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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**

Executive summary of the impact assessment

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1. BACKGROUND: THE INTERNAL MARKET FOR GOODS, HARMONISATION OF TECHNICAL REGULATIONS AND THE NEW APPROACH CONCEPT

This document provides a brief summary of the results of the impact assessment of the policy options with regard to reinforcement and simplification of internal market legislation for goods and explains the approach proposed.

Free movement of goods, a central pillar of the Single Market, is a major driver for competitiveness and economic growth in the EU. Harmonisation of technical regulations at EU level has proven to be the most successful tool in eliminating technical barriers to trade. Within this framework the “New Approach directives” (also known as “CE marking” directives) have played a major role in making the internal market for goods a reality.

The New Approach, introduced in 1985, revolutionised legislation in the area of free movement of goods, by moving away from the traditional approach of descriptive requirements to a “new approach” of laying down only performance-based and result-oriented essential requirements in relation to safety. In other words, legislation determines the level of protection but does not prejudge the choice of technical solution required to achieve that level. Limiting legislation to only what is necessary to guarantee a high level of protection has resulted in modern, flexible and technology-neutral legislation which ensures safe products and which fosters innovation and competitiveness in the marketplace. This has therefore become a role model for Better Regulation.

Today, New Approach directives cover a large proportion of products marketed in the EU in more than 20 industrial sectors, including electro-technical products, machinery, radio/telecoms equipment, toys, medical devices, construction products and high speed rail systems. It is estimated that the trade in products covered by the major New Approach sectors is in excess of € 1500 billion per year.

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. 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.

While some of these problems, i.e. CE marking, are specific to the New Approach directives, most of them concern the whole framework of free movement of goods. Therefore, different policy options to overcome these difficulties have been examined within the broader perspective beyond the New Approach, and also against the background that increased use of the New Approach concept is part of the Commission’s strategy for the simplification of the regulatory environment¹.

¹ Commission’s Communication “Implementing the Community Lisbon programme: A strategy for the simplification of the regulatory environment” COM (2005)535 final

2. HOW TO IMPROVE THE QUALITY OF THE WORK OF CONFORMITY ASSESSMENT BODIES

New Approach directives often require that products are certified by third parties before being placed on the market. These third parties are laboratories, inspection and certification bodies which are known generally as conformity assessment bodies, or more formally as “Notified Bodies”. These “Notified Bodies” play an important role in guaranteeing that products conform to the legal requirements and are safe and fit for use, and as such, these bodies are officially “Notified” by Member States to the Commission.

Member States have the responsibility for choosing which of their conformity assessment bodies fulfil the necessary criteria to become notified; not all do. The minimum criteria are set out in each of the directives and include competence, impartiality, integrity etc. Member States also have a responsibility to ensure that these bodies continue to fulfil these criteria during their lifetime of operation. A Member State is free to notify as many bodies as it wishes under each directive, and to date we have over 1800 notified bodies supporting the implementation of the directives.

Notified bodies are private companies or organisations which offer their services as a commercial business and they are, therefore, in competition with each other. This is beneficial for their customers who are the manufacturers of products. Manufacturers are free to shop around to find the best service at the most competitive price, and are not limited to use a body from their own Member State, they can use any. Whilst this is good for the manufacturer, it can lead to some notified bodies cutting corners in service to provide competitive prices to attract or keep customers

Also different notified bodies may take different approaches when carrying out their work, meaning that the same product may be assessed in a completely different way by two different notified bodies. This may, of course, be a perfectly legitimate interpretation of the assessment procedures, but it could also be as a result of unfair practices and less rigorous implementation of costly procedures, meaning certificates can be issued at significantly lower rates. This represents not only a risk of unsafe products on the market, but also distorts competition within the manufacturing industry.

The concept of the New Approach is based upon mutual confidence of all players involved, including notified bodies, and as such it is crucial to ensure that all notified bodies, wherever they are located, have the same levels of competence and operate to the same requirements. Under the current legislation, the assessment and monitoring of bodies is the responsibility of the parent Member State; unfortunately there is no consistency of approach and designation and monitoring requirements differ widely. Some Member States have more stringent criteria than others (the directives only set minimum requirements) which results in an unlevel playing field, and has the added risk that certificates may not be recognised in other Member States, undermining confidence in the competence of notified bodies and the system as a whole. Some Member States organise designation, assessment and monitoring of notified bodies directly through their public administration, whilst others use the support of a national accreditation body. Accreditation is a formal system which provides an independent and authoritative attestation of the competence, impartiality and integrity of conformity assessment bodies, thereby supporting the value and credibility of the work done and certificates issued.

Accreditation bodies are organised at European level into the EA (European co-operation for Accreditation) which ensures homogeneity of operation. EA ensures that National accreditation bodies all work to the same requirements, so that accreditation granted from one body is directly comparable to that granted from another. Therefore, accreditations are equally reliable and can be trusted by the direct and indirect users of them. The added value of accreditation is that it is a formal organised scheme providing consistency at Community level, however there is no requirement for use of accreditation nor does accreditation have any authority.

