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Accompanying document to the

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

laying down procedures relating to the application of certain national technical rules to products lawfully marketed in another Member State and repealing Decision 3052/95/EC

Executive summary of the impact assessment

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1. INTRODUCTION

This document summarizes the impact assessment which examines the policy options to ensure that, whenever national technical rules are being applied to products lawfully marketed in another Member State in the non-harmonised field of products, this is done in accordance with Articles 28 and 30 EC Treaty.

In the absence of EC harmonisation, national technical rules often create technical obstacles to the free movement of products lawfully marketed in another Member State. Such obstacles are still widespread: it is estimated that they reduced trade in goods within the Internal Market by up to 10% - or €150 billion - in 2000.

Technical obstacles can either be eliminated by harmonising national rules, or by applying the so-called "**Mutual Recognition Principle**." Under this principle, Member States of destination cannot forbid the sale on their territories of products which are not subject to Community harmonisation that are lawfully marketed in another Member State, unless the restrictions laid down by the Member State of destination are justified on the grounds specified in Article 30 of the EC Treaty, or on the basis of overriding requirements of general public importance recognised by the case law of the Court of Justice, and are proportionate. It is estimated that about 28% of intra-EU manufacturing trade is covered by mutual recognition. Thus intra-EU trade covered by mutual recognition is approximately 5.4% of GDP.

2. PROBLEMS

The "Mutual Recognition Principle" suffers from different fundamental problems that are all interrelated:

(a) **The lack of awareness of enterprises and national authorities about the existence of the mutual recognition principle.** In practice, many national rules give the false impression that they are the only applicable legislation or that they prevail. Moreover, no provision in the EC Treaty expressly confirms the existence of the mutual recognition principle in the area of goods. The principle is a concept developed on the basis of the "Cassis de Dijon" judgement which concerned the interpretation of measures having an effect equivalent to quantitative restrictions on the imports of goods under Article 28 of the EC Treaty.

(b) **Legal uncertainty about the scope of the principle and the burden of proof.** The consequences are, on the one hand, that national authorities are suspicious of products lawfully marketed in another Member State but which do not comply with national technical rules in the Member State of destination and, on the other hand, that enterprises are prevented from relying on the mutual recognition principle.

(c) **The risk for enterprises that their product will not get access to the market of the Member State of destination**. Enterprises run such risk when they decide to market a product in another Member State. It is difficult for businesses to find out beforehand if, how and when mutual recognition is

applied. If an enterprise faces the risk that their product will not get access to, or will be withdrawn from, the market of the Member State of destination, it may refrain from selling its product, adapt it to local rules, or start marketing it and await the outcome of market surveillance. One major consequence is therefore risk avoidance: enterprises will "play it safe" by avoiding any possible conflict or discussion with the national authorities of the Member State of destination.

(d) **The absence of dialogues between competent authorities in different Member States**: Dialogues between national administrations of different Member States in the non-harmonised area are difficult in practice, due to the lack of a common address book in the non-harmonised field of products within the EU. This complicates the tasks of market surveillance authorities.

3. COSTS OF THESE PROBLEMS

Besides the information gathering costs, compliance costs, conformity assessment costs and loss of economies of scale incurred by enterprises, an analysis of the behaviour of SMEs disclosed that the costs of gaining access to the market of another Member State are nearly twice as high as for big companies as a share of total turnover. This burden hampers SMEs efforts to become European players. A case study indicates that most of the smaller firms with a turnover of €15 million or less only export into Member States with loose regulatory systems.

The estimates of all these costs vary widely, depending on the type of product, its technical specifications, the size of the market of the receiving Member State, the size of the enterprise and many other elements. According to the case studies, these costs vary between 100% and 250% of the annual turnover of the same type of product on the national market in the Member State of destination. It is estimated that, depending on the product, the differences between technical rules in different national markets, combined with the need for multiple testing and certification, may constitute between 2% and 10% of overall production costs. These figures, however, should be read with one caveat: certain costs may be unavoidable when the technical rules of the Member State of destination comply with Articles 28 to 30 EC Treaty. The fact that national technical rules may comply with these provisions means that, even under the most effective option to improve mutual recognition, the potential reduction of overall production costs would always be lower than the total costs caused by the differences between technical rules in different national markets.

Many enterprises, having observed difficulties with mutual recognition, decide not to enter the market of another Member State. Enterprises, particularly SMEs, will not wish to incur the significant sunk costs of gaining entry to the market (i.e. investment costs incurred before a certain activity can take place, which cannot be recovered by the possible sale of the relevant asset. eg. legal and other consultancy fees). Sunk costs are an important barrier to export, especially for small and medium firms. Thus a fully functional system of mutual recognition would generate more trade within the EU. Through reduced competition, lower economies of scale and less consumer choice, reduced trade will also impact on economic output and employment in the EU.

Applying mutual recognition is usually part of market surveillance activities and does not necessarily entail extra costs for national authorities.

