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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**

Impact assessment

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1. INTRODUCTION

1.1. Procedural issues and consultation of interested parties

This impact assessment 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.

This impact assessment and the corresponding formal decision selecting the most appropriate policy option appear as item 2006/ENTR/002 in the Commission Work Programme for 2006¹. This impact assessment is drafted on the basis of input from an inter-service steering group comprised of representatives of Directorates General Enterprise and Industry, Health and Consumer Protection, Internal Market and Services, Economic and Financial Affairs, the Secretariat-General and the Legal Service of the Commission.

The data for this impact assessment were collected from the consultations set out below as well as various surveys, case studies and literature reviews.

Preparations for the impact assessment started in 2004, with a public consultation of stakeholders between 17 February 2004 and 30 April 2004 via the Commission's "Your Voice in Europe" Internet site², in accordance with the general principles and minimum standards for consultation of interested parties by the Commission³. According to the replies to the consultation, the Commission should do more to improve the functioning of mutual recognition in the non-harmonised area. About 60% of respondents thought that a legislative instrument was necessary whilst about 33% thought not. The consultation called strongly for a strengthening of administrative cooperation between national authorities, and for more transparent dialogue between business and the national authorities of the Member State of destination. Annex I contains a more detailed overview of the results.

In addition, the European Business Test Panel was consulted between May and September 2004. The results of this consultation are shown in Annex 2. Throughout the preparation, SME stakeholders were also consulted through the SME Envoy while Member States were consulted through the Senior Officials Group on Standardisation (SOGS), the Enterprise Policy Group (EPG) and the Internal Market Advisory Group (IMAC).

1.2. What is the mutual recognition principle and how does it work in theory?

Technical obstacles to the free movement of goods within the EU are still widespread. They are the consequence of applying, to goods coming from other Member States where they are lawfully marketed, national rules that lay down requirements to be met by such goods (e.g. relating to designation, form, size,

¹ COM(2005)531final of 25 October 2005.

² <http://europa.eu.int/yourvoice/consultations>.

³ COM(2002)704final.

weight, composition, presentation, labelling and packaging). If these rules do not implement secondary EC legislation, they constitute technical obstacles to which Articles 28 and 30 of the EC Treaty apply. **This is so even if those rules apply without distinction to all products.**

One of the important prerequisites for an optimally functioning internal market for goods is **the elimination of technical obstacles**. There are, in the field of goods, **two main types of instrument** for doing this, namely:

- The **approximation of national legislation** (“harmonisation of laws”) whereby technical obstacles are eliminated by the harmonisation of national technical rules **through secondary EC legislation** (directives, regulations and decisions) under Article 95 of the EC Treaty.
- **Mutual recognition under Articles 28 and 30 of the EC Treaty**⁴. Under the “Mutual Recognition Principle”⁵, different national technical rules continue to co-exist within the internal market. The principle means that, notwithstanding technical differences between the various national rules that apply throughout the EU, 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, even if they were manufactured according to technical and quality rules different to those that must be met by domestic products. The only exceptions to this principle are restrictions that are justified on the grounds described in Article 30 of the EC Treaty (e.g. the protection of public morality or public security, the protection of health and life of humans, animals or plants, etc), or on the basis of overriding requirements of general public importance recognised by the case law of the Court of Justice⁶, and are proportionate to the aim pursued.

⁴ Articles 28 of the EC Treaty states “quantitative restrictions on imports and all measures having equivalent effect shall be prohibited between Member States”. According to Article 30 EC Treaty, the “provisions of Articles 28 and 29 shall not preclude prohibitions or restrictions on imports, exports or goods in transit justified on grounds of public morality, public policy or public security; the protection of health and life of humans, animals or plants; the protection of national treasures possessing artistic, historic or archaeological value; or the protection of industrial and commercial property. Such prohibitions or restrictions shall not, however, constitute a means of arbitrary discrimination or a disguised restriction on trade between Member States”.

⁵ The principle of mutual recognition results from an analysis of, but is not expressly mentioned in, the case law of the Court of Justice. The principle originates in the famous “Cassis de Dijon”-judgment of the Court of Justice of 20 February 1979 (Rewe-Zentral AG v Bundesmonopolverwaltung für Branntwein, case 120/78, E.C.R. 1979, p. 649) and was the basis for a new development in the internal market for goods: see the Communication from the Commission concerning the consequences of the judgment given by the Court of Justice on 20 February 1979 in Case 120/78 (Cassis de Dijon), OJ C 256 of 3 October 1980.

⁶ In “Cassis de Dijon” and subsequent cases, the Court of Justice recognised a series of “mandatory requirements” in addition to the grounds of justification expressly set out in Article 30 EC Treaty. These additional exceptions to the principle of free movement of goods constitute complementary grounds on which mutual recognition may be denied, and are sometimes called “overriding requirements of general public importance” (see for example the judgement of 24 November 2005, case C-366/04, Georg Schwarz v Bürgermeister der Landeshauptstadt Salzburg). The “mandatory requirements” recognised so far include inter alia the prevention of tax evasion, consumer protection, the protection of the environment, the improvement of working conditions, etc.

The “Mutual Recognition Principle” in the non-harmonised field of products consists of a rule and an exception:

- a) The **general rule** that, notwithstanding the existence of a national technical rule in the Member State of destination, products lawfully marketed in another Member State enjoy a basic right to free movement, guaranteed by the EC Treaty, and
- b) The **exception** that products lawfully marketed in another Member State do not enjoy this right if the Member State of destination can prove that it is essential to impose its own technical rule⁷ on the products.

In more detail, mutual recognition in the non-harmonised field of products has the following ingredients:

- (1) A product is already lawfully marketed in one Member State;
- (2) An enterprise intends to sell it in another Member State but comes across a technical rule⁸ that actually or potentially prevents the marketing of the product in its current form, or an enterprise is able to begin selling the product in another Member State but is obliged by market surveillance authorities to withdraw it from the market or to modify it.
- (3) The part of the technical rule that is used to prevent the marketing of the product in the other Member State is not contemplated by secondary Community law.
- (4) When national authorities find that the product does not comply with certain parts of their national technical rules, the EC Treaty obliges them to analyse them in the light of Articles 28 and 30 EC Treaty. If they conclude that national law contravenes Articles 28 and 30 EC Treaty, national courts and administrations are under a duty to apply mutual recognition by giving full effect to the Treaty, i.e. by not applying the disproportionate parts of their national rules and allowing the product onto the market⁹;

⁷ For the purpose of this impact assessment, a national technical rule means a technical specification which defines the characteristics required of a product, such as its composition (quality level or fitness for use, performance, safety, dimensions, markings, symbols, etc.) or its presentation (the name under which the product is sold, its packaging, its labelling) and the testing and test methods within the framework of conformity assessment, which are obligatory, in fact or in law, in order to market or use the product in the Member State of destination.

⁸ This impact assessment does not address the mutual recognition of product conformity assessment results between conformity assessment bodies, which applies when the Member State of destination requires a conformity assessment, by a testing house or laboratory, of aspects of a product not harmonised at EU level. In that case, the tests and certificates issued by other testing houses and laboratories should be taken into account in order to avoid double checking, unless there is proof that the tests have not been performed in accordance with the state of the art or by a competent body.

⁹ See inter alia point 18 of the Judgment of the Court of 13 March 1997, Tommaso Morellato v. Unità sanitaria locale (USL) No 11 di Pordenone, Case C-358/95, European Court Reports 1997, p. I-1431. According to well-established case-law of the Court of Justice, a national court which is called upon, within the limits of its jurisdiction, to apply provisions of Community law, is under a duty to give full effect to those provisions, if necessary refusing of its own motion to apply any conflicting provision of national legislation, even if adopted subsequently, and it is not necessary for the court to request or await the prior setting aside of such provision by legislative or other constitutional means: Judgment of

Example 1:

*Member States have very different traditions for **bread and bakery products**. Some Member States regulate these products so that, at least formally, bread and bakery products that are lawfully sold in one Member State cannot be sold in another. In the past, Belgium required that the cooking salt content expressed in terms of sodium chloride and calculated on the basis of the dry matter was not allowed to exceed 2.00% in bread. The case was submitted to a national court which asked the Court of Justice to issue a preliminary ruling.*

Since it concerned an exception to the principle of the free movement of goods, it was for the national authorities to demonstrate in that case that their rules were consistent with the principle of proportionality, that is to say, that they were necessary in order to achieve the declared purpose, which in the present case was the protection of public health. According to the Court of Justice, the national authorities neglected to produce scientific data justifying their national rules (cases C-17/93 and C-123/00).

The Commission has explained in detail how mutual recognition should function in practice in several interpretative communications¹⁰.

1.3. When is mutual recognition being applied?

Mutual recognition may be applied before (“ex ante”) or after (“ex post”) the product is put on the national market of the Member State of destination.

“Ex ante” mutual recognition normally takes place in the framework of the prior administrative authorisation of a product, i.e. national legislation that subjects the product to obligatory prior approval before it can be marketed. In the non-harmonised area of products prior administrative authorisation schemes are only applied in a minority of cases. There is a dialogue, albeit quite formal, between the enterprise and the national authorities during the “ex ante” authorisation procedure which actually constitutes an additional barrier to intra-EU trade. Although this procedure can often be lengthy, costly and burdensome, it is an opportunity for businesses to present their arguments and provide the competent authorities with all relevant information about the product.

Example 2:

*In Portugal, **polyethylene pipes** imported from other Member States and intended for use in the water distribution network were subject to such procedure (case C-432/03). **Vitamin preparations and preparations containing minerals** were subject to authorisation procedures in France (case C-24/00) and Austria (case C-150/00). **Blocks of red cedar wood having natural anti-moth properties** could not be marketed in Italy without prior authorisation (case C-443/02).*

the Court of 4 June 1992, Criminal Proceedings against Michel Debus, Combined Cases C-13/91 and C-113/91, European Court Reports 1992, p. I-3617.

¹⁰

The latest communication was the “Commission interpretative communication on facilitating the access of products to the markets of other Member States: the practical application of mutual recognition”, O.J. C265 of 4 November 2003, p. 2.

“Ex post” mutual recognition is more common nowadays. It takes place when there is no prior administrative authorisation procedure but, during market surveillance, the competent authorities come across a product that is lawfully marketed in another Member State but does not comply with their national technical rules.

Example 3:

*The case on **bread and bakery products** that was submitted to the national court (example 1) was the consequence of checks carried out by food inspectors on samples of products sold in a local shop. On the basis of these checks and the corresponding samples, the national authorities should have applied mutual recognition to this specific product and should have allowed it onto the national market.*

*Another case (C-448/98) was the consequence of an inspection carried out by national inspectors at the premises of a company specialising in the cutting and packaging of portions of cheese prepacked in plastic film, intended particularly for sale in supermarkets. During that inspection, 260 whole **Emmenthal** cheeses without rind were discovered.*

1.4. Mutual recognition is a way of ensuring the free movement of goods

Hence, mutual recognition is a **means of ensuring the free movement of goods** within the EU for products for which there is no harmonisation of laws at EC level, or for aspects of products falling outside the scope of EC harmonisation measures. It remains the “**lex generalis**” unless a “**lex specialis**” (i.e. a harmonisation measure) organises intra-Community trade in a product differently.

One of the advantages of mutual recognition is that not all technical rules on products need to be harmonised throughout Europe. Some Member States have technical rules for specific types of products while others have not. Technical harmonisation means that all Member States must introduce harmonised technical rules, including those which not had them hitherto. Mutual recognition eliminates technical obstacles: Member States which have no technical rules on a specific category of products create no technical obstacles and are therefore not directly concerned by mutual recognition. Member States with technical rules on specific types of products must apply the mutual recognition principle.

Another advantage of mutual recognition is efficiency: it involves the implicit or explicit reliance, by the Member State of destination, on the level of protection assured by another Member State in which the product is already lawfully marketed. It avoids the need for products to fully comply with every technical rule in every Member States where the product is or will be marketed.

Mutual recognition presupposes **confidence** in other Member States, and specifically in the extent to which they protect relevant public interests. The combination of efficiency and confidence has made mutual recognition one of the essential legal instruments for ensuring the free movement of goods within the EU.

However, mutual recognition does not entail a comparison between the technical rules of the Member State of origin and of the Member State of destination. Mutual recognition is confined to an analysis, by the competent authorities of the Member State of destination, of the necessity and proportionality of its own technical rule in a specific case.

Because an exception under Article 30 or the mandatory requirements accepted by the Court of Justice may apply, **mutual recognition is not always automatic**. The assessment by the competent authorities in the Member State of destination of the necessity and proportionality of their technical rules under Article 30 EC Treaty or under the mandatory requirements is often not a straightforward exercise. A case-by-case assessment is therefore unavoidable in the field of mutual recognition¹¹ and can lead to very different conclusions in very similar cases¹². In addition, scientific knowledge and technical development evolve at high speed: what may have been justified and proportionate when the rule was adopted may have become obsolete following new scientific or technical developments or product innovation¹³.

1.5. The scope of mutual recognition

Mutual recognition applies to **products to which no EC directives and regulations apply, including many standard non-electrical products for daily use at home**. An important group of products, however, consists of products where mutual recognition applies to **certain aspects falling outside the scope of EC harmonisation**¹⁴. In some cases it is not always easy to establish precisely which aspects are covered by mutual recognition¹⁵.

The actual economic volume of products to which mutual recognition could be applied cannot be calculated with scientific precision, for several reasons. Firstly, it is impossible to determine the economic value of aspects of products that are only partly harmonised (mutual recognition applies to certain aspects falling outside the scope of EC harmonisation). Secondly, technical barriers for a specific type of

¹¹ Nick Bernard, “Flexibility in the European Single Market“, in Catherine Barnard and Joanne Scott (ed.), *The Law of the Single European Market – Unpacking the Premises*, Hart Publishing, Oxford, 2002.

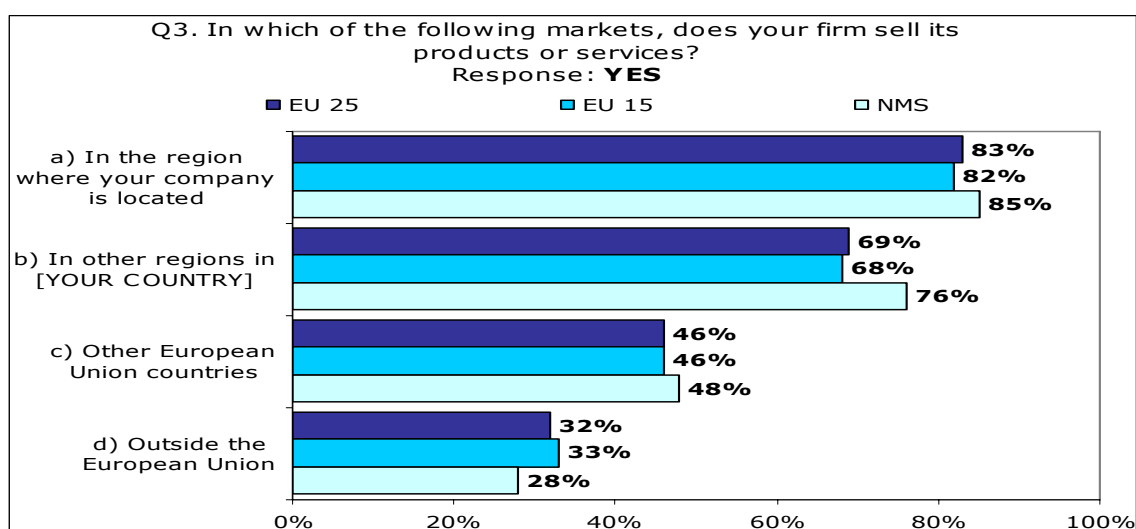
¹² In its judgment of 19 June 2003 (Commission of the European Communities v Italian Republic, case C-420/01), the Court of Justice held that a rule prohibiting the marketing in Italy of energy drinks containing caffeine in excess of a certain limit, without showing that that limit is necessary and proportionate for the protection of public health, breached Articles 28 EC and 30 EC. However, in a very similar case, the Court rejected the Commission’s complaints about a rule prohibiting the marketing in France of energy drinks with a caffeine content higher than a certain limit: judgment of 5 February 2004, Commission of the European Communities v French Republic, case C-24/00.

