are released for free circulation on the Internal Market. Controls at borders have a double positive effect: Not only can unsafe products be prevented from being placed on the market already at the entry point, but also can the information gathered thereof be useful for other customs and market surveillance authorities as it enables e.g. targeted action.

27% of respondents to a questionnaire which was addressed to public authorities expect that the obligation to carry out controls at external borders leads to a reduction of costs, 19% do not expect any significant additional costs, whilst 54 % expect additional costs. Many of the latter, however, expect on the other hand cost savings enabled by targeted action.

5.4.5. Impacts – Traceability and obligations (B5)

Once deficiencies are detected market surveillance authorities need to be able to address a responsible person in the EU in order to be able to impose corrective measures.

Market surveillance authorities prefer to first contact the manufacturers, whether situated inside their own country or in another EU/EEA country and, to an important part, even if they are situated outside the EU, in order to reach a quick and satisfying solution. It is, according to a survey however, in many cases not possible to identify the manufacturer. 89% of market surveillance authorities indicate that better traceability would improve efficiency and facilitate their work, 46% even believe that it would lead to a significant improvement. As to the impacts on their resources 42% expect additional costs (thereof only 12% expect significant costs), whilst 58% do not believe they would incur any additional costs or even expect a reduction of costs. Most of the respondents who expect additional costs nevertheless deem them to be worth it. The cost-benefit analysis for any of the measures envisaged below seems to be positive for most market surveillance authorities.

To achieve the objective of traceability different ways could be envisaged. However, economic impacts on enterprises are different.

(1) Introduce a general obligation to appoint an authorised representative for products imported from third countries

(2) Establishing a registration system for manufacturers/importers/distributors

(3) Obligation to identify the manufacturer and the importer on the product and obligation of all operators to identify the suppliers and purchasers of their products (except supplies to final users/consumers)

The majority of enterprises deem that a registration system would be the most burdensome. As to the options authorised representative versus identification of manufacturer on product/record keeping it has to be stressed that the obligation to identify the manufacturer on the product, the packaging or in the documentation accompanying the product already exists in many directives. Taxation law already requires economic operators to keep records of business transactions. No additional burden on enterprises is therefore created by making use of an existing obligation. For this reason the identification obligation should be preferred to the appointment of an authorised representative.

5.5. Meaning and credibility of the CE marking

5.5.1. No change scenario

The unclear meaning is mainly a problem from a consumer information policy perspective. The fact that the consumers do not understand the CE marking has apparently little influence on purchase behaviour[69] [70]. Enterprises also confirmed this.

To a certain extent the undermined credibility of the CE marking has also consequences for industry. Industry has frequently recourse to additional markings for consumer products. As the main reason for this is that voluntary certification marks are requested by retailers and consumers. Hence products are submitted to multiple certification which cause additional costs for industry. According to the results of the questionnaire these additional marking are however considered to have an added value and the majority answered that they would continue to use these marks even if the credibility of the CE marking would be reinforced. However some also replied that they mainly use these marks to satisfy legal and administrative requirements.

Furthermore the positive image of the CE marking in international trade relations might be deteriorated and hamper the competitiveness of European enterprises.

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[69] A study of consumers and retailers knowledge of the CE mark, The Swedish Research Institute of trade, Feb 2004, pg 10.

[70] Eurobarometer 52.1, Europeans and the EC logo, March 2000, pg12.

5.5.2. *Impacts of Option C.1: Information campaign*

Having received more information consumers will better understand the meaning of the CE marking and will reassure themselves that the products which they are buying do actually bear the CE marking. A better level of information will also reduce the misperceptions, which might mislead consumers in their purchasing decisions.

An information campaign on the meaning of the CE marking will not entail costs for enterprises. A positive effect on competitiveness can be expected from the fact that better informed consumers will more proactively look for the CE marking and avoid non-compliant products not bearing the CE marking.

The costs for the information campaign will have to be born either by the Community budget, or, if organised in cooperation with the Member States, by national budgets. In order to reach a broad public a sum of 5 000 000 € would be needed.

5.5.3. *Impacts of Option C3: Changing the meaning of the CE marking*

From the outset, a big question mark has to be put on the effectiveness of these options to improve consumers' understanding of the CE marking. There is a high probability that any change in its meaning would contribute to even more confusion. While reserving the CE marking for certified products could simplify the meaning of the CE marking, the introduction of a variant of the CE marking (CE+) for certified products is however very likely to cause additional confusion. In any case such changes would need to be combined with massive information campaigns to effectively communicate this change. The costs of such a campaign will be the same as in option C1.

Results of the survey amongst enterprises have indicated that this option would entail considerable negative impacts for the majority of enterprises, in particular in sectors where the intervention of a notified body is not (or not systematically) required (e.g.: electrical engineering, radio and telecommunication or toys).

A differentiation according to whether the product has been certified or not would wrongfully create the perception that there is a "hierarchy" of CE markings. Consequently products, which are "self-certified", would be perceived as products of less quality, safety etc, although it is not the intervention of a notified body as such, which makes the product better, safer or more performing. As it is doubtable that this message can be passed on to consumers such a differentiation would inevitably lead to even more confusion amongst consumers causing market forces to request third party certification even in cases where this is not imposed by the legislation. As a consequence enterprises would incur additional costs[71] due to the additional certification requested by the market place. Thereby, SMEs whose products might not yet have reached a certain reputation would be particularly affected.

Any change of the meaning of the CE marking would also have substantial impacts on international trade. The CE marking is a real asset for (European) products and

[71] The costs of the intervention of a notified body in the conformity assessment process have already been analysed in more detail under chapter 5.5.3

strengthens the competitive position of European manufacturers in international trade. European manufacturers' position would be considerably weakened if the CE marking would no longer appear on products which come under self-declaration. Likewise the introduction of a special marking for products tested by third parties (CE+) would negatively influence the trade relations as trading partners would need a considerable time to get acquainted to the new European marking system.

The CE marking is well established between both, customs and market surveillance authorities, giving them a clear indication of the product's compliance (until evidence of non-compliance is established). Changing the meaning of the CE marking would impair the smooth functioning of the internal market at least for a certain period of time, as all persons involved in surveillance activities would have to undergo training and get acquainted with the new rules.