4. POLICY OPTIONS

In the light of these problems, the Commission has identified four options for improving mutual recognition in the non-harmonised field of products:

– **Option 1: status quo -** continue the current policy which basically consists of examining national technical rules on a case-by-case basis, mainly through infringement proceedings and notifications under Directive 98/34/EC;

– **Option 2: a non-regulatory approach -** complement current policy with additional action: the creation of a specific website with a list of products to which mutual recognition applies, general screening by the Commission and the Member States of all national technical rules on a specific category of products and the identification of the national authorities responsible for these rules, the systematic inclusion of the final text of all technical rules notified pursuant to Directive 98/34/EC in the TRIS database, conferences and seminars organised in the Member States and targeted at enterprises and competent authorities, specific publications explaining mutual recognition for specific categories of products, more detailed “mutual recognition clauses” and administrative cooperation through the existing committees established by secondary EC legislation.

– **Option 3: the regulatory approach**, i.e. the adoption of a legislative proposal that organises mutual recognition in the non-harmonised field of products and establishes “Product Contact Points”. The proposal would define the rights and obligations of national authorities and enterprises wishing to sell in one Member State products already lawfully marketed in another, when the competent authorities intend to restrict the marketing of the product in accordance with national technical rules. In particular, the proposal would address the burden of proof by setting out the procedural requirements for denying mutual recognition. The task of the "Product Contact Point(s)" in each Member State would be to provide information on technical rules on products to enterprises and competent authorities in other Member States, as well as providing the contact details of the latter. That would allow public authorities to easily obtain information from, and engage in dialogue with, the competent authorities in other Member States.

– **Option 4: a legislative proposal accompanied by non-legislative action:** Option 4 is based on option 3, with one major difference: instead of including in the proposal a list of products or aspects of products to which mutual recognition applies, as a flanking non-regulatory measure a website would be set up containing a list of products to which mutual recognition applies, as set out under option 2.

Options 3 and 4 do not at all imply that approximation of laws under Article 95 EC Treaty would no longer be necessary. Harmonisation or further harmonisation of national technical rules remains without doubt one of the most effective instruments, both for businesses and for the national administrations. Mutual recognition cannot be a miracle solution for ensuring the free movement of goods in the single market. Therefore, greater harmonisation will continue to be indispensable in sectors where divergence of technical rules poses too many problems to permit the proper application of the principle of mutual recognition.

5. IMPACTS

Similar to the microeconomic effects, it is inherently difficult to provide a quantitative assessment of the macroeconomic impact of a better functioning mutual recognition principle in the non-harmonised field of goods. The use of a model of a perfectly integrated Internal Market with a minor extension can provide estimates of the maximum possible cost produced by failure in the implementation of the principle of mutual recognition. The extension is the assumption that a sector's share of industrial output is equal to that same sector's share of intra-EU trade. An Internal Market study estimated that 21% of industrial production or 7% of GDP inside the EU is covered by mutual recognition and about 28% of intra-EU manufacturing trade (whose value is equivalent to about 5% of EU GDP). Taking this figure as a basis for calculation and assuming the internal market were perfectly integrated, the value of trade in products covered by mutual recognition should equal their contribution to GDP (i.e. 7% of EU GDP). That would imply that current trade in products to which mutual recognition applies is 45% below what it would be in a perfectly integrated Internal Market, a shortfall equivalent to 1.8% of EU GDP. If, however, the principle of mutual recognition covers 36% of intra-EU manufacturing trade (equivalent to just over 6% of EU GDP), then actual trade in products covered by the principle is closer to what it would be in a hypothetical, perfectly integrated Internal Market, although at 13% the difference is still significant (equivalent to 0.7% of current EU GDP).

Successfully ensuring the perfect operation of mutual recognition inside the EU tomorrow would produce a maximum possible one-off increase in EU GDP of 1.8%.

There are no indications that any of the options would have a direct social or environmental impact, a specific impact on the growth of freight transport activity or a specific impact on energy demand in industry and the tertiary sector in the EU.

6. COMPARISON OF THE OPTIONS

A comparison of the options based on effectiveness and likely impact indicates that:

– Option 1 is unlikely to constitute a solution in the medium term;

– Option 2 would require substantial additional effort from the Commission and Member States but it is still unlikely to solve the problems throughout the EU, at least in the short or the medium term. The effects of option 2 would only be perceptible in specifically targeted sectors/national rules;

– Option 3, the exclusively legislative approach would offer short term solutions to many problems but would not solve satisfactorily the problem of defining the range of products to which mutual recognition applies;

– Option 4, legislative and non-legislative action, would solve the problem of the definition of the range of products to which mutual recognition applies.

Given that option 4 combines certain advantages of options 2 and 3, it would probably be the most effective for businesses and national administrations. Comparison of the options therefore suggests that option 4 would be the most appropriate.