¹³ Some national rules are drafted in the light of the results of international scientific research, are necessary to give effective protection to the interests referred to in Article 30 of the EC Treaty or accepted as mandatory requirements by the Court of Justice and, taking into account the risk of the product, constitute the least trade restrictive measure. Other national rules, however, reflect the limited information of policy makers at the time that regulations are formulated. National rules can also be a by-product of the development of independent and largely arbitrary commercial standards in once-isolated markets, or inspired by local practices and traditions. Or they can be driven by protectionist nature. See inter alia: Alan O. Sykes, “The (Limited) Role of Regulatory Harmonization in International Goods and Services Markets”, *Journal of International Economic Law* (1999) 49-70.

¹⁴ E.g. textiles, footwear, information technology, specific types of motor vehicles, electrical material, certain foodstuffs. The packaging and labelling of certain foodstuffs, for example, is fully harmonised at EU level but their content and denominations can still be covered by mutual recognition.

¹⁵ The difficulties for separating the products aspects harmonised by secondary EU law and the aspects falling under Articles 28 and 30 EC Treaty are well illustrated in a recent judgement of the Court of Justice of 10 January 2006 (case C-147/04, *De Groot en Slot Allium BV, Bejo Zaden BV vs Ministre de l’Économie, des Finances et de l’Industrie and Ministre de l’Agriculture, de l’Alimentation, de la Pêche et des Affaires rurales*) and in a judgment of 12 October 2000 (*Cidrerie Ruwet SA v Cidre Stassen SA and HP Bulmer Ltd*, case C-3/99).

product do not exist in all Member States. It would require an inventory of all national technical barriers within the EU as well as evaluation of the potential market for products that do not yet have full access to the market. The absence of reliable information about the existence of technical barriers in the Member States undermines all possible attempts to calculate the precise value of products covered by mutual recognition. Thirdly, the internal market for goods is evolving: old technical barriers are removed through harmonisation or unilateral withdrawal by Member States, while new ones emerge. Fourthly, mutual recognition does not apply when a national technical rule is justified under Article 30 EC Treaty or by the mandatory requirements in the general public interest accepted by the Court of Justice. Fifthly, enterprises may have own their own commercial or other reasons for not selling their products in another Member State, not linked to trade barriers.



Source: Innobarometer 2004

Nevertheless, it is estimated on the basis of extrapolation from existing data¹⁶ that **about 25% of intra-EU manufacturing trade could be covered by mutual recognition.**

¹⁶

See inter alia: Commission report COM(2001)736 of 7 December 2001, "Economic Reform : Report on the functioning of Community product and capital markets"; Commission Staff Working Paper SEC(2001)1993 of 7 December 2001, "Statistical and technical annex to the "Report on the functioning of Community product and capital markets; "Technical barriers to trade", Volume 1 of Sub-series III ("Dismantling of Barriers: Technical Barriers to Trade"), Single Market Review, Luxembourg, 1998; Hagemeyer J. and Michalek Jan J., "The Significance of Technical Barriers to Trade for Poland and other CEECs Acceding to the EU: Reconsidering the Evidence", *Emergo – Journal of Transforming Economies and Societies*, 2004, v. 11, No 1, p. 36; Brenton P. Sheehy J. and Vancauteran M., "Technical Barriers to Trade in the European Union: Data, Trends and Implications for Accession Countries", *Journal of Common Market Studies*, 2001, No 39, p. 241; Fabienne Ilzkovitz, Adriaan Dierx, Viktoria Kovacs and Nuno Sousa, « Steps towards a deeper economic integration: the internal market in the 21st century », *European Economy, Economic Papers*, No. 271. January 2007. European Commission.

2. PROBLEM DEFINITION

2.1. What are the problems with mutual recognition in the field of goods?

The great strength of mutual recognition is that there is no paperwork. However, the corollary is that there is **no reporting, no statistics and hence no reliable source of information** about how mutual recognition is applied. There is no inventory of possible national technical barriers to the free movement of products within the EU.

In theory, there are several **sources of information on the functioning of mutual recognition for products within the EU**. However, each of them has its limitations:

- (1) Enterprises, industry federations, citizens and other stakeholders can **report problems to the Commission** on their own initiative, through formal complaints under Article 226 EC Treaty, position papers or through public consultation. They can also go through SOLVIT or report problems to a Euro Info Centre. However useful and necessary these reporting systems may be, they will never be capable of providing systematic and exhaustive information. Enterprises and citizens are not necessarily aware that they can raise the issue through formal channels, or may prefer not to spend time reporting cases. The mere reporting of an issue to the Commission does not measure the problem in terms of an impact on intra-EU trade.
- (2) In theory, national authorities should inform the Commission and the other Member States when they refuse mutual recognition, pursuant to **Decision n° 3052/95/EC**¹⁷. In practice, they do not. After an encouraging number of notifications during the early years of Decision n° 3052/95/EC, notifications became very rare between 2000 and 2003. Since 2003, only two were made. There may be various reasons for this very low number: the number of remaining obstacles within the internal market may be very limited, or the restrictive national rules may already have been notified in another context (for example in draft under Directive 98/34/EC). Another possibility is that Member States simply do not apply the Decision correctly. There could be several reasons for this. Firstly, the Decision did not need to be transposed into national law, unlike a directive. It is therefore possible that some national administrations did not take the necessary organizational measures to correctly apply the Decision. Secondly, the Decision does not specify the consequences of a notification: it does not indicate whether the Commission must approve a notified measure or what other concrete action it might take. Thirdly, the Decision provides for a substantial number of exceptions so that certain categories of restrictive measures need not be notified to the Commission. Fourthly, it does not contain any specific sanctions for failure to notify.

¹⁷ Decision n° 3052/95/EC of 13 December 1995 establishing a procedure of mutual information on the national measures derogating from the principle of free movement of goods inside the Community, JO L321 of 30.12.1995, p. 1.

- (3) Over the years, the Commission and several Member States have organized **surveys on the functioning of mutual recognition in the area of goods**¹⁸. These surveys concerned enterprises and public authorities and revealed a number of problems. Surveys are very important in this field since they reveal problems that otherwise would not be reported through formal complaints, SOLVIT or Euro Info Centres. The results of surveys on the application of mutual recognition in the area of goods, however, are only indicative: they reflect the opinion of the sample of enterprises participating in the survey. They are therefore not necessarily wholly reliable or completely accurate. Moreover, participation in such surveys is often low. Respondents' judgment may be biased by other considerations, such as fear of identification and retaliatory measures, reluctance to disclose commercial information, etc.

Nevertheless, the combination of these various sources of information indicate that **many problems still surround the implementation of the mutual recognition principle**, specifically for technically complex products or products which can pose safety or health problems¹⁹.

- **About 25% of complaints in the field of Articles 28 to 30 EC Treaty relate to mutual recognition** while market access for products constitutes the second most important category of problems for SOLVIT²⁰. Although general research by the OECD shows that regulatory impediments to product market competition have declined in recent years and that the extent of government involvement in product markets has fallen considerably²¹, Member States' product conformity requirements are the main regulatory concern of European companies, forcing them to adapt product design, reorganise production processes and repackage and re-test their products before they can be put onto the market²².
- According to the results of a business survey presented in the October 1998 Single Market Scoreboard, 80% of the companies surveyed still found obstacles to free movement within the EU inhibiting their ability to do business in other Member States. **For products, 41% related these obstacles to differing national specifications and 34% related them to unusual testing, certification or approval procedures.**

¹⁸ Besides the surveys mentioned elsewhere in this impact assessment, see inter alia: Handelshindringer for danske eksportvirksomheder, Konsortiet:Gallup, Oxford Research og Rønne & Lundgren (<http://www.ebst.dk/publikationer/rapporter/handelsh/index.html>), Kerstin Berglöf (Swedish National Board of Trade), Trade Barriers Faced by Swedish Firms on the Single Market and in Third Countries (http://www.snee.org/publikationer_show.asp?id=102);

¹⁹ The Commission analysed the problems already in its Communication COM(1999)299final to the Council and the European Parliament of 16 June 1999 on mutual recognition in the context of the follow-up to the action plan for the Single Market, and more in detail in its first biennial report on the application of the principle of mutual recognition [SEC(1999)1106 of 13 July 1999] and in its second biennial report COM(2002)419final of 23 July 2002.

²⁰ http://europa.eu.int/solvit/site/statistics/index_en.htm.

²¹ Paul Conway, Véronique Janod, Guiseppe Nicoletti, "Product Market Regulation in OECD Countries: 1998 to 2003", OECD Economics Department Working Paper No 419, 17 February 2005.

²² Single Market Monitor Survey, September 2001, Flash Eurobarometer 106 (http://ec.europa.eu/internal_market/score/docs/score09/monitor-survey_en.pdf)

- The broad surveys made for the second biennial report²³ indicated that about **35% of enterprises reported problems with mutual recognition. About 50% of enterprises decided to adapt their products** to the rules of the Member State of destination although mutual recognition could have applied.
- An analysis of the queries addressed to the European Information Centre network, where success stories are not reported, shows that about **60% of cases in the non-harmonised field of goods concern problems caused by technical rules to which mutual recognition could apply.**
- A more recent UNICE survey shows that **57% of companies reported mandatory national requirements that result in product changes**, while 46% were confronted with requirements for extra national testing/certification of products. 17% encountered other requirements, such as extra or different documentation²⁴.

These figures highlight that the **free movement of goods is far from being achieved in the non-harmonised area**. An analysis of the different surveys and case studies as well as literature reviews indicate that these difficulties are caused by four fundamental problems that are all interrelated:

- (1) **lack of awareness** of the mutual recognition principle on the part of enterprises and national authorities;
- (2) **legal uncertainty** about the scope of the principle and the burden of proof;
- (3) **The risk for enterprises** that their products will not get access to, or will have to be withdrawn from, the market of the Member State of destination,, and
- (4) the **absence of a dialogue** between competent authorities in different Member States.

2.2. The first problem: lack of awareness of the principle

2.2.1. *The causes of the problem*

When there is no harmonised Community legislation for a specific type of product, Member States are entitled to keep their national rules provided that they comply with the principle of free movement of goods laid down in the EC Treaty. In practice, however, **many national rules give the false impression that they are the only applicable legislation or that they prevail**²⁵.

²³ COM(2002)419final of 23.7.2002.

²⁴ "It's the Internal Market, stupid! A company survey on trade barriers in the European Union", UNICE Internal Market Working Group, May 2004.

²⁵ According to settled case-law of the Court of Justice, the prohibition laid down in Article 28 of the EC Treaty does not only cover trading rules enacted by Member States which are capable of directly or actually hindering intra-Community trade, but also trading rules capable of indirectly or potentially hindering intra-Community trade. Article 28 applies therefore not only to the actual effects but also to the potential effects of national legislation: see in particular Judgment of the Court of 22 October 1998,

Moreover, **the EC Treaty does not expressly confirm 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”-judgement²⁶, which concerned the interpretation of measures having an effect equivalent to quantitative restrictions on imports of goods under Article 28 of the EC Treaty.

2.2.2. *The effects of the problem*

The main effect of the lack of awareness is that enterprises and national administrations take national technical rules for granted²⁷.

The lack of awareness disadvantages enterprises looking for business opportunities in other Member States, and in particular small and medium-sized enterprises²⁸. In most cases, enterprises check and evaluate the technical rules of the Member State of destination before marketing their products there. Almost 80% of respondents in the European Business Test Panel Consultation and 95% of responding enterprises in the I.P.M. consultation examine the applicable technical rules in the Member State of destination before marketing their products. It is not surprising that very often they take those technical rules for granted, unaware that Community law, as interpreted by the Court of Justice, provides for mutual recognition. Enterprises adapt their product to local requirements or get them retested or, in the worst case, refrain from entering the national market at all.

The European Business Test Panel Consultation shows that only 46% of respondents are familiar with mutual recognition. This confirms similar findings from sectoral surveys organised for the second biennial report:

²⁶ Commission of the European Communities v. French Republic, (“Foie gras”-judgment), Case C-184/96, E.C.R. 1998, p. I-6197.

²⁶ The mutual recognition principle in the area of goods finds its origin in the judgement of the Court of Justice of 20 February 1979 (Rewe-Zentral AG v. Bundesmonopolverwaltung für Branntwein), Case 120/78, European Court Reports 1979, p. 649. This judgement was the basis for the communication from the Commission concerning the consequences of the Judgment given by the Court of Justice on 20 February 1979 in Case 120/78 (Cassis de Dijon), OJ C 256, 3 February 1980.

²⁷ See the second biennial report COM(2002)419 on mutual recognition. According to the I.P.M. consultation, 47.7% of respondents – and 95% of responding enterprises - prefer to know the technical rules of the Member State of destination and to make an evaluation thereof before marketing their products in the recipient Member State. Only 3% of respondents (5% of responding enterprises) do not wish to know these rules before marketing their product in the Member State of destination. Almost 80% of respondents of the consultation of the European Business Test Panel would like to know (beforehand) about the technical rules in force in those Member States where they wish to market products.

²⁸ See point 5.2 of the second biennial report COM(2002)419final. The lack of awareness is illustrated by the results from the European Business Test Panel Survey (annex 2) where more than half of the enterprises participating in the survey were not aware of the mutual recognition principle prior to the survey.

<i>Sectoral surveys (2002): Enterprises' awareness of the existence of the principle</i>		
<i>Sector</i>	<i>Familiar</i>	<i>Unfamiliar</i>
Bicycles	59%	41%
Childcare articles	45%	55%
Fire alarm systems	54%	46%
Burglar alarm systems	45%	55%
Articles of precious metal	56%	44%
Tanks	52%	48%
Containers	61%	39%

Moreover, familiarity with the principle does not necessarily mean that enterprises actually invoke it. Only half of the respondents in the European Business Test Panel Consultation who expressed familiarity with mutual recognition actually relied on it to obtain access to the market of another Member State.

National administrations stick to, and strictly apply, their national rules although Articles 28 to 30 of the EC Treaty take precedence over all contrary national measures²⁹. The lack of awareness means that national authorities then consider their national rules to be the only applicable legal tool to assess product conformity³⁰.

2.2.3. *Current action*

Lack of awareness has until now been tackled by so-called “**mutual recognition clauses**”³¹ that Member States have been encouraged or obliged to insert in their national legislation. The purpose of the clause is to refer to the mutual recognition principle or to incorporate it into national law, by permitting the marketing of products lawfully manufactured and/or marketed in another Member State even though they may not comply with national rules.

However, “**mutual recognition clauses**” are suffering from different problems:

- **They are often not very detailed.** The insertion of a clause in each legal instrument has the advantage of making mutual recognition a general principle of national law. Unfortunately, many clauses simply state the mutual recognition principle without specifying how and when it will be applied.
- **Their presence in national legislations is not yet systematic.** Member States usually insert mutual recognition clauses when they prepare a draft technical regulation and notify it to the Commission under directive 98/34/EC³², or to put

²⁹ Judgment of the Court of Justice of 28 March 1995, *The Queen v. Secretary of State for Home Department, ex parte Evans Medical Ltd and Macfarlan Smith Ltd.*, Case C-324/93, European Court Reports 1995, p. I-5.

³⁰ See, for example, a survey conducted by the Swedish Agency for Public Management at the request of the Swedish government: «Förvaltning för fri rörlighet», Statskontoret, 2006:16, http://www.statskontoret.se/Statskontoret/Templates/PublicationPage_3347.aspx.

³¹ See “Commission interpretative communication on facilitating the access of products to the markets of other Member States: the practical application of mutual recognition”, O.J. C265 of 4 November 2003, p. 2.

³² Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations, OJ L204, 21.7.1998, p. 37.

an end to an infringement procedure. More recent national rules and rules about which a complaint has been lodged with the Commission are therefore more likely to contain a “mutual recognition clause” than older rules or rules that no-one has yet complained about. Thus there can be inconsistency in the way categories of similar goods are treated from the point of view of mutual recognition.