5.5.4. Protection of the CE marking as a collective Community trademark

The protection of the CE marking as a Community collective trademark may as such not automatically reinforce the credibility of the CE marking. However it reinforces the means to better police its use. Authorities will get an additional tool to take legal action against economic operators misusing the CE marking. Furthermore enterprises will be enabled to invoke the protection of the collective trade mark in proceeding against unfair playing competitors. Courts are given the means to impose fines and damages. Together with the other measures in the area of market surveillance this measure should deter irresponsible or ill minded operators from fraudulent practices, thus contributing to ensuring a level playing field for enterprises.

This option will hence have a positive effect on the competitiveness of European enterprises without creating any additional costs for industry. It will also increase the level of safety of products on the market

5.6. Inconsistency problem

5.6.1. The no-change scenario

Due to inconsistencies enterprises face additional costs. 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.

5.6.2. Creation of a reference document setting out common definitions and procedures

This option will not directly modify the existing legal framework. For this reason the assessment of its impacts is limited to a general examination of the simplification potential resulting from an alignment and consolidation of the legal framework. The concrete consequences of adaptations, like the alignment of a definition to the standard definition contained in the horizontal framework or the modification or introduction of a conformity assessment procedure will have to be assessed in the specific context of every legal instrument.

Stakeholders are strongly in favour of harmonising the terminology in EU legislation and did not see any additional burden related to such measures. In the surveys enterprises have ranked this measure amongst the four issues carrying the biggest potential to enhance the competitiveness of European enterprises. 93 % considered that it would have a positive effect on their competitiveness, and 44 % even indicated that it might lead to a reduction of costs or administrative burden. The results from the survey target to notified bodies delivered a similar picture: 100% of the notified bodies expected a positive overall effect on competitiveness, 91% considered that it would simplify the legal environment.

The potential of simplification and cost reduction by bringing more consistency into the conformity assessment procedures was also explored. Notified bodies positively assessed this option. 97% were convinced about its positive effect on competitiveness. 85% of them did not believe in additional cost linked to such increased consistency and 90% were of the opinion that the consistency would ensure more equal conditions for the operation of the notified bodies. The simplification effect of the consistency was supported by 83% of the respondents.

6. COMPARISON OF THE OPTIONS

6.1. Notified Bodies

Both, the centralisation of accreditation at Community level using an agency as well as the Community accreditation policy based on national accreditation systems are considered to be equally effective to ensure a coherent competence assessment and monitoring of notified bodies to ensure quality of conformity assessment throughout all Member States. The disadvantage of the agency option is that it would create a totally new structure instead of building upon an existing system. Important knowledge and synergy would be lost and adaptation to a new set of rules and procedures would lead to an unnecessary and additional administrative burden, both for the notified bodies and the national authorities, especially in the initial period. The strength of the Community accreditation policy concept is that it uses the existing structure of EA as a foundation, thereby representing an efficient use of resources, and in addition it improves the existing system by combining the national and European levels, whilst respecting the subsidiarity principle: **Option A4 is clearly, therefore, the best option.**

A common accreditation policy will promote more coherence of conformity assessment activities through reinforced and more coherent control of notified bodies. However, to improve the coherence of conformity assessment and to mitigate the problem of unfair competition, the creation of a network of notified bodies in which all notified bodies participate is required. The existing legal framework does not oblige such participation in co-ordination activities, and for this reason this non-regulatory approach to co-ordination and co-operation has to be combined with a legal requirement to participate in such activities (even in a 'virtual' way using web-based applications). **Option A1 is therefore proposed.**

The electronic notification system represents a major simplification to the current system and has beneficial effects for all parties concerned. It is therefore clearly to be preferred to the no-change scenario. **Option A5: is therefore proposed.**

6.2. Market Surveillance

Option B3 is split into two regimes: pre-market control or post market control. As discussed in section 4.3.3, pre-market control alone would not solve the problems arising and would need additional post market control in parallel In addition, effective pre-market control would necessitate stringent, explicit requirements and controls in the pre-market phase to ensure a level placing field between economic operators. This is in contradiction to the New Approach philosophy and would become inflexible to innovation and it is doubtful that it would sufficiently control the market. Furthermore, it would undoubtedly increase costs for certain industry sectors, hampering their competitiveness.

Therefore, a better solution is option B3(2), which is to establish a more effective post-market control mechanism. This option is intrinsically linked to options B1 and B4. Clearly, the reinforcement of the existing co-operation mechanisms for market surveillance authorities has great potential for improving the efficiency of market surveillance at Community level; however it will only be effective if it is combined with a legal obligation for all Member States to participate in these co-ordination activities. For this reason option B1 would have to be combined with the regulatory option B4 which sets out such an obligation. Option B4 also includes a number of other important benefits, including the framework to establish an effective and efficient organisation for market surveillance, but this would entail some additional costs mainly at national level for public authorities. These costs would, however, be offset by the beneficial effects to be expected from this option. Therefore, **options B3(2), B1 and B4** are proposed.

Option B5 underpins the combined options B3(2), B1 and B4; it is no use reinforcing the functioning of the market surveillance within the Community if external borders form a weak link in the chain which could be exploited by unscrupulous manufacturers or importers. Therefore, **option B5** is also proposed.

Options B2 relates to awareness raising and has not been discounted, but such activity does not fall in the framework of the overall proposal. It is seen as a complementary action and should be nevertheless pursued in parallel.

6.3. CE marking

The abolition of CE marking has already been discounted at an early stage due to its detrimental effects for both industry and the functioning of the internal market. Business has been working with the CE marking concept now for many years. The effectiveness of changing the meaning of marking itself is also doubtable. There is a high probability that any change will not correct the current situation of misunderstanding, but only lead to further confusion. In addition, this would have negative impacts on the competitiveness of European industry and the functioning of the internal market.

An information campaign on the meaning of CE marking is the most effective tool to clarify consumer understanding of the marking and will not have any negative consequences for business. However, the credibility of the CE marking needs to be reinforced with the formal protection of the marking as a Community collective trade

mark which will generate positive effects without no additional cost. **Options C1 and C4 are, therefore, proposed.**

6.4. Inconsistency problem

Since the option of modifying the definitions and procedures in all Community product legislation at the same time is not really feasible; a full assessment of the impacts on each sector should be undertaken first, the only credible option is to establish framework legislation which cold serve as a reference document for future legislation and modifications to legislation. The consultation process has clearly demonstrated the need for simplification and harmonisation to remove inconsistencies and therefore the no-change option is not an option. **Therefore, option D2 is proposed.**

6.5. The choice of the legal instrument

6.5.1. Relationship to the existing legal framework

Following the choice of the specific policy measures to be implemented a decision has to be made on the most effective way in which to integrate the options into the existing legal framework, i.e. the sector specific regulations and directives. In this context the following options have been identified:

(1) A "vertical" solution: meaning individual modification of all existing directives and regulations;

(2) Full "horizontal" solution: the creation of a horizontal framework containing all common elements which would immediately modify all the existing directives and regulations;

(3) General framework solution: the creation of a horizontal framework which does not directly modify the existing directives and regulations but constitutes a general framework which serves as a reference document for future legislation.