There is clearly a need to improve coherence and comparability of designation, operation and monitoring of notified bodies throughout the Community and, therefore, different options were considered. One possibility was to centralise the whole notification system through the creation of an Agency at EU level to centralise competence assessment, notification and monitoring, however this has been discounted as costly, burdensome and unfeasible to implement. The preferred option is to build upon the existing system and to introduce elements to significantly strengthen it and ensure comparability throughout the Community.

Therefore, the proposal is to continue the decentralised competence assessment and monitoring under the responsibility of each Member State, but to introduce a legal framework for accreditation and co-ordination at EU level and to use the existing organisation of EA for this accreditation and co-ordinating role. Doing this will provide EA with public recognition and provide it with the authority it currently lacks. It will also ensure that all Member States use accreditation as a means to notification.

Using an already established infrastructure such as EA, represents a more efficient use of resources, will lead to fewer additional costs and resource requirements, and will have the advantage of building upon the vast depth of existing knowledge and experience acquired over the time. It also successfully combines the two levels involved – national and European. This option respects the subsidiarity principle, whilst reinforcing the existing structures, and is therefore the best option.

Some changes to the existing accreditation structures are expected to be necessary in a few Member States, notably Germany. However, these are not expected to be great and the benefits outweigh the costs. Given the different organisational structures in the Member States it is difficult to estimate the potential additional costs. However, the overall costs of this option are considerably lower than the costs for establishment of an agency.

3. HOW TO IMPROVE MARKET SURVEILLANCE AND THE ENFORCEMENT OF OUR LEGISLATION

Legislation can only achieve its objectives if it is effectively enforced. Under the current situation, market surveillance legislation is not carried out coherently or rigorously throughout the Community. As a consequence, large numbers of non-compliant (and potentially dangerous) products reach the market every year.

On the one hand, national authorities lack the necessary means to apply market surveillance efficiently and consistently. They are constantly confronted with new challenges, for example fast changing economies, new products on the market and increasing number of third country imports, and in the main, resources have not kept pace with these developments. In addition, the increased internationalisation and complexity of commercial transactions make it more

and more difficult to identify the actors in the distribution chain and authorities are often unable to find the right person to address when there is a problem.

On the other hand, the way in which market surveillance is currently organised in Europe is no longer adequate for an internal market without internal borders. Products circulate freely inside the Community without passing any internal checkpoints, but the powers of national authorities are limited to their own territory. Cross border co-operation is, therefore, essential to effectively pursue dangerous products as well as unlawful manufacturers or importers. Some successful co-operation mechanisms, such as the RAPEX system, are already in place; however they are limited to certain activities, sectors or aspects. For this reason, information is not always passed on and has to be reproduced in other Member States, thus reducing the efficiency of market surveillance at Community level. Furthermore, the intensity of controls and the rigour by which national authorities prosecute non-compliant cases differs considerably from one Member State to another. By targeting markets where there is a low level of supervision, unlawful operators can enter the Community market and undermine the enforcement efforts of Member States.

By exploiting these deficiencies, some unlawful manufactures or importers can repeatedly play the system. This puts consumers at risk from dangerous products and jeopardises the objectives of the legislation to protect citizens; citizens then question the capacity of Community law to protect them. It also leads to situation where responsible manufacturers who respect the law, lose out to unscrupulous competitors offering cheaper products, due to savings on compliance costs. Compliance with the law hence becomes a competitive disadvantage, which again seriously undermines confidence in the legal framework.

Awareness-raising information campaigns or guidance documents, or other such legally non-binding initiatives, have been considered, but this would not substantially improve the situation. More stringent controls, such as systematic recourse to use of a notified body, before the product is placed on the market have also been considered, however this would impose additional burdens and costs for the manufacturers without necessarily guaranteeing that all manufacturers comply. Those who are intent on circumventing the rules would have no incentive to respect more rigorous rules. However stringent the pre-market requirements may be, there is always a need for control of products once they are circulating on the market.

Therefore, to ensure an equivalent level of market surveillance throughout the Community, a common legal framework, which allows flexibility of organisation at national level, whilst establishing specific minimum requirements for operation and organisation, is considered to be the most effective solution. This framework also foresees the extension of the existing co-operation mechanisms, improves the traceability of products and clarifies the obligations for all economic operators, i.e. manufacturers, distributors, importers, etc.

The proposed framework seeks to build upon the existing national structures. Modification costs will only arise where an existing national market surveillance system does not yet reach the general standard. Enhanced information and co-operation obligations will require additional resources but this will be offset by significant savings from more effective controls and efficient pooling of resources.

4. HOW TO IMPROVE THE UNDERSTANDING OF CE MARKING

CE marking on a product indicates that all regulatory requirements have been fulfilled; it is essentially a mark for enforcement authorities, which leads to confusion. Unfortunately, many consumers do not understand the real meaning and believe that it is an indication of origin or an indication that the product has been tested and approved by some authority. As a result, consumers do not proactively seek CE marking on products. For the most people, the fact that a product is CE marked or not, does not influence their decision to buy. This is an unsatisfactory situation: Firstly, un-informed consumers may buy potentially dangerous products; secondly, better informed and more pro-active consumers would avoid products without the CE marking, which would inevitably lead to better level of compliance in the marketplace.