- **The obligation to insert them in national legislation is often questioned**, especially when the authorities have determined the rules on the basis of scientific or technical evidence. Some argue that they do not need a clause as they will update their national rules in the light of product innovation and international scientific research. Moreover, the Court of Justice has also cast some doubt on the need to include the clauses in national legislation³³.

Although they offer a visible legal basis to national authorities to apply mutual recognition, the number of enterprises and national administrations that invoke mutual recognition clauses is limited:

<i>Sectoral surveys (2002): Application of the mutual recognition clause</i>		
<i>Sector</i>	<i>Enterprises</i>	<i>Authorities</i>
Bicycles	3%	0%
Childcare articles	3%	12%
Fire alarm systems	11%	25%
Burglar alarm systems	0%	24%
Articles of precious metal	1%	19%
Tanks	1%	53%
Containers	4%	40%

The European Business Test Panel Consultation shows that, of 46% of respondents familiar with mutual recognition, only 36% check whether national rules contain a mutual recognition clause.

The Commission has published **interpretative communications** setting out how mutual recognition should actually work. It has also organized **conferences, seminars and round tables** to raise awareness in businesses and national authorities. It is, however, very difficult to reach businesses through these gatherings, especially when they are organised across different industrial sectors.

2.3. The second problem: legal uncertainty about the scope of the principle and the burden of proof

2.3.1. The causes of the problem

It is often unclear to which categories of product mutual recognition applies. Mutual recognition is residual, i.e. it only applies if and when the national rules on such goods do not implement secondary EC legislation. Moreover, harmonisation or approximation of national laws does not always cover all products or all essential aspects of products³⁴. There is no list of products or aspects of products to which

³³ Judgement of the Court of Justice of 5 February 2004, Commission v. France, Case C-24/00.

³⁴ Alarm systems, for example, are regulated by three EC Directives (73/23/CEE, 89/336/CEE and 1999/5/CE) but functionality testing, climatic tests and efficiency testing of these products nevertheless

mutual recognition should apply. This means that, for every special aspect of a product, enterprises and national administrations should first examine whether it is formally regulated in secondary EC legislation before concluding whether mutual recognition applies. This requires a profound knowledge of EC law.

Secondly, the text of Articles 28 and 30 EC Treaty is so concise that its interpretation has produced **abundant jurisprudence of the Court of Justice**. Roughly 300 judgements of the Court of Justice relate to mutual recognition in the area of goods. The term “mutual recognition” has almost never been used in the jurisprudence of the Court, so that a profound knowledge of the Court’s jurisprudence is also necessary to distinguish the case-law on mutual recognition from the other case-law on Articles 28 and 30 EC Treaty.

Thirdly, the most important problem is without any doubt the **widespread legal uncertainty about the burden of proof**. Some enterprises wrongly believe that if a product is lawfully marketed in another Member State, they need not provide any information to the market surveillance authorities of the receiving Member State. For reasons of administrative facility, some national laws put the onus on enterprises to show that the product meets the requirements of the Member State of destination. Even if it is not expressly stated, some competent authorities wrongly believe that the enterprise must demonstrate that the imported product affords a level of protection equivalent to that required of the domestic product.

2.3.2. *The effects of the problem*

Apart from the strict adherence to national rules, uncertainty makes **national authorities very cautious** towards products lawfully marketed in another Member State but not in conformity with the national technical rules of the Member State of destination.

Since national rules define the roles, functions and liability of controlling officers, few are likely to put their national rules aside, however outdated or restrictive they may be, and let the EC Treaty prevail. For some authorities, not applying mutual recognition has advantages: there is no need to enter into discussion with enterprises whose products do not comply with national rules. In addition, the non-application of mutual recognition may benefit competing local manufacturers³⁵.

³⁵

fall within the scope of the mutual recognition principle: judgment of the Court of Justice of 8 May 2003, ATRAL SA v Belgian State, Case C-14/02.

Klaus Wallner, “Mutual Recognition and the Strategic Use of International Standards”, in S-WOPEC Scandinavian Working Papers in Economics, No 254 (1998).

<i>National authorities having encountered problems with mutual recognition (2002):</i>	
Alarm systems	32%
Bicycles	45%
Beverages	50%
Tanks and containers	43%
Ladders and scaffolding	29%
Precious metals	50%
Construction products	35%
Childcare products	24%
Canned food	53%
Food supplements	87%

This legal uncertainty prevents enterprises from relying on the mutual recognition principle³⁶. The European Business Test Panel (EBTP) consultation in 2004³⁷ shows that 25% of enterprises that already relied on mutual recognition when selling goods in another Member State have had problems. This is in line with similar findings in the sectoral surveys:

<i>Proportion of enterprises that have encountered problems with mutual recognition (2002)</i>	
Bicycles	33%
Childcare articles	18%
Fire alarm systems	28%
Burglar alarm systems	43%
Objects in precious metals	27%
Tanks	41%
Ladders and scaffolding	29%
Canned food	33%
Non-alcoholic beverages and beer	41%
Fortified products	89%
Construction products	54%
Containers	18%

2.3.3. *The current actions*

The scope of mutual recognition has not received systematic attention. The most important reason is that the insertion of a “mutual recognition clause” in all national technical rules on products that do not transpose secondary EC law avoids the need for careful analysis of the scope of mutual recognition. The presence of a “mutual recognition clause” confirms that mutual recognition applies to this category of products. However, the absence of a clause does not necessarily imply that mutual recognition does not apply.

The question of the burden of proof is hard to solve with current legal tools. It has indeed been noted that far too often “**mutual recognition clauses**” only nominally incorporate the mutual recognition principle in national legislation without specifying how it is to be implemented in practice. The dilemma of the “mutual

³⁶ Jacques Pelkmans, “Mutual Recognition in Goods and Services: an Economic Perspective”, BEEP briefing no. 2, December 2002.

³⁷ See Annex 2.

recognition clause”, however, is that the mere reference to Articles 28 and 30 EC Treaty is legally and formally sufficient but that, on the ground, this is not sufficiently explicit to create legal certainty for enterprises and national administrations.

It should be noted in this context that the case-law of the Court of Justice does not necessarily allow the Commission to require much more from Member States than a mere reference to Articles 28 and 30 EC Treaty in their national rules: the Court has indicated that Member States enjoy a margin of discretion in determining what measures are most appropriate to eliminate barriers to the imports of products. It is therefore not for the Community institutions, according to the Court, to act in place of the Member States and to prescribe for them the measures which they must adopt and effectively apply to safeguard the free movement of goods in their territories.

Since the early eighties, the Commission has tried to summarize the Court’s jurisprudence on mutual recognition in various **interpretative communications**, such as the interpretative communication on mutual recognition³⁸.

2.4. The third problem: The risk for enterprises that their products will not get access to, or will have to be withdrawn from, the market of the Member State of destination

2.4.1. The causes of the problem

Enterprises run the risk for enterprises that their products will not get access to, or will have to be withdrawn from, the market of the Member State of destination. Most enterprises assess and manage such risks by starting with risk identification (i.e. identifying national rules with a potential negative effect on the marketing of the product in the receiving Member State) followed by a risk assessment (i.e. evaluation of the risks posed by these rules). On that basis, enterprises decide how they will market the product in the receiving Member State. **It is difficult for businesses to find out beforehand if, how and when mutual recognition is applied.**

Such risk identification is the first difficult step for enterprises in the non-harmonised field of goods. Almost 80% of respondents in the European Business Test Panel Consultation like to know beforehand about the technical rules in force in those Member States where they wish to market products. The public consultation gave similar results:

<i>Do you prefer to know the technical rules of the Member State of destination and to assess them before marketing your products in the recipient Member State?</i>	
Yes	95%
No	3%

Getting specific information on national technical rules and the implementation of mutual recognition poses a problem for certain enterprises:

³⁸ O.J. C265 of 4 November 2003, p. 2.

<i>European Business Test Panel consultation (2004)</i>	
<i>Types of difficulties with obtaining information on how mutual recognition is applied</i>	
Difficulties to get sufficient information on the technical rules in force in the receiving Member State	33%
Difficulties to identify the competent national authorities	28%
<i>Would it be helpful if the information on technical rules and on the application of mutual recognition becomes more accessible?</i>	
Yes	88%
No	12%

It is a paradox, at least from an internal market point of view, that the risk for enterprises that their products will not get access to, or will have to be withdrawn from, the market of the Member State of destination is reduced under an **“ex ante” mutual recognition schemes**³⁹. In that case, market authorisation or its refusal officially confirms whether the product is allowed onto the national market. The national market authorisation procedure is already an important obstacle to the free movement of goods, due to the unavoidable delay in market access and the costs to businesses. However, despite its inconveniences from an internal market stance, such procedures allow direct contact with the competent authorities before the product is put on the national market.

The subsequent paradox is that when there is no paperwork as in **“ex post” schemes**⁴⁰ the risk for enterprises that their products will not get access to, or will have to be withdrawn from, the market of the Member State of destination is much higher. The enterprise will not know in advance of marketing the product in the receiving Member State if, when and how mutual recognition will be applied and if the product will be considered lawfully on the market in the Member State of destination. Market surveillance activities may reveal non-compliance with national rules. In that case, the competent authorities may decide to take action against the product and require its immediate withdrawal from the market for non-compliance with their national rules.

This risk is also determined by the nature of the restrictive measures that can be taken by the authorities of the receiving Member State in the case of non-compliance of the product with national rules. Usually, the only possible way a business can avoid the product being sanctioned or even withdrawn from the market, is **litigation in the Member State of destination** to suspend or the annul the decision to withdraw the product. There are almost no alternative, more consensual methods. Businesses established in the Member State of destination and facing the possibility of litigation costs are likely not to go ahead with selling products originating in another Member State, while enterprises established in another Member State would

³⁹ “Ex ante” mutual recognition normally takes place in a system of prior administrative authorisation of a product, i.e. where national rules submit the product to an obligatory prior approval before it can be marketed.

⁴⁰ “Ex post” systems do not provide for a formal authorisation procedure before the product is put on the market. They rely on market surveillance activities during which products that do not comply with national technical rules are found, usually well after their being put on the market

have to engage in a cross-border dispute, involving lengthy proceedings and high court costs⁴¹.

2.4.2. *The effects of the problem*

If an enterprise faces the risk for enterprises that their products will not get access to, or will have to be withdrawn from, the market of the Member State of destination, it can refrain from selling the product, adapt it to local rules, or start marketing and await the outcome of market surveillance activities.

One major consequence of such risk is risk avoidance: enterprises will “play it safe” by avoiding any possible conflict or discussion with the national authorities of the Member State of destination. In this regard, SMEs might behave differently to larger enterprises. Surveys suggest that SMEs are more inclined to steer away from such problems because it is, or is perceived to be, too difficult and too expensive to confront national authorities. By comparison larger enterprises seem more inclined to tackle problems and seek solutions, partly because they have greater resources and partly because they are keen to seek economies of scale through the equal treatment of their products throughout the internal market. This may explain why SMEs seem to give up on mutual recognition long before larger enterprises in a similar situation. Of the respondents of the European Business Test Panel Consultation who had problems with mutual recognition, more than 20% simply gave up and decided not to sell on that national market.

13% of companies participating in a recent Flash Eurobarometer⁴² would like to export but are concerned about encountering barriers. The response of managers in Germany and France stand out from that in other Member States, with one in five managers who would like to export but are concerned about encountering barriers. Over one in ten managers in Greece, Portugal, Belgium and Spain would like to begin exporting to other Member States but are also concerned about encountering barriers. 11% of companies participating in the same Flash Eurobarometer would like to export but are in need of more information. Especially company executives in Germany (16%), Greece (16%), Spain and France (both 11%) need more information. 7% actually encountered problems.

When there is a high risk that the products will not get access to, or will have to be withdrawn from, the market of the Member State of destination, it is usually easier for the individual enterprise to adjust its products to national requirements (if the market is sufficiently large and attractive), or to stay out of the market (if it is small), than to launch a lengthy, time-consuming dispute with national authorities which may entails a number of negative implications⁴³. The additional litigation costs and procedural delays can give local competitors substantial commercial advantages. Besides these financial costs, litigation has a negative impact on further contact between the administration and the enterprise. In addition, it often entails fewer risks and is more cost effective to give up and conform to the technical rules of the

⁴¹ See Commission Green Paper of 9 February 2000 “Judicial cooperation in civil matters: the problems confronting the cross-border litigant”, COM(2000)51 final.

⁴² Flash Eurobarometer 180 (June 2006) - http://ec.europa.eu/internal_market/strategy/index_en.htm#hearing.

⁴³ See figures 7.4.8 to 7.4.12 of the second biennial report COM(2002)419final.

Member State of destination rather than wait for a possible positive outcome to litigation⁴⁴. The costs of adapting products are often high and can only be offset by businesses which sell in sufficiently large volume. Nevertheless, the policy of avoiding risks that the products will not get access to, or will have to be withdrawn from, the market of the Member State of destination is understandable - most enterprises wish to avoid damage to the reputation of their product, caused for example by the possible subsequent suspension of marketing by the authorities of the Member State of destination.

Some enterprises will attempt to reduce the risk through dialogue with the national authorities in the receiving Member State. However, the possibility of such contact with the competent authorities before the product is put on the national market depends often upon the goodwill and accessibility of the national authorities and their willingness to indicate whether the product can be lawfully marketed although it does not comply with the national technical rules. In any event, there is strong demand from European enterprises for reducing such risk by better organised and structured dialogue with the competent authorities of the receiving Member State:

<i>European Business Test Panel consultation (2004)</i>	
<i>Would it be helpful if enterprises could discuss the application of mutual recognition with the national authorities of the receiving Member State?</i>	
Yes	80%
No	6%

2.4.3. *Current action*

Current policy to minimize the risk for enterprises relies partly on “**mutual recognition clauses**” (see above) and partly on **reporting restrictive measures** taken by the authorities of the Member State in case of non-compliance of the product with their national rules:

- Individual cases can be reported to the **SOLVIT on-line problem solving network**⁴⁵ in which EU Member States work together to solve (without legal proceedings) problems caused by the possible misapplication of Internal Market law by public authorities. In the SOLVIT-system, an enterprise or citizen submits the problem to the local SOLVIT Centre, which enters the case in an on-line database. The case is then forwarded automatically to the SOLVIT Centre in the other Member State where the problem has occurred. The number of cases dealt with in the non-harmonised area of goods is increasing: 43 cases in 2005 compared with 15 in 2003 and 10 in 2004. In 2005, about 60% of SOLVIT cases on the free movement of goods reached a solution that was accepted by the SOLVIT Centre that introduced the case. In other words, in more than half of the cases the product was eventually marketed in the Member State of destination thanks to the SOLVIT mechanism. The fact that the remaining 40% did not reach

⁴⁴ Nick Bernard, “Flexibility in the European Single Market“, in Catherine Barnard and Joanne Scott (ed.), *The Law of the Single European Market – Unpacking the Premises*, Hart Publishing, Oxford, 2002.

⁴⁵ Commission Recommendation 2001/893/EC of 7 December 2001 on principles for using "SOLVIT" -- the Internal Market Problem Solving Network, OJ L 331, 15/12/2001, p. 79. <http://europa.eu.int/solvit/>

a satisfactory solution does not necessarily mean that the Member State in which the cross-border problem occurred was wrong in refusing market access. It is possible that the legislation was justified by mandatory requirements of public interest and represented the least trade-restrictive measure. Although the SOLVIT network managed to resolve a substantial number of cases, much depends on the goodwill of the local Centre. It is not obliged to accept or to solve the case. When it accepts a case, it must merely “use its best endeavours to resolve the case in close cooperation with other parts of its Administration”. Furthermore, the SOLVIT system is conceived for solving actual problems and does not play a role in preventing problems. Nor does it suspend deadlines for an appeal before the national court. The system is still young and needs to be further developed.