The vertical solution (1) would be a temporary solution. It would bring more consistency to the existing legal framework, but would have no means to ensure that inconsistencies did not arise in future due the adoption of new directives or regulations. Furthermore, the vast number of legal instruments affected by this initiative makes this option unrealistic to achieve.

In order to achieve the objective of long term coherence, the creation of a horizontal framework removing all inconsistencies in the individual instruments (2) would be more effective. This approach would also be more efficient as common elements in the horizontal framework would not have to be repeated in sector specific instruments. However, as already discussed this would be unfeasible due to the large number of texts affected. In addition, an immediate change of existing legislation would require detailed impact assessment for every sector. For this reason, the modification of the existing directives should be carried out in a separate exercise.

Therefore **(3) is the proposed option**, as it would address certain aspects not yet regulated in the current legislation but would also establish key elements for

improving the current situation and set out a common horizontal framework for future legislation. The alignment of existing legislation to a new horizontal framework would follow in a second step. This would be the most flexible solution which offers the additional advantage of flexibility to take into account sector-specific situations.

6.5.2. The choice of the legal form

Certain important elements of the horizontal framework which underpin the proper functioning of the internal market, namely market surveillance and accreditation, are not fully addressed in the existing legislation. Provisions for these could go into operation immediately to complement the current legislation. Therefore, the choice has to be made between a directive or a regulation.

A regulation has the advantage of guaranteeing a consistent legal framework throughout the EU. However the provisions must be sufficiently clear and precise so that they can be applied directly without any transposition measures of the Member States.

In order to avoid confusion and legal uncertainty, issues which are currently addressed in the existing legislation (like definitions or the safeguard clause procedure) cannot figure in a regulation or in a directive. For this reason the legal form of a decision is chosen. This decision will constitute a reference document for future legislation.

7. ADMINISTRATIVE COSTS

The proposal foresees various obligations for the stakeholders involved in the process to provide certain information. This chapter examines how this obligation affects the stakeholders involved in terms of additional administrative burden, over and above the current situation.

It should be remembered that it is only the Regulation that will directly impose obligations on the different actors. The elements contained within the decision, which are reference texts providing guidance to the legislator, will only have an effect when they are introduced into legislation addressed to individuals or the Member States. For this reason the analysis will focus on the measures encompassed in the Regulation, i.e. accreditation and market surveillance.

7.1. Accreditation

The framework on accreditation introduces a legal basis for what we have as an existing system, which is already in place and operating in line with most of the rules proposed. For this reason the most important obligations imposed on Member States and accreditation bodies, for example the pre-requisite requirements to become an accreditation body or the organisation and participation in peer evaluation, should not lead to any additional costs over and above the current situation.

Therefore, the activities identified as generating administrative cost are mainly related to the increased responsibility of national authorities vis-à-vis their accreditation bodies and the ancillary duties linked to work at the European level.

Member States will have to have a close link with their national accreditation body and will have to closely monitor their operation. However, as peer evaluation is designed as a monitoring tool, the latter obligation should not lead to significant additional costs. Ensuring a close relationship may, however, require Member States to have specific additional staff responsible for accreditation policy and for following the activities of the national accreditation body. Member States will also have to keep each other informed regarding, for example, results of the peer evaluation or on the agreement to use services of another accreditation body (cross frontier accreditation). We estimate that on average two man years will be needed (one for policy development and monitoring and one for exchange of information), however the actual cost depends on the national organisational structure. As already discussed in section 2.1, accreditation is operated as a public activity in the vast majority of Member States. In some of them, accreditation bodies are part of governmental structures and additional staff will not be required at all.

National *accreditation bodies* must inform the other accreditation bodies, the competent authorities and the Commission, about which accreditation activities they perform (and keep that information updated). In addition, this information and the results of their peer evaluation must be made publicly available. The costs for accomplishing these tasks will depend largely on the size of the accreditation body and the volume of its activities. While the impacts for bigger accreditation bodies will probably be limited, smaller bodies may need to reinforce staff by one man year of effort.

The main burden is expected at the beginning. The introduction of the information channels and the exchange of basic information will require a certain effort (e.g. Member States will have to inform each other and the Commission about their national accreditation body). However, once this is information system is established and populated with the basic data, most information will only have to be updated, entailing fewer costs at the structure evolves. Of course, there will always be a certain workload due to updating and ongoing information obligations. However, this information exchange is crucial for guaranteeing the transparency of the system and ensuring mutual confidence.

The costs incurred by *notified bodies*[72] to obtain an accreditation certificate can also be qualified as administrative costs. The new rules are effectively a confirmation of the system in place and mainly concern the organisational aspects of accreditation. Since the competence assessment activity performed by accreditation bodies will not substantially change, the impacts for notified bodies, which are already accredited and undergo regular monitoring, will be marginal; they will incur more or less the same costs. Accreditation bodies are not expected to change their pricing policy towards their customers, a view confirmed by notified bodies.[73] Hence additional costs will only concern those notified bodies, which are currently neither accredited nor subject to another equivalent assessment and monitoring regime. In order to maintain their status as a notified body, they will in future need to demonstrate their

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72 Economic aspects of product testing-final report, Study carried out by PWC Consulting for the Dutch Ministry of Economic Affairs, The Hague 2002.

73 Cf table on page 42. 26% considered that there would be no change in the costs, 25% expected a reduction of costs and only 11% believed that it would lead to an increase in costs.

competence through accreditation (or to an equivalent means of demonstration of competence).

Due to the limited impact on the costs resulting from accreditation, the new rules on accreditation are not expected to entail any additional administrative costs for *manufacturers*. The fact that the few notified bodies which are not yet accredited may subsequently become accredited is also not expected to have significant impact on certifications costs. In general, the costs for conformity assessment are mainly determined by personnel costs, travelling costs and overheads for testing equipment. The costs for accreditation therefore constitute a marginal proportion of the overall costs for conformity assessment and certification costs account for a small proportion of the manufacturing costs. On average, conformity assessment costs constitute only 1% to 2% of the overall unit production costs (and even less for large scale production).