All options were considered and the options to fundamentally change the meaning of the CE marking or even to abolish it completely have been excluded, as these ideas would not solve the basic problem and have additional drawbacks. CE marking is a real asset in international trade and strengthens the competitive position of European manufacturers. Any change to the meaning of the CE marking and certainly its abolition would heavily affect this situation. Furthermore, abolition of the marking would mean that enforcement authorities would no longer have a clear indication of compliance as they do at present.

Although the CE marking is not a guarantee, it is an indication that all applicable requirements have been respected. Whilst a market surveillance officer can never be sure that a CE marked product is completely safe, he can legitimately assume that when it is missing he is confronted with a non-compliant and, therefore, potentially dangerous product. Abandoning the CE marking without substitution of another 'mark' or clear mechanism would deprive surveillance authorities of this easy and quick indication of compliance. This is neither in the interest of the enforcement authorities nor in the interest of the consumers.

Therefore, the best way to solve consumers' ignorance without creating disproportionate negative impacts for industry and authorities is enhanced communication. A visible Community-wide information campaign, targeted at a large number of consumers throughout Europe will improve the understanding of CE marking. This will be much more effective than changing the legal text. Better informed consumers and economic operators will seek CE marked products, avoiding non-CE marked products which have a positive effect on competitiveness.

The CE marking stands for the whole regulatory system on which the New Approach directives are based. Deficiencies, which are often attributed to CE marking, such as lack of credibility, are in fact weaknesses in the system behind the CE marking. It is therefore not by changing the marking, but by improving this system that these problems can be really solved. Strengthening the control of notified bodies and improving market surveillance are two important steps in this direction. Another important element is the value of the CE marking itself as a marking. The CE marking should be registered as a Community collective trade mark. This would then give authorities additional means to take legal action against manufacturers who misuse the CE marking, again contributing to credibility of the mark.

5. HOW TO IMPROVE CONSISTENCY OF THE LEGAL FRAMEWORK

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 covered by more than one directive, which sometimes proves difficult because common elements, e.g. definitions, procedures for demonstrating conformity, etc are not treated in the same way. Sometimes definitions or legal provisions are not sufficiently precise and leave room for diverging interpretations, which leads to incompatibilities, legal uncertainty, unnecessary duplication and confusion.

This has a negative effect on industry, as they are in the complex situation of having to comply not only with one piece of legislation, but with a variety of legal instruments. Due to different wording and concepts it is sometimes extremely difficult for manufacturers to understand their legal obligations, let alone apply them. They are forced to seek legal help in order to correctly comply with the law. These inconsistencies and legal uncertainty also make it difficult and more complicated for national authorities to properly implement and enforce the legislation. In addition, this can lead to different interpretations in different Member States which undermines the free movement of goods in the Community.

The existing inconsistencies in the legislation can only be solved by changing the existing legal framework. A co-ordinated **modification** of the relevant articles of each existing directive and regulation would temporarily improve the situation, but to ensure a co-ordinated approach in the future it would be more efficient to create a **horizontal framework**. This would contain all the common elements of product legislation, e.g. definitions, conformity assessment procedures, provisions on CE marking and on notified bodies. The objective here is to ensure coherence but not to force solutions which may be inappropriate; therefore the framework should operate as a toolbox providing the various common elements and guidance on how to apply them in Community legislation. For this reason, the actual adaptation of the individual directives should be carried out in a separate exercise, which will allow elements of the toolbox to be applied in sector-specific situations.

6. CONCLUSIONS:

This proposal reinforces the efficiency and transparency of the existing accreditation and market surveillance systems. This will have the effect of improving the credibility of the CE marking and encouraging the uptake of the New Approach concept in future legislation. The creation of a horizontal framework for internal market legislation will lead to more coherence and constitutes an important step in simplifying the regulatory environment.

Consumers, workers and end users will all benefit from safer products on the market, due to enhanced monitoring of notified bodies and a reinforced Community-wide market surveillance system. The information campaign will improve consumer knowledge of CE marking and counteract the current position of confusion and misunderstanding. This will not affect product prices.

The proposal will have positive implications for the competitiveness of European enterprises. More coherence in the conformity assessment procedures and reinforced action against unfair competition from operators not applying the rules will help to ensure a level playing field for European industry. Enterprises will also benefit from a more transparent and more coherent legal framework providing legal certainty and simplifying its implementation.

Member States' confidence in each other's policies and administrations will be enhanced by a common and transparent legal framework on both accreditation and market surveillance. Whilst some of the measures envisaged might cause minimal additional costs for national administrations, the added value of these measures in terms of increased safety, ensuring a level playing field for economic operators, competitiveness for European industry will easily outweigh these potential costs.

Overall, this proposal will facilitate further the free movement of goods by eliminating deficiencies, inconsistencies and unnecessary red tape from the existing legal framework. It will reinvigorate confidence in the internal market legislation from all stakeholders, consumers, industry and Member States. It will be a cornerstone for the future strategy on internal market policy.