- **Infringement proceedings under Article 226 EC are normally launched on a case-by-case basis and depend mainly on complaints.** Infringement proceedings usually aim to removing technical barriers laid down in national rules. They are, however, less suited for solving problems encountered by individual enterprises, as they do not provide redress in specific cases but rather tackle the national rule on the basis of which the individual restriction was imposed. In addition, even if infringement proceedings succeed in removing the barrier to trade, it is too slow an instrument for enterprises. Few can afford to await the outcome of the procedure before entering the market of another Member State. Finally, a judgement of the Court of Justice on the basis of an infringement procedure has no direct or immediate impact on the complainant, since it does not serve to resolve individual cases. It merely obliges the Member State to comply with Community law.

2.5. The fourth problem: the absence of a dialogue between competent authorities

2.5.1. The causes of the problem

Dialogue between national administrations of different Member States in the non-harmonised area is difficult in practice, due to the **lack of a common address book** in the non-harmonised field of products within the EU. It takes place on an ad-hoc basis whereas, by contrast, administrative cooperation is well organised in the harmonised area where it is put in place by the secondary EC legislation.

These contacts are nevertheless often necessary for getting more information about the product and the technical rules in the Member State of origin.

2.5.2. The effects of the problem

The absence of a dialogue between national administrations of different Member States in the non-harmonised field of products complicates the task of market surveillance authorities, which often rely on a single source of information, i.e. the enterprise marketing the product. Conversely, that enterprise will be requested to transmit more information than if market surveillance authorities had received information directly from their colleagues in other Member States.

This lack of administrative cooperation is worrying since it is a legal obligation according to settled case-law of the Court of Justice: “*Strict compliance with* [the obligation to bring about a relaxation of the controls existing in intra-Community

trade] requires an active approach on the part of the national body to which an application is made for approval of a product or recognition, in that context, of the equivalence of a certificate issued by an approval body of another Member State. Further, such an active approach is also required, where appropriate, of the latter body, and in this respect it is for the Member States to ensure that the competent approval bodies cooperate with each other with a view to facilitating the procedures to be followed to obtain access to the national market of the importing Member State⁴⁶.”

2.5.3. Current action

No specific action has been taken yet to organise dialogues between national administrations of different Member States in the non-harmonised field of products. **Such dialogue takes place on an ad-hoc basis**, through informal contacts (for example established via the Standing Committee set up by Directive 98/34/EC) and/or through SOLVIT.

2.6. What are the costs of these problems?

The administrative charges that result from difficulties related to mutual recognition are considerable: there is a wide variety of costs, to (a) enterprises that, despite the technical obstacle, choose to enter the market, (b) society (consumers, firms and labour) as a result of firms being put off entering the market and (c) national administrations.

2.6.1. Administrative charges and other costs incurred by enterprises

Enterprises incur **information gathering costs** for obtaining information on the (future) rules of the Member State of destination⁴⁷. Enterprises may need to translate national rules into their own language, to hire lawyers to find and to explain these rules, to identify the competent national authorities, and so forth. These costs tend to be greater for companies established in another Member State. They worst affect SMEs.

Furthermore, since the costs of learning about national rules in another Member State may be largely unrelated to the enterprise's output, they tend to add more to the unit costs of firms that have a smaller market presence. In addition, advance notice of impending regulatory changes can confer a competitive advantage on local manufacturers so that they can serve their local market sooner than others. At least during a transitional period, they will have exclusive access to the local market and, in the longer run, some competitive advantage.

Compliance costs are incurred when enterprises wish to market, in the Member State of destination, a product lawfully marketed or manufactured in another Member State, without relying on mutual recognition – or when mutual recognition

⁴⁶ Judgement of the Court of Justice of 10 November 2005, Commission of the European Communities v. Portuguese Republic, case C-432/03.

⁴⁷ Jacques Pelkmans, “Mutual Recognition in Goods and Services: an Economic Perspective”, BEEP briefing no. 2, December 2002.

is denied. In that case, the product will have to be adapted, increasing the cost of doing business⁴⁸.

This compliance cost can also be considered a cost advantage for domestic manufactures which anyhow have to ensure the compliance of their products with the rules of the Member State of manufacture. Compliance costs are a very important deterrent to enterprises exploring new markets. If the Member State of destination has different regulatory requirements, the costs of adapting products and modifying manufacturing processes will put a lot of enterprises off⁴⁹. When Member States pursue their regulatory objectives in different ways, enterprises may become subject to redundant regulatory requirements that increase their costs of doing business in different Member States. These unnecessary costs tend to fall exclusively on firms that engage in intra-Community trade.

<i>Non-application of mutual recognition and compliance with national technical rules (2002)</i>					
<i>Sector</i>	The economic operator was ultimately able to place or keep the product on the market without having to adapt it	The economic operator adapted the product	<i>Changes made mainly at the request of the importer or purchaser</i>	<i>Changes made mainly at the request of the authorities of the Member State of destination</i>	<i>Actions or measures by the country which led directly or indirectly to changes being made to the product</i>
Bicycles	44%	48%	21%	10%	27%
Childcare articles	10%	61%	39%	27%	31%
Fire alarm systems	53%	36%	9%	26%	26%
Burglar alarm systems	38%	54%	29%	5%	6%
Articles of precious metal	27%	52%	15%	23%	26%
Tanks	21%	60%	19%	11%	17%
Containers	77%	17%	7%	0%	0%

The costs of complying with the rules of the Member State of destination can be distinguished from **conformity assessment costs**, i.e. the costs of *proving* compliance with the rules of that Member State. Conformity assessment procedures often create language barriers and entail dealing with an unfamiliar body in the Member State of destination, which increases costs, especially for enterprises not yet present on that market. Enterprises with larger output can spread the costs over a larger base. If there is a conformity assessment procedure in the Member State of

⁴⁸ Luigi Russi, « Economic Analysis of Article 28 EC after the Keck Judgement », German Law Journal, Vol. 07 No 5, p. 479.

⁴⁹ Akiko Suwa-Eisenmann and Thierry Verdier, "Reciprocity and the Political Economy of Harmonization and Mutual Recognition of Regulatory Measures" (January 2002), CEPR Discussion Paper No 3147.

origin, the enterprise wishing to market its product in another Member State will face double costs.

Loss of economies of scale occurs when enterprises decide to divide their manufacturing operations into separate components that each need only to comply with the regulations in one market. Different manufacturing operations to serve different markets of Member States will often increase unit costs considerably and may forfeit economies of scale in manufacturing, management, marketing, risk diversification, etc. Where economies of scale are important, enterprises may not be able to enter a market without doing so on a large scale, an option that may be quite unattractive due to the number of risks involved or the existence of substantial capacity in the market of the Member State of destination.

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. In the off-road machinery sector, for example, nearly no small firms export to Member States with high requirements and third-party certification.

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**⁵⁰, 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. For companies offering several product types on the national market of a receiving Member State, these costs amount to approximately 2% of their entire annual turnover on that market. For companies specialised in one specific product type, compliance costs are reported to amount to approximately 10% to 15% of their entire annual turnover on a larger market. These percentages increase fast for smaller national markets⁵¹.

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**.

⁵⁰ See annex 3.

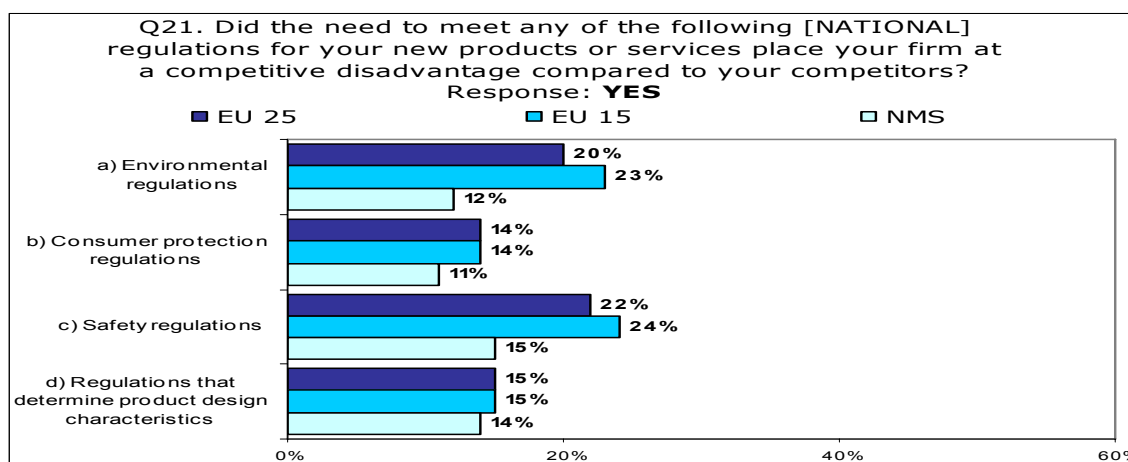
⁵¹ See also Fabienne Ilzkovitz, Adriaan Dierx, Viktoria Kovacs and Nuno Sousa, « Steps towards a deeper economic integration: the internal market in the 21st century », European Economy, Economic Papers, No. 271. January 2007. European Commission.

2.6.2. Cost to society as a result of firms not entering the market due to problems regarding mutual recognition

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 firms⁵². 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.

A lack of mutual recognition creates **competitive advantages** for larger enterprises and enterprises that adapted their products to national rules, since competing products are barred from entering that national market. Larger enterprises often prefer to follow the strictest national rules so that products can be accepted in all markets and economies of scale fully exploited⁵³. This situation is fundamentally different from the situation for a typical smaller enterprise that wants to export its products under mutual recognition. The small enterprise has often established the product on the home market first before contemplating selling the product elsewhere.

Source: Innobarometer 2004



⁵² Matteo Bugamelli and Luigi Infante, "Sunk costs of exports", Banca d'Italia, Temi di discussione del Servizio Studi, Number 469 - March 2003; Mark J. Roberts and James RP Tybout, An Empirical Model of Sunk Costs and the Decision to Export, The World Bank - International Economics Department L ; International Trade Division, March 1995.

⁵³ Meeting the strictest rules is a strategy to ensure that a product can be marketed on all markets. For the retailer it is also a cost efficient strategy eliminating costs of communicating with national authorities in destination Member States, that otherwise would have to accept a product with less strict rules applied to it. The strategy also enables the retailer to place products on the market faster than otherwise, because fewer obstacles are met. The strategy is, however, at times difficult to apply in practice: Besides the difficulty of finding accurate information about specific product and material requirements for all the national market where the firm operates, it is at times difficult to assess which national rules are the strictest, as the rules of two sometimes contradict each other.

2.6.3. *Costs to national administrations*

Applying mutual recognition is usually part of market surveillance and does not necessarily entail extra costs for national authorities. Whether they apply mutual recognition correctly or apply national technical rules without mutual recognition, they have to gather information, assess the product, decide whether the product can be allowed in its current form and, if not, inform the economic operator, stating reasons and the methods of appeal open to him. The only formal difference is the content of the statement of reasons which, for mutual recognition, will be based on Articles 28 and 30 EC Treaty while it will be limited to the national technical rules when mutual recognition is not applied.

In contrast with enterprises, **national authorities incur few costs** when mutual recognition is not applied. Refusal is the cheapest, easiest solution for national administrations which, even in the worst case, probably only incur litigation costs.

2.7. **Does the EU have the right to act?**

The EU has the right to act to ensure the functioning of the internal market for goods. Pursuant to Article 14(2) of the EC Treaty, the internal market shall comprise an area without internal frontiers in which the free movement of goods, persons, services and capital is ensured in accordance with the provisions of the Treaty. The prohibition, as between Member States, of measures having equivalent effect to quantitative restrictions on imports of goods is one of the main principles of the EC Treaty (Articles 3(1)(a) and 28 to 30).

If a comparison of the options from the point of view of their effectiveness and likely impact indicates that a **non-regulatory option** would be the most appropriate way to improve the functioning of the “mutual recognition principle”, the Commission has the right to act pursuant to Articles 211, 226 and 228 EC Treaty, Directive 98/34/EC and Decision 3052/95/EC.

However, if a comparison of the options points to a **regulatory approach**, the EC has the right to act on the basis of Article 95(1) EC Treaty. It specifies that, by way of derogation from Article 94 and save where otherwise provided in the Treaty, the objectives set out in Article 14 can be reached by adopting measures for the approximation of the provisions laid down by law, regulation or administrative action in Member States which have as their object the establishment and functioning of the internal market.

3. **OBJECTIVES**

Further integration of the internal market for goods in the non-harmonised area requires, in the light of chapter 2, the removal of these problems surrounding the implementation of the mutual recognition principle. The objectives are:

- (1) **Enterprises and national authorities** facing a technical rule actually or potentially hindering imports of a product lawfully manufactured or marketed in another Member State **should be aware of the existence of the mutual recognition principle**, so that they understand that such rules are not

necessarily insurmountable obstacles to the marketing of products lawfully manufactured or marketed in another Member State;

- (2) **Enterprises and national authorities should have legal certainty concerning the scope of the principle and the burden of proof** so that they know what they can reasonably expect and understand their rights and obligations when mutual recognition is, or ought to be, applied;
- (3) **The risk for enterprises that their products will not get access to, or will have to be withdrawn from, the market of the Member State of destination should be reduced;**
- (4) **Dialogues between national authorities of different Member States** should be facilitated so that can easily exchange information.

These objectives do not at all imply that approximation of laws under Article 95 EC Treaty will 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.

4. POLICY OPTIONS

4.1. Rejected options

This impact assessment aims **to identify and analyse alternative policy options for improving mutual recognition**, i.e. the functioning of Articles 28 and 30 of the EC Treaty in the field of national technical rules. During the assessment process, **two policy options were quickly discarded** as being likely to create more problems than they would resolve:

- (1) **The creation of an official certificate of lawful marketing in the Member State of origin:** certain sources argued that official certificate of origin, confirming that a product is lawfully marketed in the Member State of origin, would help to dismiss doubts about the product. However, the would constitute a heavy financial and administrative burden for enterprises and national administrations and would certainly lead to more red tape and disproportionate administrative costs. Moreover, it would not provide any additional useful information that could not be presented through other means. The certificate would also not prevent national authorities of the Member State of destination disregarding mutual recognition.
- (2) **A preliminary opinion of the competent authorities on market access for a specific product:** This idea is inspired by tax legislation in several Member States which provides for the possibility of a "ruling". This is a legal instrument by which the competent tax authority determines how the law would apply to a hypothetical situation or individual operation. The "ruling"

is a commitment by the competent authority to treat the situation or operation in accordance with the "ruling" and gives the applicant tax certainty for a certain period. A similar system of voluntary conformity assessment could in theory be envisaged in the field of the free movement of goods, to reduce the risk for enterprises. The receiving Member State would confirm that a product, although not fully compliant with the legislation of the receiving Member State, can be lawfully sold. This issue was controversial during consultation with stakeholders: many were reluctant to go for a voluntary system of preliminary opinions on market access, while participants in the European Business Test Panel consultation showed more interest:

<i>Public consultation of stakeholders</i>	
<i>Should such “preliminary opinion on market access” be introduced to facilitate the entry to the national market?</i>	
Yes: such a system would reduce the uncertainty	44.7%
No: this system would be cumbersome and that it risks becoming de facto compulsory	39.4%

<i>European Business Test Panel consultation (2004)</i>	
A system of “preliminary opinions on market access” would be:	
Very useful	41.6%
Helpful	43.8%
Not useful	14.6%

The Commission rejected this option since it would create new barriers rather than eliminate existing ones. In practice such a system would very quickly develop into a de facto obligatory system in all Member States, which would create many additional obstacles in the internal market for goods. It would result in a new generation of administrative procedures that would be very burdensome and slow for enterprises. In addition, it would be difficult to manage for national authorities which would be obliged to set up new administrative structures with the necessary technical and scientific expertise to examine the products. The system would also be at odds with the general policy of the EU to reduce administrative burdens for enterprises and national authorities.

4.2. Policy options

Besides **using existing instruments** (status quo – option 1), the specific objectives set out under chapter 3 could be achieved through **complementary non-regulatory actions** (option 2), a **regulatory instrument** (option 3) or **through a combination of regulatory and non-regulatory actions** (option 4).

4.2.1. Option 1: status quo

The existing instruments are set out in more detail under chapter 2, under the headings “Current action”.