7.2. Market surveillance

The framework for market surveillance sets out certain requirements for Member States on how to organise and carry out market surveillance. Some of these requirements are linked to administrative costs, for example the complaint management. The framework also provides for enhanced co-operation and information exchange at European level. This will lead to initial additional costs in terms of personnel, training and travelling costs. However, reinforced co-operation is also expected to lead to considerable efficiency gains through sharing of information and resources.

Market surveillance enforcement authorities were asked to assess the costs linked to these additional obligations, unfortunately most of the respondents declared not to be in a position to assess these costs. Therefore, in the absence of significant data, we can only make a broad estimate that the increased costs in relation to initial set-up to comply with the framework will be in the region of 5% to 10%. These costs will be for administrations in charge of market surveillance and would not affect manufacturers.

Compliance with the minimum requirements should only create significant costs for Member States which do not yet have a functioning market surveillance system in place; however if this were the case then that Member State would not yet correctly fulfil their existing obligations to effectively implement Community law, and the full cost of the system could not be attributed to the new framework.

Some replies were received to the questionnaire but they varied significantly between sectors. However, some very general observations can be made. In the pyrotechnics sector, one responsible authority estimated that co-ordinated targeted actions would lead to 10% increase in administrative costs, whilst for the measuring instruments sector, one authority estimated that targeted actions will have only a minor impact (+2%) on resources required. It was noted that these costs would be linked to the increased obligation to register and deal with complaints, increased co-operation mechanisms and need for additional resources.

The vast majority of authorities, however, did respond that they considered that enhanced co-operation would improve the effectiveness of their work, and on

balance 60% expect an overall reduction in costs due to the savings from more targeted controls which will allow improved information flows and sharing of resources.

7.3. Obligations for economic operators

The decision sets out a number of *obligations for economic operators* involved in the supply and distribution chain. It has already been noted that the decision as such will not impose any obligations at all and will, therefore, not lead to any administrative burden whatsoever. However, since the articles of the decision are intended to be used as standard articles in future legislation the following section provides a general assessment of administrative costs which could be linked to their implementation. A detailed assessment can, however, only be provided in a sectoral context.

It should be stressed that the vast majority of these obligations already exist today; this holds true for most manufacturers' obligations. The establishment of technical documentation, the EC declaration of conformity, the indication of the manufacturer's name on the product are foreseen in the New Approach directives. Obligations for importers and distributors may at first sight seem to be unusual, as most harmonisation instruments have not addressed these operators at all. However, they are, in fact, already included in existing national and European legislation. The General Product Safety Directive (GSPD) has laid down a number of similar obligations for manufacturers, importers and distributors[74], which have been made more precise in this proposal, in order to clarify exactly what is expected from manufacturers/operators.

In order to reinforce market surveillance and to enable public authorities to efficiently prosecute unscrupulous operators, enhanced traceability requirements have been introduced. Traceability is ensured by an obligation for every economic operator to be able to identify both the suppliers and the purchasers of their products. No specific documentation requirements are foreseen and it is left to operators to organise this for themselves. This should not impose any additional burden as the existing legal obligations already require them to put adequate procedures into place[75], for example, existing taxation law requires economic operators to keep records on their business transactions. Therefore, this obligation should not be linked to any additional costs. However, traceability needs to be ensured and there will be a requirement to identify a product by a serial/batch number, by the name of manufacturer and by the name of the importer. This last obligation is a rather new requirement in Community law and may give rise to some extra costs for importers. However, clearer competition is a counterbalance of this cost.

Hence these obligations will entail limited minimal administrative costs for economic operators which should be outweighed by the positive effects expected from a more level playing field in the market.

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74 Article 5 of Directive 2001/95/EC: The General Product Safety Directive: http://ec.europa.eu/consumers/cons_safe/prod_safe/gpsd/currentGPSD_en.htm

75 Such an obligation already exists under the GPSD. Furthermore under the product liability directive (85/347/EEC) a distributor can only acquit liability for damages caused by a defective product, when he can indicate the identity of his supplier: http://ec.europa.eu/enterprise/regulation/goods/liability_en.htm

8. MONITORING AND EVALUATION

One of the main objectives of this initiative is to reinforce the functioning of the current legal framework and to improve its enforcement. For this reason the measures envisaged to improve market surveillance and the control of notified bodies have a number of in-built mechanisms allowing national authorities, Member States and the Commission to closely monitor the implementation.

As regards the co-ordination of accreditation activities, EA will be obliged to send an annual report of its activities and the Commission will have observer status in EA. In addition, national accreditation authorities will have to inform the Commission and the other Member State of the withdrawal of accreditation certificates from conformity assessment bodies.

For market surveillance, information exchange systems provided for in the legal framework will give regular feedback on the level of implementation and on the effectiveness of this policy. Further information will be obtained through the various other co-ordination and co-operation activities, such as ADCO groups or ad hoc co-operation projects. The reinforced market surveillance framework should lead to a reduction in the number of safeguard clauses received by the Commission.

To examine whether consumers' understanding of the CE marking has improved after the information campaign, a new survey amongst consumers on their knowledge about the CE marking could be carried out. A comparison with the results of previous surveys will allow conclusions to be drawn. Information received in this way will be complemented by feedback received from co-operation mechanisms already in place, e.g. notified body groups and ADCO groups etc.

ANNEX I
The "New Approach"

The "New Approach"

The New Approach is a legislative technique used in the area of free movement of goods, particularly of industrial products. Introduced in 1985, it has revolutionised the way legislation is written in the EU by moving away from complex and detailed prescriptive technical requirements by fixing only the essential public interest requirements to which products must comply. This results in a flexible and technology-neutral legal framework. The objectives were firstly to avoid political negotiations on technicalities, second to gather together, in one text, a large range of products concerned by the same requirements relating to common risks and third to provide flexibility for manufacturers to conform to the requirements and to demonstrate compliance.

The standardisation policy gave the Community the means to achieve the technical harmonisation outside of the legislative texts and to involve the participation of stakeholders.

The general principles of the New Approach policy are laid down in three instruments: the 1985 Council Resolution "A New Approach to technical harmonisation and standards" which established the principles of essential requirements and the use of harmonised standards, complemented in 1989 by the Council Resolution "A Global Approach to conformity assessment" and followed in 1993 by a Council Decision setting out on the detailed testing and certification procedures, intended to be used in the harmonisation directives and providing guidelines for the use of the CE marking.

The existing legal framework basically consists of:

- the individual sector specific directives/regulations;
- the horizontal instruments, e.g. the Resolution of 1985 and Decision 93/465/EEC;
- the General Product Safety Directive (GPSD) in the area of consumer goods.

This legal framework is completed by a number of non-legislative instruments (guidance documents) and cooperation infra-structures which have the objective to facilitate and ensure coherence in the implementation of New Approach legislation.

Horizontal New Approach elements

The "Blue Guide"[76] is considered to be an "authoritative expression of opinion" and provides a comprehensive explanation and clarification on the interpretation of elements common in all New Approach directives. Published in 1994, it has become the reference document for all stakeholders involved in the implementation of New Approach legislation.

In addition, horizontal aspects are regularly discussed with the SOGS (Senior Officials Group on Standardisation and Conformity Assessment Policy) who are responsible for the implementation of the horizontal elements of the directives.

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[76] Guide to the implementation of directives based on the New Approach and the Global Approach, http://ec.europa.eu/enterprise/newapproach/legislation/guide/index.htm

Sector-specific measures

The implementation of specific sectoral New Approach directives is co-ordinated by sector specific experts groups, which are complementary groups to the SOGS. Stakeholders in the form of industry, standardisation organisations and consumer organisations are usually also represented in these groups. The Commission, after discussion and consultation of these expert groups, has published implantation guidance papers under almost all New Approach directives.

Performance of notified bodies and notification procedure

Existing EU legislation sets minimum criteria which notified bodies must meet. It is up to the Member States to check that the bodies actually meet these requirements. Currently nearly all Member States operate national accreditation systems in order to assess the competence of notified bodies (plus certification bodies and testing and inspection bodies). In some countries accreditation bodies are private organisations, e.g. in Germany, whilst in others, accreditation is carried out by public bodies. As a result, accreditation systems between countries and sector. EA, the European co-operation structure in the area of accreditation goes some way to address these differences. However, EA is a private, independent group whose members are the national accreditation bodies. Membership is voluntary and the results of an EA accreditation have no legal foundation.

Between 1996 and 1998 a series of horizontal guidance document setting out the general policy on notification, designation and accreditation (so-called "CERTIF" documents) were elaborated and agreed upon in SOGS. For example, sector-specific groups of notified bodies have been established at Community level to share experience and best practices and ensure a coherent and transparent conformity assessment.[77] However, not all notified bodies participate and the guidelines developed by these groups are not always respected by all notified bodies.

In relation to notification electronic notification has now been possible since March 2006 allowing Member States to notify much more efficiently in the form of electronic notificaiton.

Market surveillance

Administrative Co-operation groups (ADCOs) are currently established under some New Approach directives, such as toys, machinery, electrical appliances, personal protective equipments, cableways, etc. The proper application of Community law depends upon smooth administrative co-operation to ensure uniform and efficient enforcement of the law in all Member States. The ADCO groups aim to minimise the effects of different surveillance practices and reduce the overlap of national surveillance operations. Co-operation also involves the spread of good practice as national authorities can compare methods to find improvements, e.g. during comparison activities or joint surveys, etc.

Moreover co-operation can be useful to clarify how monitoring in the marketplace takes place, and what corrective actions and other activities the surveillance authority is entitled to take. This could also help when exchanging views and solving practical implementation problems.

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[77] The operation of these bodies is outlined in chapter 3 of working document Draft CERTIF 2005-8: Creating a network of notified bodies: http://ec.europa.eu/enterprise/newapproach/pdf/draft_certif_2005_8.pdf

Sector-specific groups of national experts meet regularly at European level to discuss technical implementation issues, but also to foster mutual trust and transparency between themselves. These groups consist of Member States enforcement authority officers for the particular sectoral legislation plus other interested parties, such as industry, standardisation organisations, consumer organisations and notified bodies. Moreover, mutual assistance is promoted to foster information exchange. Mutual joint visit programmes carried out in the late 90s was a mechanism to exchange best practice to promote a better understanding of different national enforcement mechanisms under certain New Approach Directives. Several sectors were selected, including toys, electromagnetic compatibility, low voltage equipments, machinery, recreational craft, etc. All Member States plus Norway participated in this programme and the conclusions were discussed at a seminar in 1999 and constitute the basic principles of the proposed market surveillance framework.

Moreover, the Commission has also promoted cross-border sectoral market surveillance actions. This initiative brought together, for the first time, public enforcement authorities related to a specific subject in order to pursue effective market surveillance to avoid unnecessary bureaucratic complication and duplication of existing systems due to national administrative structures. Projects were designed to create synergies between at least two Member States to promote exchange of information.

ANNEX II
List of New Approach directives

(1) **Simple Pressure Vessels Directive:** Council Directive 87/404/EEC on the harmonisation of the laws of the Member States relating to simple pressure vessels;

(2) **Toys Safety Directive:** Council Directive 88/378/EEC on the approximation of the laws of the Member States concerning the safety of toys;

(3) **Construction Products Directive:** Council Directive 89/106/EEC on the approximation of laws, regulations and administrative provisions of the Member States relating to construction products;

(4) **Electromagnetic Compatibility Directive**: Council Directive 89/336/EEC on the approximation of the laws of the Member States relating to electromagnetic compatibility;

(5) **Personal Protective Equipment Directive:** Council Directive 89/686/EEC on the approximation of the laws of the Member States relating to personal protective equipment;

(6) **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;

(7) **Active Implantable Medical Devices Directive**: Council Directive 90/385/EEC on the approximation of the laws of the Member States relating to active implantable medical devices;

(8) **Gas Appliances Directive:** Council Directive 90/396/EEC on the approximation of the laws of the Member States relating to appliances burning gaseous fuels;

(9) **Hot Water Boilers Directive**: Council Directive 92/42/EEC on efficiency requirements for new hot-water boilers fired with liquid or gaseous fuels;

(10) **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 uses;

(11) **Medical Devices Directive:** Council Directive 93/42/EEC concerning medical devices;

(12) **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;

(13) **Recreational Craft Directive:** Directive 94/25/EC of the European Parliament and of the Council on the approximation of the laws, regulations and administrative provisions of the Member States relating to recreational craft;

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

(15) **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;

(16) **Machinery Directive**: Directive 98/37/EC of the European Parliament and of the Council on the approximation of the laws of the Member States relating to machinery;

(17) **In-vitro Diagnostic Medical Devices Directive**: Directive 98/79/EC of the European Parliament and of the Council on in vitro diagnostic medical devices;

(18) **R&TTE Directive:** Directive 1999/5/EC of the European Parliament and of the Council on radio equipment and telecommunications terminal equipment and the mutual recognition of their conformity;

(19) **Cableway Directive**: Directive 2000/9/EC of the European Parliament and of the Council relating to cableway installations designed to carry persons;

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

(21) **EUP Directive**: Directive 2005/32/EC of the European Parliament and of and of the Council establishing a framework for the setting of eco-design requirements for energy using products.