4.2.2. Option 2: the non-regulatory option

The non-regulatory option consists of **a combination of existing instruments and the following new action:**

- (1) **The creation of a website with a list of products to which mutual recognition applies.** Until now, there has been no list of products or aspects of products to which mutual recognition should apply. This contributes to legal uncertainty and means that, for every special aspect of a product, enterprises and national administrations should first examine whether it is formally regulated at EC level before deciding whether mutual recognition applies. The creation of a website with a list of products to which mutual recognition applies would address this problem. The list of products would, for example, be inspired by the Combined Nomenclature (CN) used in customs matters⁵⁴, since the CN is also used in intra-Community trade statistics. The CN is comprised of the Harmonized System (HS) nomenclature with further Community subdivisions, which results in a very detailed list. However, another product classification could also be used. The list on the site would then specify the aspects to which mutual recognition applies and refer directly to the applicable secondary EC legislation on EUR-LEX. When the product is subject to mutual recognition, the site could, for example, refer to the most relevant jurisprudence of the Court of Justice or to any other useful information. The site would fit the new thematic approach of the general website of the Commission - structured by theme and topic rather than on the basis of the Commission's internal organisational structure.
- (2) **A sectoral approach:** The establishment of a list of products to which mutual recognition applies would then serve as a basis for general screening by the Commission and the Member States of all national technical rules on a specific category of products and the identification of national authorities responsible for these rules. The screening would determine how the free movement of this category of goods could best be organised. The approach would also be used to set up voluntary administrative cooperation between national administrations.
- (3) The list of products and the general screening would serve as a basis for awareness raising actions through **conferences and seminars organised in the Member States and targeted at enterprises and competent authorities** and through **specific publications explaining mutual recognition for specific categories of products.**
- (4) **The systematic inclusion of the final text of all technical rules notified pursuant to Directive 98/34/EC in the TRIS database.** Article 8(3) of the Directive obliges Member States to communicate the definitive text of a technical regulation to the Commission without delay. However, they have not always fulfilled this obligation. The systematic inclusion of the final text of the technical rules IN the TRIS database would improve their accessibility.

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Annex I to Council Regulation (EEC) No 2658/87 on the tariff and statistical nomenclature and on the Common Customs Tariff.

- (5) **A new generation of “mutual recognition clauses”:** Member States that opt for “mutual recognition clauses” to eliminate barriers regularly use vaguely worded, ambiguous clauses which state the principle without specifying how it will be implemented. Under this non-regulatory option, all clauses would have to indicate in detail how mutual recognition is applied in practice. Templates would be provided by the Commission.
- (6) **The organisation of dialogue between national authorities through existing committees.** Many instruments of EC law provide for committees which assemble representatives of national authorities with technical expertise in their field. These committees could look into the application of mutual recognition to products which, although outside the scope of their directive or regulation, are similar.

4.2.3. *Option 3: the regulatory option*

The fact that this impact assessment aims to identify and analyse policy options to improve the application of Articles 28 and 30 EC Treaty in the field of national technical rules has two consequences for the identification of regulatory options:

- A regulatory option that would consist of harmonising national technical rules on products necessarily falls outside the scope of this impact assessment. It is indeed established case-law of the Court of Justice that Articles 28 and 30 EC Treaty only apply in the absence of EC harmonisation of technical rules.
- There is no need to intervene by regulatory means in cases where the free movement of goods within the EU functions well and where there is no actual or potential barrier caused by a national technical rule.

Consequently, **a regulatory option would only have to address cases where technical obstacles arise or could arise.** The legislative instrument would therefore be strictly limited to the application of technical rules in the receiving Member State.

Within these parameters, the regulatory option would first address the difficulties related to the burden of proof and the risk for enterprises that their products will not get access to, or will have to be withdrawn from, the market of the Member State of destination:

- (1) The **scope** of the legislative instrument would consist of **a list of products or aspects of products to which mutual recognition applies.**
- (2) The legislative instrument 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 under national technical rules. In particular, the legislative instrument would **concentrate on the burden of proof by setting out the procedural requirements for denying mutual recognition.** In a nutshell, Member States would remain obliged to allow the marketing of a product lawfully manufactured or marketed in another Member State. If, however, the recipient Member State intends to refuse or to restrict the marketing of such product, it should explain

clearly the technical or scientific reasons. It should also prove to the enterprise concerned, on the basis of all relevant scientific information available to that State, that there are overriding grounds in the general public interest for applying the technical rule concerned and that less restrictive measures could not have been used. The competent authority must invite the enterprise to submit any comments within a reasonable period before restricting the marketing of the product⁵⁵. The final decision to do so should be notified to the enterprise and should state the methods of appeal available.

- (3) It should be noted that creating legal certainty on the burden of proof does not address the problem of **the risk for enterprises that their products will not get access to, or will have to be withdrawn from, the market of the Member State of destination**. This risk could be reduced by establishing one or several **"Product Contact Points"** in each Member State. Their main task 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 also allow public authorities to identify their colleagues in other Member States so that they can easily **obtain information from, and start a dialogue with, the competent authorities in other Member States**. The Product Contact Points should respond as quickly as possible to any request for information. The concept of "Product Contact Points" would allow, but not oblige, each Member State to set up only one contact point for its entire territory. The number of Product Contact Points in each Member State, and their institutional nature, would vary depending on the internal organisation of the Member State and in particular regional or local competencies or the activities concerned. Product Contact Points might be the authorities that are directly competent for the legislation or bodies that function as intermediaries between enterprises and the competent authorities, such as SOLVIT-centres, EuroInfoCentres and other existing organisations. It should be noted that 65.2% of interested parties in the public consultation consider that the legislative instrument should establish a kind of national helpdesk for answering questions on the actual implementation of mutual recognition.
- (4) The problem of the lack of reliable facts and figures about the actual implementation of mutual recognition for specific products in the Member States could be solved by an **efficient monitoring scheme allowing Member States and the Commission to be informed on a regular basis about denials of mutual recognition**. Such a scheme should not increase the

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Obviously, urgent measures taken by national authorities for safety reasons should be excluded, such as measures taken pursuant to Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety, measures taken by the national authorities pursuant to Article 50(3)(a) Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, in the context of the rapid alert system for the notification of a direct or indirect risk to human health deriving from food or feed established by the Regulation. Moreover, Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules lays down a specific procedure to ensure that the economic operator remedies a situation of non-compliance, which should also be excluded from the scope.

administrative burden on national authorities. Under the regulatory option, this would either require amendment of Decision 3052/95/EC to ensure its convergence with the new legislative instrument (and to address the current weaknesses of the Decision) or the repeal of the Decision and the incorporation of its main principles into the new legislative instrument. Better Regulation principles suggest the latter is the better option.

The choice of the most appropriate form of legislative instrument depends on its content. It is important that the burden of proof and the procedural requirements for denying mutual recognition are incorporated in national law, so that they can be immediately implemented by the competent authorities. In this particular case, the specificity of mutual recognition in the non-harmonised field of goods is that it always has to be applied in conjunction with an existing national technical rule. In other words, mutual recognition only comes into play when a national technical rule would prevent the marketing of a product lawfully marketed in another Member State. The regulatory approach would mean, *inter alia*, that “mutual recognition clauses” would no longer have to be inserted in (draft) national rules to ensure compliance with Articles 28 and 30 EC Treaty. Instead, (draft) national rules would either have to transpose the directive or refer to the regulation.

On the one hand, if the objective is to ensure that mutual recognition is indeed applied when a national rule is to be applied, it would be necessary to incorporate mutual recognition in national law. This would make national authorities fully aware that the product does not only have to be assessed in the light of the national technical rule but also in the light of the national rule transposing the directive. A directive would, in this case, establish a level playing-field in the “regulatory competition” between the national rule and the mutual recognition principle. In addition, a directive would offer have the advantage that Member States would have to reflect, during the transposition process, on any necessary amendments of existing legislation and the setting up of “Product Contact Points”. On the other hand, a regulation would ensure a uniform application of the mutual recognition principle throughout the EU. It would also avoid difficult transposition questions and it would be certainly more efficient for enterprises and Member States.

Consequently, a regulation would seem the most appropriate legislative instrument for the regulatory option.

4.2.4. *Option 4: a combination of regulatory and non-regulatory actions*

A final option that should be examined is a combination of regulatory and non-regulatory action that could address the possible shortcomings of an exclusively regulatory or non-regulatory approach.

Option 4 is based on the regulatory approach (a regulation) set out under option 3, with one major difference: instead of including a list of products or aspects of products to which mutual recognition applies in the regulation, option 4 **creates, as a flanking non-regulatory measure, a website with a list of products to which mutual recognition applies**, as set out under option 2.

5. IMPACT ANALYSIS

5.1. Impact on enterprises

5.1.1. Microeconomic impact

The application of mutual recognition reduces the effect of non-tariff barriers on intra-EU trade of goods. Generally, the elimination of trade barriers **facilitates market entry by new enterprises and contributes to the introduction of new products into different national markets**. Consequently, competition would increase and a decline in profit margins can be expected, in particular for producers that fail to adapt.

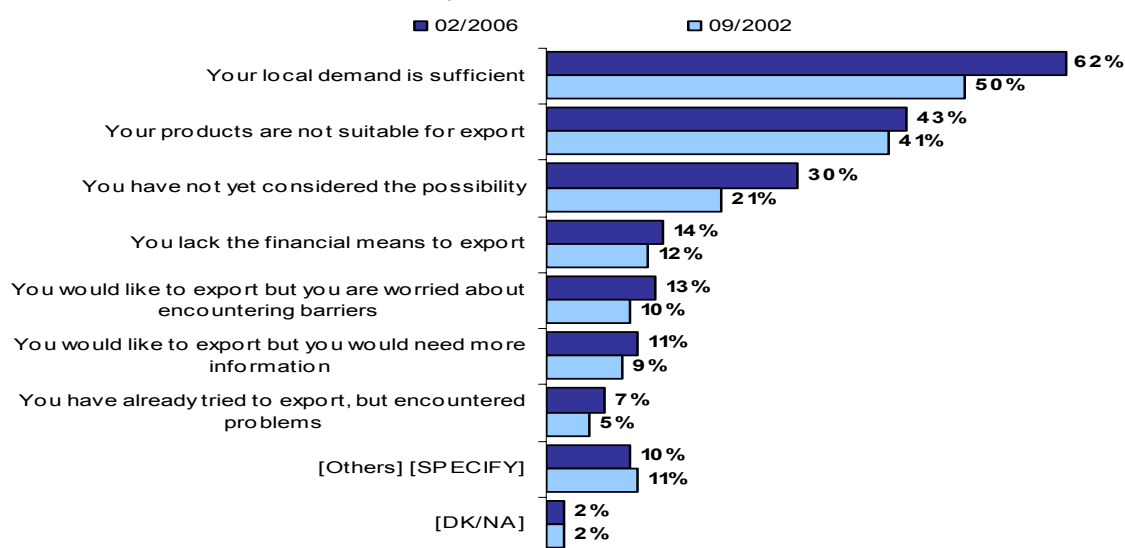
A quantitative measurement of the microeconomic effect of the removal of national non-tariff barriers for individual products is difficult. Firstly, the removal of barriers to trade has been a continuous process of EU integration. Therefore, even if existing economic data can be extrapolated to assess the economic impact of an improvement in mutual recognition, the specific changes, notably the increased mutual recognition in the non-harmonised field of goods cannot be clearly distinguished from many other contributing factors⁵⁶. Secondly, the assessment of the precise impact on businesses in specific markets of a reduction of trade barriers is difficult to predict. Increased competition and the subsequent decline in profit margins may cause firms to reduce production costs or implement strategies to increase their market power. Thirdly, measurement is made difficult by the fact that changes in market conditions - firms behaviour and industrial organisation – do not necessarily occur in sequence. Rather, they are continuous and dynamic⁵⁷. For example, 62% of companies participating in a recent Flash Eurobarometer⁵⁸ do not sell their products in another Member State since their local demand is perceived to be sufficient. 43% of companies not exporting to other Member States consider that their products are not suitable for export:

⁵⁶ See also Jacques-Bernard Sauner-Leroy, “The impact of the implementation of the Single Market Programme on productive efficiency and on mark-ups in the European Union manufacturing industry”, European Economy, No 192, September 2003.

⁵⁷ See : Adriaan Dierx, Fabienne Ilzkovitz and Khalid Sekkat (Ed.), European Integration and the Functioning of Product Markets, Edward Elgar Publishing Ltd, 2004.

⁵⁸ Flash Eurobarometer 180 (June 2006) - http://ec.europa.eu/internal_market/strategy/index_en.htm#hearing.

Q9 What are the main reasons why your company is not exporting to other countries within the Single Market? (SEVERAL ANSWERS POSSIBLE) % EU15 (BASE: 2257 respondents)



Regarding the expected microeconomic effects of the three observed policy options, the following statements can be made:

- **Policy Option 1** would normally generate little measurable impact on the introduction of new products into different national markets unless the relevant Member State decides to start implementing mutual recognition in a well-determined area of regulated products. The case-by-case approach for infringement proceedings and notifications pursuant to Directive 98/34/EC under this option would have a case-by-case impact, the dimensions of which would also be determined by other factors such as the size of the national market, the scope of the national technical rule, demand for the product, etc.
- **Policy Option 2** is expected to have a positive microeconomic impact in the product categories that have undergone sectoral screening only after its gradual implementation in all Member States. Therefore, it is unlikely that this option would have a noticeable short-term impact on the introduction of new products. Moreover, if Member States resist the non-regulatory approach and more infringement proceedings have to be started, measuring the microeconomic impact may require a substantial adjustment period. In addition, the fact that option 2 would only be gradually implemented may result in a failure to convince businesses that it is worthwhile to introduce a new product in a specific national market. The information gathering costs and possibly conformity assessment costs would remain under option 2, while compliance costs and loss of economies of scale would be reduced in the specific product markets of Member States that start implementing mutual recognition correctly. The sectoral approach implies that microeconomic impacts can only be estimated after the selection of the sectors that would be handled first. This makes it impossible to quantify the microeconomic impacts of option 2.
- **Policy Options 3 and 4** should both substantially facilitate the introduction of new products into different national markets. This in turn should have already a short-term microeconomic impact via the above-described effects of *allocative efficiency*, resulting in increased competition and a subsequent decline in profit

margins. This may cause enterprises to reduce production costs or implement strategies to increase their market power. In the medium-term, competition typically has a corrective effect on the behaviour of managers and workers, thus leading to greater *productive efficiency* in the organisation of work. In the longer term *dynamic efficiency* effects can be expected, thus stronger competition provides an increased incentive for producers to invest in product and process innovations and allows them to move to the technology frontier more rapidly. In practical terms, one way to reduce production costs is to concentrate production in sectors where the enterprise has a leading position in the market (“return to core business”). This implies a decline in sectoral diversification⁵⁹. Another possible reaction is to exploit economies of scale by expanding into new geographical markets. This would inevitably imply a strengthening of the multinational character of the firm. Such changes should be reflected in average cost reductions, that is, gains in productive efficiency, and thus should contribute to the restoration of profit margins. A further possibility is to increase product differentiation in order to distinguish the product from that of competitors or from its own product marketed in other Member States. However, product differentiation requires investment in R&D and advertising, so that the enterprise may be forced to focus on its core business and to abandon non-essential activities⁶⁰. Efficiency improvements arising from removing barriers to intra-EU trade of goods are secured by a positive and permanent increase in the level of total factor productivity. The reason for this is that previously protected enterprises may have produced with excess capacity, and increased competition forces enterprises to use available resources more efficiently⁶¹.

The efficiency improving and adjustment effects of policy options 3 and 4 would be hardly identifiable under options 1 and 2, since the increased competition would occur in specific national product markets in each Member State that decides to implement the mutual recognition principle in a specific product sector. In addition, the **compliance and redundancy costs, loss of economies of scale and conformity assessment costs** would be strongly reduced under options 3 and 4.

Information gathering costs would probably be slightly reduced under option 3 but would certainly continue to exist, due to uncertainty over the scope of mutual recognition. These costs would normally decrease sharply under option 4, given the fact that the information on national technical rules and on the application of mutual recognition would be readily available to enterprises, through the list of products.