List of directives which are based on certain elements of the New Approach

(22) **Low Voltage Directive**: Council Directive 73/23/EEC on the harmonization of the laws of Member States relating to electrical equipment designed for use within certain voltage limits;

(23) **Packaging and Packaging Waste Directive**: European Parliament and Council Directive 94/62/EC on packaging and packaging waste;

(24) **Interoperability of Trans-European High-speed Rail System Directive**: Council Directive 96/48/EC on the interoperability of the trans-European high-speed rail system;

(25) **Marine Equipment Directive**: Council Directive 96/98/EC on marine equipment;

(26) **Interoperability of the Trans-European Conventional Rail System Directive**: Directive 2001/16/EC of the European Parliament and of the Council on the interoperability of the trans-European conventional rail system;

(27) **Energy Efficiency Requirements for Household Electric Refrigerators Directive**: Directive 1996/57/EC of the European Parliament and of the Council on energy efficiency requirements for household electric refrigerators, freezers and combinations thereof;

(28) **Transportable Pressure Equipment Directive**: Council Directive 1999/36/EC on transportable pressure equipment;

(29) **Noise Emission Directive**: Directive 2000/14/EC of the European Parliament and of the Council on the approximation of the laws of the Member States relating to the noise emission in the environment by equipment for use outdoors

(30) **Energy Efficiency Requirements for Ballasts for Fluorescent Lighting Directive:** Directive 2000/55/EC of the European Parliament and of the Council of 18 September 2000 on energy efficiency requirements for ballasts for fluorescent lighting**.**

ANNEX III
Information on Notified Bodies and Safeguard clauses

EU			EEA-EFTA			MRA	
Country	*Number of Notified Bodies*		*Country*	*Number of Notified Bodies*		*Country*	*Number of CABs*
	*2002 **	*2006 ***		*2002 **	*2006 ***		*2006 ***
Austria	37	45	Iceland	2	4	Australia	3
Belgium	31	46	Norway	16	19	Canada	2
Cyprus	-	-	Liechtenstein	0	0	Japan	1
Czech Republic	-	32				Switzerland	15
Denmark	22	35				United States	17
Estonia	-	9					
Finland	15	24					
France	81	107					
Germany	185	298					
Greece	14	22					
Hungary	-	22					
Ireland	4	7					
Italy	227	248					
Latvia	-	14					
Lithuania	-	14					
Luxembourg	5	9					
Malta	-	-					
Netherlands	29	55					
Poland	-	70					
Portugal	22	32					
Slovakia	-	27					
Slovenia	-	13					
Spain	54	76					
Sweden	47	52					
United Kingdom	224	256					
Total	**997**	**1513**	**Total**	**18**	**23**	**Total**	**38**

Table 1: Number of Notified bodies per country

*** figures to 30.10.2002**
**** figures to 15.05.2006**
- information not available

Table 2: Number of notified bodies per directive

Directive		Number of Notified Bodies	
		2002 *	2006 **
87/404/EEC	Simple pressure vessels	79	94
88/378/EEC	Toys	56	72
89/106/EEC	Construction products	183	489
89/336/EEC	Electromagnetic compatibility	40	42
89/686/EEC	Personal protective equipment	103	115
90/384/EEC	Non-automatic weighing instruments	320	321
90/385/EEC	Active implantable medical device	18	24
90/396/EEC	Gas appliances	37	46
92/42/EEC	Hot-water boilers	39	49
93/15/EEC	Civil explosives	6	11
93/42/EEC	Medical devices	60	64
94/25/EC	Recreational craft	22	33
94/9/EC	Potentially explosive atmospheres ATEX	31	54
95/16/EC	Lifts	156	151
96/48/EC	High-speed rail systems	20	28
96/98/EC	Marine equipment	28	37
97/23/EC	Pressure equipment	88	295
98/37/EC	Machinery	146	195
98/79/EC	In vitro diagnostic medical devices	17	25
99/36/EC	Transportable pressure equipment	92	141
99/5/EC	Radio and telecommunications terminal equipment	54	70
2000/9/EC	Cableway installations designed to carry persons	2	19
2000/14/EC	Noise from equipment for outdoor use	41	69

*** figures to 30.10.2002**
**** figures to 15.05.2006**

Note: Some bodies are notified under more than one directive. The total number of bodies in Table 1 (listed by country) is therefore lower than the total number of bodies in Table 2 (listed by directive)

Table 3: Number of safeguard clauses submitted to DG ENTR in 2005

	Toys	Medical devices	R&TTE	EMC	LVD	PPE	Machinery
Notifications received in 2005	81	2	18	20	418	0	2
Ongoing safeguard clause procedures	23	2	-	-	1	11	24
Total of safeguard clauses treated in 2005	104	2	18	20	419	11	26
Safeguard clauses closed in 2005	58	1 (manufacturer took corrective action, no formal opinion)	5	0	all	5	10
Positive Opinion	58 However sometimes our opinion is based on a different reasoning)	-	Always	Always	No need to express opinion unless one MS disagree with a safeguard procedure issued by another MS, so 100%	5	All - but there are (some) cases where the overall opinion is positive but not on all points raised by the Member State.