⁵⁹ Laura Rondi, Leo Sleuwaegen and Davide Vannoni, “Changes in the industrial and geographical diversification of leading firms in European manufacturing”, in Adriaan Dierx, Fabienne Ilzkovitz and Khalid Sekkat (Ed.), *European Integration and the Functioning of Product Markets*, Edward Elgar Publishing Ltd, 2004.

⁶⁰ Adriaan Dierx, Fabienne Ilzkovitz and Khalid Sekkat, “Product market integration in the EU: an overview”, in Adriaan Dierx, Fabienne Ilzkovitz and Khalid Sekkat (Ed.), *European Integration and the Functioning of Product Markets*, Edward Elgar Publishing Ltd, 2004.

⁶¹ Giovanni Notaro, « European Integration and Productivity : Exploring the Gains of the Single Market », *London Economics*, May 2002.

5.1.2. *Administrative costs*

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 costs are likely to remain under **policy option 2**, the impact of which on enterprises would be hardly identifiable. This is mainly due to the fact that the effects of case-by-case actions would only be felt by new entrants in national markets where mutual recognition would start to be applied. The case studies, the surveys and the consultation show that **for enterprises, most of the problems outlined above would probably continue to exist under option 2.**

Policy options 3 and 4 would have an immediate effect on enterprises and would reduce their administrative charges. Besides the fact that enterprises would almost immediately become aware of their rights and obligations through a regulation, the risk for enterprises that their products will not get access to, or will have to be withdrawn from, the market of the Member State of destination would be very much reduced. The impact would obviously differ from company to company. There are a number of other factors that would determine whether a regulation would have an impact on a specific enterprise. Currently the firms that experience higher costs are those that are more innovative than their competitors (there are manufacturers with life cycles for their products of well under three years), have to manufacture a high number of variants or manufacture a small number of units only, especially SMEs. A case study reveals, for instance, that the delivery of a small number of specialised machines into another Member State can raise homologation costs up to 5% of turnover. 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. Therefore, **options 3 and 4 would reduce the administrative costs of SMEs wishing to sell their products in another Member State.** The case studies and existing surveys suggest that for larger enterprises entering a new national market and under the best circumstances, the impact could be estimated at 100% of the annual turnover of the same type of product on the national market of the Member State of destination. For SMEs, the case studies and existing surveys seem to indicate that up to 250% of the annual turnover of the same type of product on the national market of the Member State of destination could be saved. Nevertheless, such quantitative assessment can probably not be applied across the board.

5.2. **Impact on national authorities**

5.2.1. *Quantitative assessment of administrative costs*

For national authorities, **the precise amount of administrative costs depends on a number of different factors for some of which no data are available**, such as the size of the national market, the existence and the type of regulatory barriers, the availability of similar products on that market, the current implementation of mutual recognition, the level of market surveillance and many other elements.

Mutual recognition and market surveillance are already part of Community law, and should have been applied throughout the EU. Conformity assessment by national authorities and the dialogue with enterprises and/or authorities in other Member States should therefore not generate extra administrative costs for the Member States

that already apply mutual recognition and ensure that national rules are accessible to third parties. A global estimate of existing administrative costs⁶² for Member States is set out in annex 4.

However, not all Member States apply mutual recognition correctly throughout all non-harmonised product sectors. Consequently, new administrative costs will only be incurred by the national authorities that do not yet apply mutual recognition correctly and do not yet provide information on technical rules.

5.2.2. *Assessment of other administrative impact on national authorities*

Under **policy option 2**, the impact on national administrations would be **sectorally and geographically dispersed**:

- (1) Many national authorities would feel a **heavier legislative burden** if requested to amend individual technical rules to include more detailed “mutual recognition clauses” or to repeal unjustified or disproportionate technical rules. It is likely that, in the longer term, the impact would be more tangible for administrations of Member States with a larger national market: the national rules of these Member States would be likely to attract more complaints following awareness raising actions. These national rules would therefore be more likely to become the subject of infringement proceedings. Indeed, it would then be more interesting for businesses to gain access to a bigger national market and to make the effort to file a complaint, since the economic return on the investment of drafting a complaint would be higher if the product had free access to a large national market. Conversely, the impact on national authorities which amended their national technical rules for strictly internal considerations or reasons other than making them comply with Articles 28 and 30 EC Treaty, would probably be negligible. Inserting a detailed “mutual recognition clause” or abolishing unjustified or disproportionate national technical rules would in such case not require any additional effort.
- (2) **The implementation of the mutual recognition principle in daily practice** would only have an impact on national authorities not yet applying mutual recognition. The impact would probably not be perceptible for all other national authorities.
- (3) It is not excluded that, when national authorities start applying mutual recognition, the **current lack of organised administrative cooperation** in the non-harmonised field of goods would constitute an **additional burden for the authorities** responsible. The absence of such organised cooperation

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Administrative costs are, in this case, the costs incurred by public authorities in meeting legal obligations to provide information on their action or production, either to public authorities or to private parties. They are calculated in conformity with Annex 10 of the Impact Assessment Guidelines (http://ec.europa.eu/governance/impact/docs_en.htm) on the basis of the average cost of the required action (Price) multiplied by the total number of actions performed per year (Quantity). The estimate is made on the basis of policy options 3 and 4, whereby the frequency of required actions and the relevant costs parameters are extrapolated from data on the number of questions addressed to the EICs, data on the number of cases submitted to SOLVIT and averages for dealing with complaints, infringement cases, notifications under Directive 98/34/EC and notifications under Decision 3052/95/EC.

would probably force them to seek more information about the product and its lawful marketing in another Member State otherwise than by administrative cooperation. Administrative cooperation could also be helpful to evaluate the proportionality of the technical rules of the Member State of destination. It is possible that an assessment of one's own rules in the light of technical and scientific information gathered from other Member States could shed a different light on the proportionality of the application of these rules to a specific product.

- (4) Conversely, national authorities that applied mutual recognition would no longer suffer from uncertainty about when mutual recognition should be applied. The increasing implementation of the mutual recognition principle by national authorities would result in **administrative efficiency gains**.

Options 3 and 4 would have an immediate and general impact throughout the EU:

- The main difference with option 2 is that **one harmonised method of applying mutual recognition would apply throughout the EU**, so that a level playing field would be created for all national authorities and businesses.
- The **implementation of the mutual recognition principle in daily practice** would have a very tangible impact on the workload of national authorities that do not yet apply mutual recognition. The situation would normally be the same as under option 2.
- **Setting up "Product Contact Points"** would be obligatory in all Member States and would certainly result in initial costs to Member States that do not yet provide for easily available administrative information on national technical rules and on the implementation of mutual recognition. The "Product Contact Points" would only result in additional operational costs for Member States that decide to establish new structures, instead of using existing structures like SOLVIT-centres, Euro Info Centres etc.
- National authorities would probably benefit from the **organised administrative cooperation** between them in the non-harmonised field of goods. It would allow them to seek more information on the product and its lawful marketing in another Member State. Moreover, easily available information about the technical and scientific information on the basis of which other Member States have drafted their technical rules would facilitate the evaluation of the proportionality of the technical rules of the Member State of destination⁶³. However, Member States that do not yet provide for easily available administrative information to enterprises and citizens would incur certain costs.

⁶³

If the Internal Market Information System (IMI) was used, the unit cost of administrative cooperation between Member States would be reduced. IMI should therefore lead to net benefits rather than net costs. There should be no hardware or software costs to Member States. IMI would however require some investment costs related to organisation which would depend on how Member States choose to implement it. Member States who choose a centralised approach in which information flows through central contact point(s) would minimise the effort needed to collect data on competent authorities. But the contact point(s) would need to be involved more often in the exchange of information. Member States who choose a decentralised approach would need to collect more data on competent authorities but the contact point(s) would be involved less often in the exchange of information.

- Uncertainty about the burden of proof would cease and would result in **administrative efficiency gains**.
- **The number of infringement proceedings pursuant to Article 226 EC treaty should decrease dramatically.** The regulation would serve as a basis for handling individual cases through appeals in national courts.
- Finally, the **website with a list of products to which mutual recognition applies, as set out under option 4**, would probably be more helpful to, and efficient for, national authorities than a full and exhaustive list of products in the text of the regulation which would have to be applied by them.

5.3. Macroeconomic impact

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 design of market institutions is multifaceted and often of a highly qualitative nature, which is not easily described by aggregated quantitative indicators. Moreover, significant gaps in data that are comparable across countries and over time pose serious problems to econometric analysis, as well as the fact that an unfavourable macroeconomic environment may have a restraining impact on the potential positive effects of the elimination of technical barriers within the EU

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 recognition⁶⁴. 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 study⁶⁵ 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 integrated⁶⁶, 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 trade⁶⁷ (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).

⁶⁴ Of course, differences between trade in a perfect internal market and today's real internal market are not just down to failures of mutual recognition. There are a host of factors other than lack of mutual recognition that cross-border trade has to overcome (e.g., language and geography).

⁶⁵ The single market review, Subseries III, volume 1: Technical barriers to trade, November 1996.

⁶⁶ A hypothetical situation in which the proportion of products consumed in a Member State that were domestically produced equals that Member State's share of EU GDP; the rest of consumption consists of imports from EU partners. This reasoning is based on a methodology proposed by J. Frankel in Globalisation of the economy for the NBER (August 2000)

⁶⁷ European Commission, Cardiff Report, January 2000

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%⁶⁸. In any event, it is estimated that the failure to properly apply the principle of mutual recognition reduced trade in goods within the Internal Market by up to 10% or €150 billion in 2000⁶⁹.

A number of econometric studies have attempted to link increases in trade to increases in GDP. However, the results of such studies have varied widely. In two of the most respected of such studies, Frankel and Romer⁷⁰ suggest that a percentage point increase in the trade to GDP ratio raises real income per capita by around 1 per cent over a 20 to 25 year period, while more pessimistically, Frankel and Rose⁷¹ argue that the same increase in trade would result in a 1/3 percentage point increase in per capital income.

In order to estimate the possible increase in GDP from an improvement in the system of mutual recognition, it would be necessary to know both a) the percentage of EU trade as a percentage of GDP covered by mutual recognition and b) the percentage by which we would expect that trade to increase as result of improvements in mutual recognition.

As to the mutual recognition trade/GDP ratio, Eurostat data suggest that the present ratio of OVERALL intra-euro area trade over GDP is 19%. It is estimated that about 28% of intra-EU manufacturing trade⁷² is covered by mutual recognition. Thus intra-EU trade covered by mutual recognition is approximately 5.4% of GDP⁷³

For illustrative purposes, in order to estimate the effect of improvements in mutual recognition, one can use four different scenarios also applied by the two previously cited papers. According to those calculations, improvements in mutual recognition led to increases in trade in the sector covered by mutual recognition of 10%, 20%, 50% and 100%.

<i>Percentage increases in EU GDP under different scenarios as a result of improvements in mutual recognition</i>				
Trade increase to GDP increase	Percentage increase in mutual recognition trade			
	10%	20%	50%	100%
Frankel&Romer (1996) - 1	0.54	1.08	2.71	5.4
Frankel&Rose (2000) - 0.33	0.18	0.36	0.9	1.8

⁶⁸ SEC(2001)1993.

⁶⁹ SEC(2001) http://europa.eu.int/comm/internal_market/en/update/economicreform/cardiff02ensta.pdf, p. 24

⁷⁰ Jeffrey A. Frankel & David Romer, 1996. "Trade and Growth: An Empirical Investigation," NBER Working Papers 5476, National Bureau of Economic Research, Inc.

⁷¹ Jeffrey A. Frankel & Andrew K. Rose, 2000. "Estimating the Effect of Currency Unions on Trade and Output," NBER Working Papers 7857, National Bureau of Economic Research, Inc

⁷² op cit

⁷³ This assumes that services trade exhibits a similar behaviour in relation to mutual recognition as manufacturing trade.

Thus even under the most pessimistic scenario of a 10% improvement in trade covered by mutual recognition and the weaker link between increased trade and GDP, there is potential for an increase in GDP of 0.18% over a 20 to 25 year period.

5.4. Impact on prices

The integration of different national product markets, through mutual recognition or harmonisation measures, is likely to induce allocative efficiency gains stemming from the reduction of monopoly returns. Indeed, an increase in competition induced by trade liberalisation would result in both an increase in the number of competitors in the market and, everything else being equal, in a reduction of the market power of firms and, consequently, in a reduction of prices and mark-up levels. This may happen even in the absence of entry or even in the case of only a few entries into the market, just because entry is possible⁷⁴.

Potential price differences for **consumer products** across areas and Member States may invite consumers to take advantage of the arbitrage possibilities to buy in lower priced areas. Certainly, for a single customer it is in general not reasonable to cover long distances or even cross borders to buy standard products for daily use for a lower price than in their hometown – except for local border traffic. But retailers or traders may observe the price difference and realize potential profits. Consumers would then benefit from decreased price dispersion due to these arbitrage-effects.

It is not expected that any of the options would have an impact on prices of **products for industrial consumption**, which either fall within the scope of harmonised Community law or for which there are no technical barriers. Enterprises already profit directly from price differences for products for industrial consumption across Member States and search for the best cost/benefit deal across the European market.

5.5. Impact on the EU budget

Option 2 would without any doubt be the most expensive option. It is the most labour-intensive option and requires action at different levels. Besides the costs of creating and updating the site, option 2 entails many tasks that normally would have to be outsourced or would need subcontracting. The costs related to option 2 can be reasonably estimated at around €2,000,000 per year during the first five years. Moreover, the extension of the TRIS-database would probably require in its starting phase at least €13,000,000 and an additional annual cost of at least €5,000,000 (see point 6.2).

The impact of option 3 on the EU budget would be fairly limited. A contribution to the training costs of staff employed in Product Contact Points and meeting costs would have to be made. These costs depend on the number of Product Contact Points that Member States appoint. An uncertain factor would be the form that administrative cooperation might take, and the costs associated with it. This should be discussed within the committee of representatives of Member States that would be established by the regulation.

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Giovanni Notaro, « European Integration and Productivity : Exploring the Gains of the Single Market », London Economics, May 2002.

The cost of option 4 would be higher, as a consequence of the creation and the maintenance of the web site listing the products to which mutual recognition applies. The costs of establishing a list of products and creating the site could be estimated at 400,000 EUR. The cost of updating the list and the site is estimated at 30,000 EUR annually.

5.6. Other impact

5.6.1. Social impact

Productive efficiency gains, dynamic efficiency gains and allocative efficiency gains normally result in price adjustments. If, however, prices adjust only sluggishly, enterprises may face temporary demand weakness, and in that case the short-run employment effect of an increase in productivity is likely to be negative. An efficiency improvement, however, would increase capital intensity in the long run.

Therefore, similar to the case of increased competition, it would depend on other social factors whether and by how much employment is going to expand. In addition, more competition on the product market is generally expected to have a positive impact on labour market performance, essentially by shifting the labour demand curve resulting in higher employment over the medium term.

Consequently, there are no indications that any of the options would have a direct social impact.

5.6.2. Impact on transport

More cross-border movement of goods would have an impact on the transport sector. **Under normal conditions, freight transport activity is projected to increase by 2.1% p.a.** during the period 2000-2030. Certain sources argue, however, that in comparison to past trends the growth of freight transport activity is expected to exhibit a significant slowdown. Although goods transportation is closely associated with overall economic activity and, historically, has grown at least as fast as GDP, the structural shift of the EU economy towards services and high value added manufacturing activities would give rise to some decoupling between GDP and freight transport growth since these sectors would be less freight intensive than the more traditional basic manufacturing and extraction activities⁷⁵.

Moreover, **energy intensity gains in freight transport** are estimated at 0.25% p.a. as energy consumption increases by 1.9% p.a. in 2000-2030. Although technological progress is of key importance in influencing the projected growth of energy consumption in the transport sector, efficiency improvements in freight transport (7.5% in 2000-2030) are expected to be less pronounced than in passenger transport, mainly because of the shift towards road freight that is a much more energy intensive activity compared to rail freight. Thus, this shift to less energy efficient modes largely offsets the significant intensity gains at the level of the different transport modes.

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European Commission, European Energy and Transport Trends to 2030, January 2003.

The assumption is therefore that **none of the options would have a specific impact on the growth of freight transport activity.**

5.6.3. *Environmental impact*

More cross-border movement of goods and more **freight transport activity**, in particular by road, would be likely to have an environmental impact. However, efficiency gains for trucks would reach +16% in 2000-2030 driven by better management and technological progress. The vehicle fleet is gradually becoming cleaner due to improvements in the technology required to meet European emission standards. Improvements would be occurring significantly faster than the growth in traffic volumes, with absolute reductions in emissions of harmful substances to the air. Reductions in emissions of particulates (PM10), acidifying substances (NOX, NMVOCs) and ozone precursors (SOX, NOX, NH3) come mostly from innovations in exhaust gas treatment in road vehicles and improved fuel quality. EC standards for automotive emissions and fuel quality (reduced sulphur concentration) will continue to have great effect⁷⁶. Consequently, if and when it is correct to state that there would be a decoupling between GDP and freight transport growth, there would probably not be any specific negative environmental impact of increasing freight transport due to growing technological progress. But this thesis is not generally accepted.

Besides the environmental impact of growing freight transport, it is uncertain whether the elimination of technical obstacles could have an impact on **waste flow** when the consumption of products increases as a consequence of the better functioning of the mutual recognition principle. Due to the law of conservation of matter, all material inputs from the environment during the production process would become material output flows to the environment sooner or later, i.e. the inputs determine the outputs at least in quantitative terms. On the basis of Material Flow Accounting (MFA) techniques, it is estimated that the EU economy directly takes in about 17 tonnes of raw materials per capita for further processing in the production system (DMI)⁷⁷. Domestic material consumption (DMC) consists of the total amount of material directly used in the consumption activities of an economy, i.e. domestic used extraction plus imports minus exports. Within DMC, construction and demolition waste is the largest waste stream. On the aggregate EU level, DMC has developed more or less in parallel to DMI and stayed fairly constant at around 15.5 tonnes per capita in the second half of the 1990s⁷⁸. It is therefore not expected that

⁷⁶ European Environment Agency, Ten key transport and environment issues for policy-makers, EEA Report No 3/2004.

⁷⁷ The directly used material input comprises about 13.5 t/cap of domestically extracted material and about 3.5 t/cap of imports. During use in the economic system, fossil fuels in particular are transformed and immediately released into the environment in terms of air emissions. After use, products become waste and may be recycled or finally disposed of in landfills or incineration plants. These outputs from processing to land, air and water amount to about 12 t/cap in the EU. Of those, air emissions constitute the bulk with some 10-11 t/cap, of which more than 95% is CO₂. About 1 t/cap of the processed output is actually waste landfilled and some minor 300 kg/cap are dissipative uses of products (e.g. fertilisers) and dissipative losses from product use (e.g. from tyres). About 40% of DMI is determined by construction minerals. Biomass and fossil fuel amount to one fourth each. With some 9%, industrial minerals and metal ores play a minor role within DMI.

⁷⁸ Stephan Moll, Stefan Bringezu and Helmut Schütz, Resource Use in European Countries, An estimate of materials and waste streams in the Community, including imports and exports using the instrument of material flow analysis, March 2003, European Topic Centre on Resource and Waste Management.

measures to improve mutual recognition would have a direct and immediate impact on the waste flow.

The generation of **packaging waste** is closely coupled to economic growth and consumption patterns. From 1997 to 2001 the amount of packaging waste increased by 7 % in the then European Union as a whole. Current preliminary projections suggest that volumes of packaging waste are likely to continue rising substantially in the future. Some of this increase is attributable to the proportionately higher generation of packaging waste from small households, but also to the growth of the internal market and the consequently greater need to transport packaged goods. With rising emphasis on health and food safety, the amount of food packaging has also been increasing. In 2001, the packaging waste arising per capita amounted to 172 kg⁷⁹. It is therefore expected that this figure may slightly increase when mutual recognition functions better.

5.6.4. *Impact on energy*

As regards **energy demand in industry in general**, structural changes in industrial sectors led to a decline in energy demand by 6% between 1990 and 2000. In the same period, industrial value added increased by 14% with implied intensity gains reaching 1.9% p.a. In the period 2000-2030, energy demand in European industry is projected to grow by 24.3% driven by higher economic growth, regardless which option is chosen to improve mutual recognition.

However, **energy intensity gains** remain significant over the same period (+1.6% p.a.) driven by structural changes towards less energy intensive manufacturing processes but also by the exploitation of energy saving options. Energy demand in the tertiary sector (including distribution and retailing) grew much slower than economic growth in 1990-2000 and is projected to grow at a rather uniform pace of +1.2% p.a. in the period from 2000 to 2030. The improvement of energy intensity in the sector is projected to reach 1.3% p.a. during the same period.

It is therefore unlikely that any of the options could have a specific impact on energy demand in industry and the tertiary sector in the E.U.

6. COMPARING THE OPTIONS

6.1. Is there a need for change?

The current policy which basically consists of examining the compliance of each national technical rule with Articles 28 and 30 EC and the corresponding voluntary self-removal of barriers by Member States, infringements and notifications, has been **quite successful**. It succeeded in eliminating an overwhelming amount of technical barriers without harmonisation measures at EC level when the internal market was completed.

⁷⁹ Pira International and Ecolas, Study on the implementation of the Packaging Directive and options to strengthen prevention and re-use, February 2005.

Stakeholders, however, have indicated that **current policy has reached its limits** or that it has come to a standstill. Consequently, the functioning of the mutual recognition principle has long been on the political agenda. The Internal Market Council of March 1998 stressed the need for political attention to be directed towards the effective application of mutual recognition. It also underscored the direct responsibility of the Member States in this matter. The Council supported the Commission by adopting a Council Resolution on mutual recognition on 28 October 1999⁸⁰.

According to the “**Kok report**”⁸¹, the free movement of goods within the EU continues to be hindered by a range of local rules, often applied arbitrarily and in clear contradiction to the mutual recognition principle. The report suggests that such obstacles must no longer be tolerated and that the Commission should treat the removal of these obstacles as a top political priority.

Business federations made a similar demand⁸². 61.4% of respondents in the I.P.M. consultation believe that Community rules are necessary, while the general outcome of the consultation of the European Business Test Panel was that the operation of mutual recognition should be overhauled and that reform would bring tangible benefits for enterprises.

Furthermore, 64% of business leaders participating in a recent Flash Eurobarometer⁸³ are convinced of the importance of **removing remaining technical barriers to trade in goods**.

The results⁸⁴ of the **public consultation on the future of the Internal Market** launched by the Commission in April 2006 confirm that national technical rules still constitute important barriers to free trade within the EU. Respondents complain about the weak application of the rules and their enforcement, in particular in the non-harmonised product sectors. They argue that national technical rules still lead to substantial obstacles to the free movement of goods within the EU, and that this causes extra administrative controls and tests. They also consider that the current system of market surveillance needs considerable improvement.

6.2. Comparison of the options with respect to the problems outlined under section 2

It is certain that **the problems outlined under chapter 2 would continue to exist under option 1**. Moreover, the main weakness of option 1 is its **fragmentation** and its **slow pace**. Only problems reported to the Commission are examined and solved, at a rhythm determined by notification or infringement proceedings, as set out in more detail under the sections “current actions” (sections 2.2.3, 2.3.3, 2.4.3 and 2.5.3). Option 1 is therefore unlikely to solve the problems in the foreseeable future.

⁸⁰ 12122/99

⁸¹ « Facing the challenge – The Lisbon Strategy for growth and employment”, Report from the High Level Group Chaired by Wim Kok, November 2004.

⁸² “It’s the Internal Market, stupid! A company survey on trade barriers in the European Union”, UNICE Internal Market Working Group, May 2004.

⁸³ Flash Eurobarometer 180 (June 2006) - http://ec.europa.eu/internal_market/strategy/index_en.htm#hearing.

⁸⁴ SEC(2006)1215 of 20.09.2006.

Consequently, only options 2, 3 and 4 should be further examined on the basis of all elements set out above.

PROBLEM 1: LACK OF AWARENESS		
OPTION	EFFECTS OF THE OPTION	CONCLUSION
<i>Option 2 (non-regulatory approach)</i>	Option 2 would be fairly slow, labour-intensive and fairly expensive in creating awareness. The organisation of conferences and seminars and the publication would also require close cooperation with local industrial federations and competent authorities in the Member States. Moreover, this option has almost no visible economic impact. It would to some extent increase the legislative and administrative burden on national authorities.	+/-
<i>Option 3 (regulatory approach)</i>	A regulation would normally eliminate the lack of awareness within national administrations. It should be noted that 61.4% of respondents of the I.P.M consultation believe that a regulation is necessary.	++
<i>Option 4 (mix of regulatory and non-regulatory approaches)</i>	Idem as option 3	++

PROBLEM 2: LEGAL UNCERTAINTY ABOUT THE SCOPE OF THE PRINCIPLE AND THE BURDEN OF PROOF		
OPTION	EFFECTS OF THE OPTION	CONCLUSION
<i>Option 2 (non-regulatory approach)</i>	This option operates on a case-by-case analysis of national technical rules and the insertion of a comprehensible mutual recognition clause in all of them, as well as the screening of national technical rules and their inclusion into the TRIS database. The risk of this option is that TRIS would still not be an exhaustive source of national rules. TRIS only contains the draft technical rules notified since the establishment of the database (July 1995). TRIS does not yet contain the final versions of most technical regulations that were notified under Directive 98/34/EC, nor does it contain the draft technical regulations notified before July 1995 or	+/-

	<p>their final versions. Correspondingly, older (draft) technical rules (adopted before 1984) are also not in TRIS. Using TRIS as a database of all national technical rules would require enormous efforts by MS to send all applicable technical rules in their territory to the Commission, and for the Commission to include them into the database. An additional budgetary line for financing and updating the database and for translating all national technical rules would be indispensable. The problem of legal uncertainty can therefore only be solved in the long term since removing the legal uncertainty would require much time and efforts.</p>	
<p><i>Option 3 (regulatory approach)</i></p>	<p>This option would immediately solve the problem of the burden of proof. As regards the uncertainty about the scope of mutual recognition, it is not expected that this option would alone solve the problem without accompanying non-legislative measures: although the regulation would immediately offer sufficient information as regards the products mutual recognition actually applies to, it would be very difficult in practice to include a full list of such products into the regulation. Even if the inclusion of such list were practically possible, new and innovative products put on the market after the adoption of the regulation would have to be included in the scope of the instrument, through amendment. The inclusion of a list of products in the regulation may therefore work as an impediment to innovation. In addition, all new secondary legislation harmonising technical rules on products would require an amendment of the regulation. This would have negative effects on legal certainty for national authorities.</p>	<p>+</p>
<p><i>Option 4 (mix of regulatory and non-regulatory approach)</i></p>	<p>Option 4 would immediately solve the problem of the burden of proof. As regards uncertainty about the scope of mutual recognition, the creation of a website with a list of products to which mutual recognition applies could clarify this.</p>	<p>++</p>

PROBLEM 3: THE RISK FOR ENTERPRISES IN THE RECEIVING MEMBER STATE		
OPTION	EFFECTS OF THE OPTION	CONCLUSION
<i>Option 2 (non-regulatory approach)</i>	Given the fact that this option operates on a case-by-case analysis of (draft) national technical rules and the insertion of a comprehensible mutual recognition clause in all of them, the risk for enterprises that their products will not get access to, or will have to be withdrawn from, the market of the Member State of destination could therefore only be reduced in the long term.	+/-
<i>Option 3 (regulatory approach)</i>	Although this option cannot offer the certainty that harmonisation of technical rules could offer, it should normally reduce the risk for enterprises that their products will not get access to, or will have to be withdrawn from, the market of the Member State of destination to a fairly low level through organisation of the burden of proof and the establishment of "Product Contact Points".	+
<i>Option 4 (mix of regulatory and non-regulatory approach)</i>	Idem as option 3	+

PROBLEM 4: THE ABSENCE OF DIALOGUES BETWEEN COMPETENT AUTHORITIES		
OPTION	EFFECTS OF THE OPTION	CONCLUSION
<i>Option 2 (non-regulatory approach)</i>	The organisation of dialogue between national authorities of different Member States through the existing committees could look into the application of mutual recognition for products which, although they fall outside the scope of their directive or regulation, are similar. However, there is a fair amount of products for which there is no EC harmonisation and for which no committee would be competent.	+/-
<i>Option 3 (regulatory approach)</i>	The establishment of "Product Contact Points" would create the basis for a dialogue between competent authorities.	+

<i>Option 4 (mix of regulatory and non-regulatory approach)</i>	Idem as option 3	+
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6.3. Outcome of the comparison

A comparison of the options from the point of view of their effectiveness and likely impact shows the following results:

OUTCOME OF THE COMPARISON			
	OPTION 2	OPTION 3	OPTION 4
<i>Problem 1: lack of awareness</i>	+/-	++	++
<i>Problem 2: legal uncertainty about the scope of the principle and the burden of proof</i>	+/-	+	++
<i>Problem 3: the regulatory risk in the receiving Member State</i>	+/-	+	+
<i>Problem 4: the absence of dialogues between competent authorities</i>	+/-	+	+
<i>Impacts on enterprises (section 5.1)</i>	+/- (short term) + (medium term)	++	++
<i>Impacts on national authorities (section 5.2)</i>	+/- (short term) + (medium term)	+	++
<i>Impacts on prices (section 5.3)</i>	+/-	+/-	+/-
<i>Impacts on the EU budget (section 5.4)</i>	- (most expensive option)	+	+/- (second cheapest option)

The outcome of the comparison indicates that **Option 2** is unlikely to solve any of the problems, at least in the short or the medium term. **Option 3**, i.e. the exclusively legislative approach, would not be able to solve the problem of the definition of the range of products to which mutual recognition applies. The **creation of a website with a list of such products, as mentioned under Option 4**, would probably be a necessary additional measure for businesses and national administrations.

Under these circumstances, **option 4 would probably be the most appropriate solution.**

7. MONITORING AND EVALUATION

Monitoring and evaluation have traditionally been a major problem for mutual recognition: complaints to the Commission and SOLVIT cases only reveal the most problematic cases raised by enterprises that have taken the time and done the effort to bring their case to the Commission and SOLVIT.

The other existing instrument, namely **Decision No 3052/95/EC** of the European Parliament and of the Council of 13 December 1995 establishing a procedure for the exchange of information on national measures derogating from the principle of the free movement of goods within the Community, does not function (see point 2.1). Implementation of the Decision has not enabled the Commission to be better informed about the functioning of Articles 28 and 30 of the Treaty, nor to identify sectors where they might be functioning poorly and where harmonisation might be appropriate. In addition, the Decision did not provide the intended rapid resolution of certain free movement problems. Therefore, if option 4 would be selected, the Decision should be repealed and replaced by a more effective monitoring and evaluation scheme, in accordance with the principle of simplification of EC law.

Consequently, **the monitoring and evaluation system must avoid the shortcomings of Decision No 3052/95/EC.** The proposal would therefore specify that Member States send to the Commission, upon request, a report containing detailed information about the implementation of the Regulation, including detailed information about the written notices and decisions by competent authorities to economic operators.

Besides these instruments, the more traditional instruments of complaints and infringements proceedings under Articles 226 EC and the SOLVIT mechanism would remain monitoring and evaluation tools.

Annex 1:

Results of the public consultation on future options in the field of mutual recognition of goods

1. OBJECTIVE OF THE CONSULTATION

This wide consultation of interested parties on options to improve mutual recognition in the non-harmonised area of goods was open from 17 February 2004 until 30 April 2004 via the Commission's "Your Voice in Europe" Internet site: <http://europa.eu.int/yourvoice/consultations>. For this internet consultation the Interactive Policy Making (IPM) consultation tool was used.