Negative Opinion	-	-	-	-	-	-	-
Average time	9 months	The currently pending one was notified in August 2005	> 1 year	> 1 year	3 months	6 months	From 6 months
Non-complicated cases	7 months	-	> 1 year	> 1 year	3 months	6 months	
Complex cases	More than 1 year	-	> 1 year	> 1 year	1 year	6 months	
Extreme cases	> 1 year due to lack of technical data and resources	-	> 1 year	> 1 year	> 1 year	6 months	+- 1.5 years
How often do you need to collect additional information	Frequently	In all cases	-	-	3 times (out of 419)	Very often	always
How often has the manufacturer not been contacted beforehand	It happened in a few cases	We did not have such case	Many Member States only contact the local representative, even where the manufacturer or importer is based in another MS We try to encourage MSs to directly contact the	Many Member States only contact the local representative, even where the manufacturer or importer is based in another MS We try to encourage MSs to directly contact	once	-	Almost never

			manufacturer	the manufacturer			
How often did notifications concern formal problems rather than "real" problems (i.e. a dangerous product)	None	None	Real problems are in general found with non-CE marked products that operate on frequencies that are not allocated in the EU. Problems with CE marked products are in general minor	Real problems are in general found with non-CE marked products that operate different frequencies that those in the EU. Problems with CE marked products are generally minor	Member states do not issue notifications for formal reasons only. If there are formal problems (such as missing CE-marking) MSs use the LVD INFO procedure. Under this procedure MS issued 58 INFO Notifications during 2005	rarely	Almost never
How often were the products imported from 3rd countries	81% from China; 8% unknown origin; 11% EU countries	-	The percentage of Chinese products under R&TTE is high; the non-compliance of Chinese products is only slightly higher		75-80%	33%	20-30%
Do you often have cases where a NB us involved and has not done its job correctly	-	-	-	-	Approx 50% of products have a certification mark from an organisation that is also a NB, which often proves to be a counterfeit mark or a different model was approved. However, in 5-10% of cases there are major disagreements between the different NBs or between the NB involved and the MS.	-	sometimes

In some sectors no safeguard clauses have been receive so far: Recreational craft, cableways, civil explosives.

ANNEX IV
Involvement of accreditation bodies in the notification process and their relationship with the notifying authorities

This Annex contains information relating to the involvement of accreditation bodies (ABs) in the notification process and their relationship with the notifying authorities. The data are extracted from two questionnaires:

(1) The EA (European co-operation for Accreditation) survey on Accreditation Bodies' assessment of notified bodies; and

(2) A Commission questionnaire targeted at Accreditation Bodies.

(1) The EA (European co-operation for Accreditation) survey on Accreditation Bodies' assessment of notified bodies.

The questionnaire was to designed to ascertain the current situation regarding the involvement of EA Members in the assessment of Notified Bodies under New Approach directives. Responses were received from 31 accreditation bodies and are summarised below. EA has 34 full members and there are a few who are not members of EA, so the responses can be considered to be representative of the accreditation community.

		Response	
	Question	***Yes***	***No***
(a)	Are you as an Accreditation Body involved in assessing the competence of notified bodies for any New Approach Directives?	28	3
(b)	Have you developed specific procedures or requirements for the assessment of notified bodies?	18	13
(c)	Do you differentiate in any way the activity of assessing a notified body from accreditation in the voluntary sector?	10*	
(d)	In your country, is accreditation (without extra requirements and granted in the voluntary field) a requirement for notified bodies in any of the Directives?	16	15
(e)	For which Directives do you act as the notifying authority? 27 ABs responded that they are <u>not</u> the notifying authority 3 ABs are notifying authorities for some of New Approach directives 1 AB is the notifying authority for all New Approach directives)		

* reported some differences.

The number of ABs assessing each of the directives is shown in the following table:

Directive	Number of ABs Assessing the Directive
Low Voltage	18
Simple Pressure Vessels	19
Safety of toys	16
Construction products	22
Electromagnetic compatibility (EMC)	15
Machinery	20
Personal protective equipment (PPE)	16
Non-automatic weighing instruments	17
Active implantable medical devices	8
Appliances burning gaseous fuels	17
Efficiency requirements for new hot-water boilers fired with liquid or gaseous fuels	14
Explosives for civil uses	10
Medical devices	14
Equipment explosive atmospheres (ATEX)	14
Recreational craft	14
Lifts	20
Pressure equipment	22
In vitro diagnostic medical devices	6
Radio Equipment and Telecommunications Terminal Equipment	13
Cableway installations designed to carry persons	5
Measuring instruments	8
Packaging and packaging waste	3
Interoperability of trans-European high-speed rail system	5
Marine equipment	12
Interoperability of trans-European conventional rail system	5

(2) Commission questionnaire targeted at Accreditation Bodies

The questionnaire was targeted at accreditation bodies from 25 Member States, 2 acceding countries and the EFTA countries. A total of 25 replies were evaluated. The relationship between the accreditation bodies and the national authorities was addressed in the following questions:

		Response	
	Question	***Yes***	***No***
(a)	What kind of relationship do you have with your public authorities in charge of designating notified bodies? Formal contract agreement 4 Formal recognition on the basis of a specific public authority act or decision 9 Another type of arrangement* 12 * includes no formal relationship; AB as a notifying authority; AB as a member of an Approval Committee; a Memorandum of Understanding; informal arrangements with notifying authorities		

(b)	If you also carry out assessments in areas covered by directives that do not provide for notifications, do you have a similar arrangement for those areas with your relevant public authority?	15	5
(c)	Do you get financial support from your public authorities for your activities for the purpose of notifications?	7	15
(d)	Do your public authorities commit themselves to other kinds of support for your activities for the purpose of notifications?	6	16
(e)	How do you cover the costs of your participation in the work of European co-operation for Accreditation (EA)? From the accreditation fees 6 From the public authority assistance 9 From a combination of the two sources above 10		
(f)	In the case of withdrawing accreditation do you inform your national authorities? No, never 4 Seldom 6 Frequently 2 Always 11		

ANNEX V
Evaluation of options for the organisation of accreditation at the EU level

The accreditation bodies were asked to evaluate the following options for the organisation of accreditation at the European level:

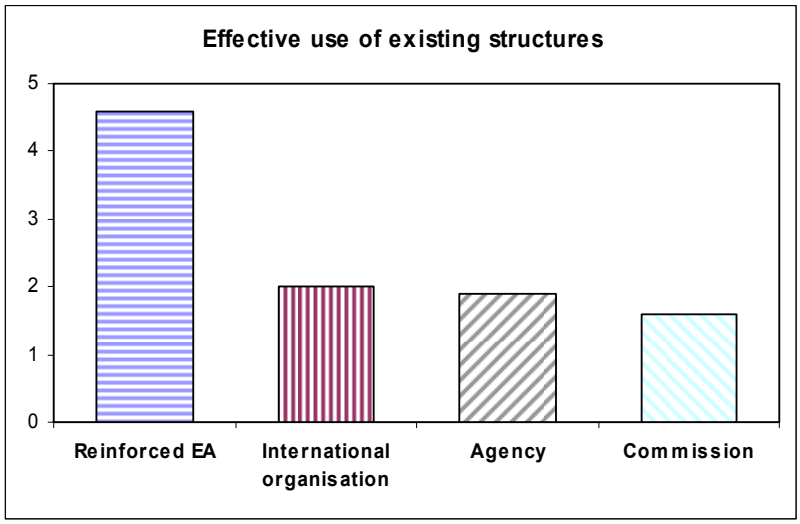
(1) Formal recognition of the European co-operation for accreditation (EA) by the Member States as the European accreditation infrastructure

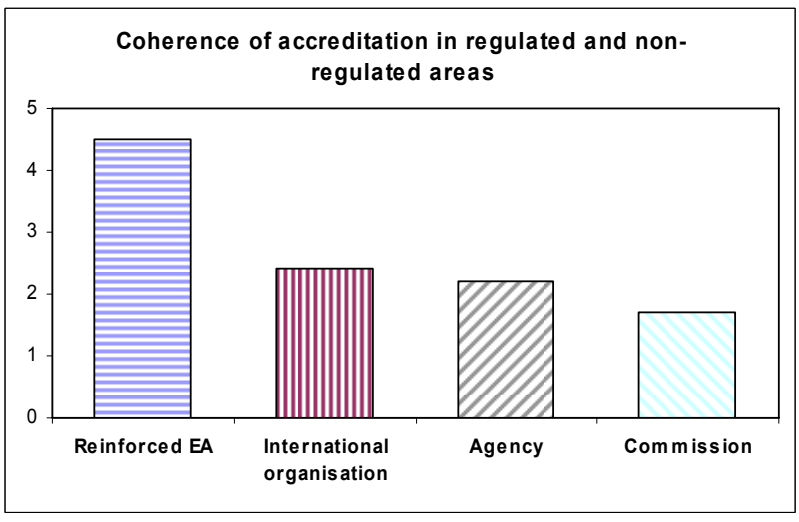
(2) Creation of a centralised international organisation for accreditation at European level

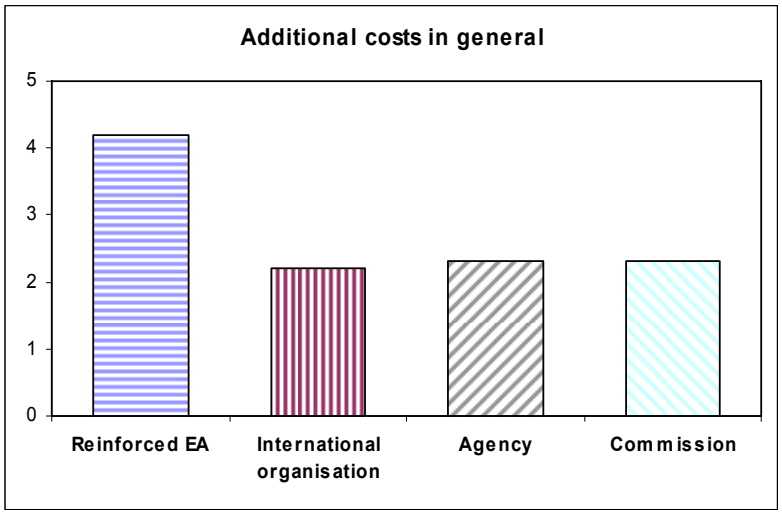
(3) Creation of a specialised EU agency for competence assessment and monitoring of notified bodies at EU level

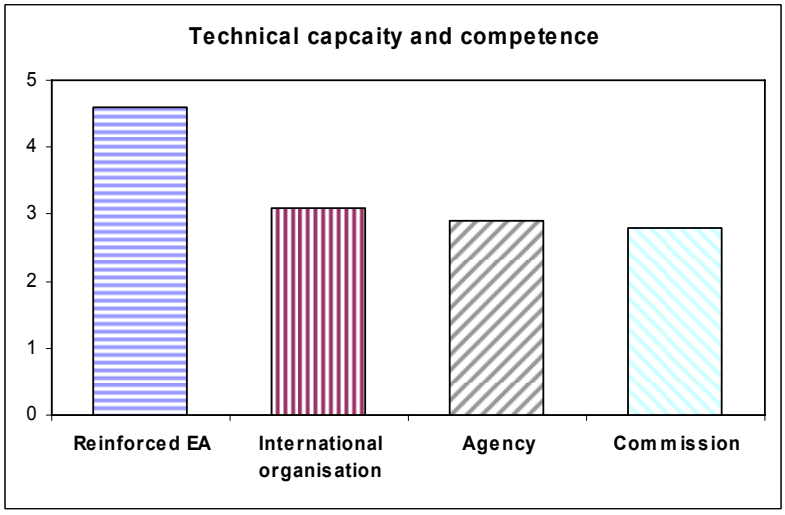
(4) Centralised competence assessment and monitoring of notified bodies at EU level carried out by the Commission

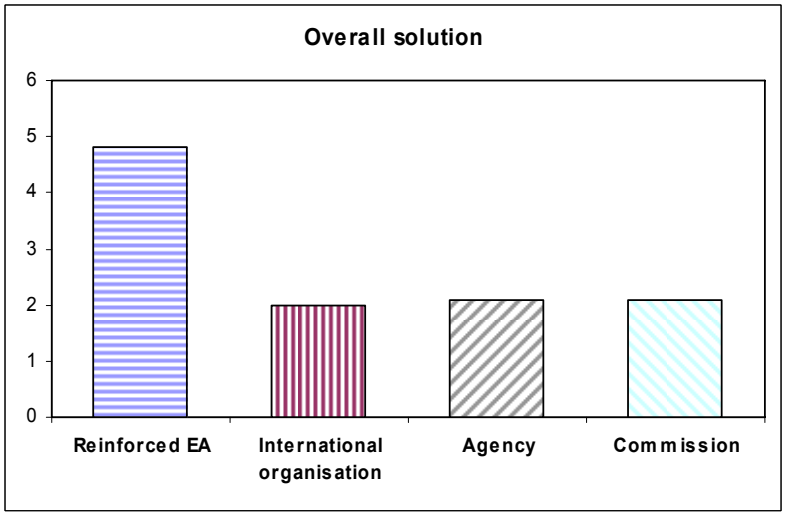
The results of the evaluations of the options in terms of effectiveness, costs, technical competence etc, are shown below. (The scale is 5: best solution, 1: the worst solution):






Additional costs in general
5
4
3
2
1
0
Reinforced EA
International organisation
Agency
Commission


Technical capcaity and competence
5
4
3
2
1
0
Reinforced EA
International organisation
Agency
Commission


Overall solution
6
5
4
3
2
1
0
Reinforced EA
International organisation
Agency
Commission