The objective of the consultation was to canvass the opinion of Member States, businesses and consumer organisations on possible options for improving the functioning of mutual recognition in the field of products. The target audience was informed of the existence of the consultation through a press release, announcements on different EU web sites, a specific e-mail to the mailing list of persons interested in the subject, a specific e-mail to the presidents of the package meetings of the current Member States, a specific e-mail to our correspondents in the new Member States, letters to approximately 280 European federations and associations selected from the SG database and letters to IMAC Members. In addition, the SME Envoy was asked to encourage SME's to participate in this consultation, while the SOLVIT Centres, the 98/34/EC-committee and the Euro Info Centres were also informed. The consultation was mentioned in the latest issue of the Single Market News. 135 replies were received which seems to be the average number of replies for a consultation on a technical issue.

<i>Respondents</i>	
Representative organisations	22.7%
Enterprises	19.7%
Public bodies	13.6%
Consumers	31.1%

2. STRUCTURE OF THE CONSULTATION

An internet consultation requires a limited number of questions around specific themes. It has been shown that an extensive number of questions has a strong discouraging effect and that most people then abandon the questionnaire before completing it. Therefore, the questionnaire was built on a list of specific problems for which different solutions were proposed.

The underlying philosophy is that there are three options that could be taken into account for the improvement of the functioning of mutual recognition in the field of products:

- **Option 1:** Continue current policy unchanged;
- **Option 2:** Improve current policy without new Community legislation;
- **Option 3:** A new Community Regulation

3. OPTION 1: CONTINUE CURRENT POLICY UNCHANGED

The **lack of awareness** is still a problem. A large number of enterprises do not know exactly to what extent goods which are not harmonised at Community level may have access to the market of another Member State, without being adapted to the rules of the Member State of destination⁸⁵. One cannot expect that all enterprises have sufficient expertise in, or access to, European law. Many enterprises prefer to know the technical regulations and to make an evaluation thereof before marketing their products in the recipient Member State. Very often they take the technical rules of the Member State of destination for granted, without considering that Community law provides for mutual recognition.

<i>Do you prefer to know the technical rules of the Member State of destination and to assess them before marketing your products in the recipient Member State?</i>	
Yes	95%
No	3%

Most enterprises wish to avoid any event having a negative impact on the reputation of their product, such as the possible subsequent suspension of marketing, by the authorities of the Member State of destination.

In this case, the economic operator may wish to **contact the competent administration** for the application of mutual recognition on his product. But one of the challenges for enterprises will certainly be identifying the relevant service⁸⁶. Unfortunately, enterprises do not find it easy to locate an official source for more precise information. They may turn to other, costly channels to obtain the necessary legal or administrative information.

<i>Should national authorities be obliged to indicate in their technical rules which service is responsible for their application?</i>	
Yes, through an EC Regulation	65%
Yes but not through an EC Regulation	25%
No	6%

The Court of Justice has repeated several times that Articles 28 to 30 of the EC Treaty take precedence over any national technical regulation. Nevertheless, very few enterprises realise this. The simple presence of a national technical regulation can thus discourage enterprises from marketing their products on the territory of the recipient Member State, even if their products provide an appropriate recognised protection level in some other Member States.

Moreover, the qualified administration of the recipient Member State often hesitates to apply Articles 28 to 30 of the EC Treaty when it does not have specific legal basis in its national technical regulation to evaluate the conformance of an EEA/Turkey product. Therefore, Member States are encouraged to insert **“mutual recognition” clauses**⁸⁷ in their national legislation.

⁸⁵ Communication COM(1999)299final to the Council and the European Parliament of 16 June 1999 on mutual recognition in the context of the follow-up to the action plan for the Single Market. First biennial report on the application of the principle of mutual recognition [SEC(1999)1106 of 13 July 1999] and second biennial report COM(2002)419final of 23 July 2002. These documents may be consulted on http://europa.eu.int/comm/internal_market/en/goods/mutrec.htm.

⁸⁶ See, for example, item 5.1 of the biennial report.

⁸⁷ The Commission watches over the integration of such a clause not only within its management of infractions but also in all the new technical regulations, thanks to the notification procedure provided for by Directive 98/34/CE. For a more specific outline, see the COM (2003)200 report of 23 May 2003 relating to the operation of Directive 98/34/EC from 1999 to 2001.

<i>Should the Commission continue to require the insertion of a mutual recognition clause on a case-by-case basis?</i>	
Yes	32.6%
No: a Community Regulation would be better	61.4%

Administrative cooperation between the various competent authorities of the Member States in the non-harmonised field of goods is still far from perfect. It is sometimes difficult to identify the competent administration in the other Member State and/or to find the information concerning the applicable legislation. If the other Member State does not have legislation concerning the product in question, it is not very probable that a contact point can be found. Moreover, certain administrations could suffer, in some cases, from linguistic barriers.

<i>Should administrative cooperation be improved?</i>	
Yes	91.7%
No	6.1%

4. **OPTION 2: IMPROVE CURRENT POLICY WITHOUT NEW COMMUNITY LEGISLATION**

In practice, the only possible method of making national rules and competent authorities more accessible is to encourage Member States to make them more accessible. There seems to be no legal basis in Community law that obliges Member States to take action on this issue.

<i>Should the accessibility of national rules be improved?</i>	
Yes, through a so-called "one-stop shop"	70.5%
Yes, through other means	18.2%
No	6.1%

Even if the legislation of the receiving Member State contains a mutual recognition clause for goods which guarantee for example an equivalent safety level, it is sometimes difficult for the economic operator to know if the technical solution that it chose does indeed offer equivalent protection.

<i>Should national rules expressly set out which legitimate public interest they seek to protect?</i>	
Yes	70.5%
No	2.3%

<i>How can market entry be made more transparent?</i>	
By giving more publicity to the references of technical regulations and standards of other Member States which have already been accepted	55.3%
Member States should publish the references of types of product which are considered to be lawfully marketed as a result of mutual recognition	46.2%

Several Member States provide in their tax legislation for the possibility of a "ruling". This is a legal instrument by which the competent tax authority determines how the law will apply to a situation or to an individual operation which has not yet produced effects for tax purposes. The "ruling" is a commitment of the competent authority to treat the situation or the individual operation in accordance with the "ruling" and gives the applicant tax certainty for a certain period. A similar system could be envisaged in the field of the free movement of goods. In order to eliminate any uncertainty, a system of voluntary conformity assessment could be set up in each Member State. In order to comply with Community law, any such system should be entirely voluntary and based on objective and verifiable criteria. The

procedure should be short, effective and not very expensive. It should also avoid controls which, in substance, duplicate controls which have already been carried out within the framework of different procedures, either in the same, or in another Member State.

<i>Should such “ruling” be introduced to facilitate the entry to the national market?</i>	
Yes: such a system would reduce the uncertainty	44.7%
No: this system would be cumbersome and that it risks becoming de facto compulsory	39.4%

One of the frequently occurring problems is the repetition of tests already carried out in another Member State, or the refusal to recognize certificates granted by bodies established in another Member State.

<i>How can the acceptance of tests and certificates be improved?</i>	
Through the publication of the references of bodies approved and accredited in the Member States would help the acceptance of tests carried out by inspection bodies in another Member State	62.1%
Community legislation should set out the criteria which the inspection bodies are required to meet	48.5%
National legislation should establish these criteria, based on considerations of technical competence, independence and impartiality.	33.3%

5. OPTION 3: NEW REGULATION LAYING DOWN KEY PRINCIPLES

The third option consists of a new Community Regulation establishing key principles. The objective of the Regulation would be to increase the effectiveness of the mutual recognition principle, so that the negative impacts of the poor functioning of the principle would be reduced. The Regulation would define the rights and obligations of enterprises wishing to trade their products in another Member State. The Regulation would be built on the key principles accepted by the Court of Justice, i.e. basically those set out in chapters 4 and 5 of the interpretative communication C(2003)3944, published in the O.J. C265 of 4 November 2003.

In a nutshell, these principles oblige Member States to explain clearly for which technical or scientific reason they intend to refuse or to restrict the marketing of a product legally manufactured and/or marketed in another Member State. The recipient Member State should prove to the economic operator concerned, on the basis of all the relevant scientific elements available to that State, that there are overriding grounds of general interest for imposing these elements of the technical rule on the product concerned and that less restrictive measures could not have been used. It would have to invite the economic operator to submit any comments within a reasonable period, before taking any individual measure restricting the marketing of the product. The final decision restricting the marketing of the product should be notified to the economic operator and should state the methods of appeal available.

<i>Is a new Community Regulation establishing key principles necessary?</i>	
Yes	61.4%
No	32.6%

When the competent authority of the Member State of destination submits a product legally marketed and/or manufactured in another Member State to an evaluation of conformity with its own technical rules, it would be logical that it should first contact the economic operator who is in a position to supply the necessary information within a reasonable time.

<i>Which information should be provided by whom?</i>	
The economic operator should provide the market surveillance authorities with detailed technical documentation on the product	64.4%
The conformity of the product with the legislation of the Member State of origin should be established by an independent body	43.2%
Written proof of conformity of the product with the legislation of the Member State of origin	37.1%

The period of consultation and dialogue with the Member State of destination could be extended upon request.

<i>The period of consultation and dialogue between the national authorities and the enterprise</i>	
The enterprise should be entitled to request an extension of the period of consultation and dialogue	72%
The Commission should also be entitled to request the extension	46.2%
The Member State of origin should be entitled to request an extension	43.9%

The automatic recognition of the validity of tests carried out by certain bodies established in another Member State could avoid all repetition of tests.

<i>Recognition of tests and certificates</i>	
Automatic recognition of tests and certificates requires that the technical ability, independence and impartiality of the testing body can easily be verified	48.5%
The testing body should be officially approved in the Member State of establishment on the basis of a national regulation	28.8%
The testing body should be only lawfully established in a Member State	15.2%

The Regulation could also provide for a period of consultation and dialogue, during which the product could still be marketed. During this period, enterprises would have the possibility of furnishing proof that the product was lawfully marketed elsewhere in the EU.

<i>Is a stand-still period for consultation and dialogue between the national authorities and the enterprise necessary?</i>	
Yes	70.5%
No	21.2%

The Regulation could also specify that the final decision to refuse the marketing of a product could not be imposed on an enterprise if the latter was not duly informed.

<i>Is it necessary to include a sanction into the Regulation when it is not correctly applied?</i>	
Yes	51.5%
No	31.1%

Annex 2:

Results of the consultation of the European Business Test Panel

1. SUMMARY

Most respondents are not familiar with the principle of mutual recognition and only half of those trading across borders rely on it. A minority of enterprises continue to experience different types of problems when trying to trade across borders. Enterprises would like to have better information on how national rules are applied.

The operation of mutual recognition should be overhauled. Reform would bring tangible benefits for enterprises.

2. PARTICIPATION

610 panellists provided answers. This represents a response rate of 25 %.

Higher response rates (between 30 and 40 percent) were achieved among Italian, Dutch, Belgian and German panellists. 60% of respondents are based in Germany, Italy, the Netherlands, Denmark and the United Kingdom. 5% of respondents reside in Iceland/Norway.

All economic sectors are represented among respondents with a strong showing (30%) by the manufacturing sector. Strong participation by three size categories (10-49, 50-249, 500+). These account for 70% of respondents. 61% of respondents (371) actually trade across borders.

3. FAMILIARITY WITH/MAKING USE OF THE PRINCIPLE OF MUTUAL RECOGNITION

46% of respondents claim to be familiar with mutual recognition. 50% claim to rely on it when selling goods in another Member State.

25% of the 296 who answered questions on their experiences of using mutual recognition, claim to have problems while 75% do not.

Problems are encountered across all Member States. Of the 152 indications of problems, Germany accounts for 27, France for 20, the UK for 15 and Poland for 12. There is no indication that trading with new entrants is particularly problematic – these account for 30 of 154 citations.

As to the nature of the problems encountered, responses indicate that “non-conformity” with national rules is the most common (36 out of 104 replies). More worrying is the indication that 31 never received a clear explanation or claimed not to know why the product did not conform.

In response to the question what did you do when faced with problems, respondents (on the basis of 108 indications) either provided additional information/negotiated with the relevant authorities (28), contacted their business association etc (12), supplied additional information (37) or modified their products (13). However, 20 claim to have simply given up.

Of the 74 respondents who answered the question were your problem solved, two thirds replied yes and one third no.

4. OBTAINING INFORMATION ON MUTUAL RECOGNITION - IDENTIFYING NATIONAL AUTHORITIES

Almost 80% of respondents would like to know (beforehand) about the technical rules in force in those Member States where they wish to market products but only 36% check whether these rules contain a clause confirming that mutual recognition could apply.

20% of respondents (121 responses) have had difficulties in getting sufficient information on the technical rules in force. However this percentage would rise to 33% if the 121 responses are attributed to the 371 who actually trade across borders.

There are difficulties in obtaining sufficient information in all Member States. Of the 295 citations, the new entrants account for 30% (91)

When it comes to being able to identify/find national authorities, 104 (17% of those who replied) respondents indicated that they had difficulties. Again if we assume that the 104 replies come from those 371 who trade across borders, the percentage (of those with difficulties) would rise to 28%.

Difficulties are encountered across all Member States (236 citations). The new Member states account for 86 (citations) or about 36%.

Although respondents use a wide range of sources to get information on the operation of mutual recognition or on the responsible authorities, most (233 out of 506 who expressed a clear answer) take the view that better access to information on technical rules and the principle of mutual recognition and on national authorities, would be a significant help while 209 indicate that it would be of some help. 61 suggest it would not make any difference.

5. PROPOSALS TO MAKE MUTUAL RECOGNITION WORK BETTER.

5.1. Use of Electronic Certificate

The vast majority of respondents (406) favour the idea of an electronic certificate. Only 10% think that it would not be helpful or would be burdensome.

Respondents support the use of electronic certificates (about 50% favour self certification and 50% favour independent certification) when providing information on their products.

5.2. Role of national authorities

5.2.1. *Publishing details on the application of mutual recognition*

The vast majority of respondents (470) would like to see Member States publish precisely how they apply the mutual recognition principle for goods lawfully manufactured/marketed in another Member State. About 52% of respondents expressing a view on this issue, think that this would be of significant help while 4 2% think that it would be of some help. Only 6% consider the idea unhelpful.

5.2.2. *Providing advance confirmation*

Respondents strongly support the idea that it would be useful to have a system of prior (but provisional) confirmation that goods could be sold. Of the 502 who expressed a clear view on this, 209 stated that it would be very useful and 220 said it would be helpful. Only 73 (15%) suggested that it would not be useful.

The vast majority of respondents feel that, were such a system in place, it would bring a variety of tangible benefits e.g. encourage trade and reduce costs and uncertainties.

5.2.3. *Informing operators in the event that access to markets is denied*

Most respondents would like to be informed directly if they are denied access and also think that their national authorities should also be informed. Overall, respondents feel that such decisions should be communicated to interested parties.

Equally, most respondents (70%) feel that any failure to provide this information should be grounds for invalidating decisions ordering the withdrawal of products from the market.

6. **CREATING A DIALOGUE WITH NATIONAL AUTHORITIES**

The vast majority of respondents (489 out of 610) feel that it would be helpful if enterprises (who have been denied or may be denied access) have the right to discuss this with national authorities. Only 37 respondents feel that having this right would not make any difference.

As to how the dialogue should be conducted, respondents strongly supported the following:

- It should be conducted within a reasonable time;
- Enterprises should be able to present supporting documents/expert opinion and call on an independent body to give its opinion;
- Public authorities (denying/withdrawing access) should set out their reasons;
- No charges should be imposed if a dialogue is opened;
- Decisions denying access or ordering withdrawal should be suspended when the dialogue is opened.

Annex 3: Case studies

The following case studies were collected mainly through face-to-face interviews with the involved companies and through the use of existing product or business sector studies.

ENTERPRISE CASE STUDY 1: MOBILE WORKING TOWER	
Type of enterprise: Multinational	Type of product: Scaffolding – Mobile working Tower
Type of technical barrier: 1. Rules on performance, safety and dimensions; 2. Recognition of tests and certificates	
Estimate of costs caused by the lack of mutual recognition: 10% of the total annual turnover of the company on the market of the receiving Member State and 218% of the total annual turnover of this product type of the company on the market of the receiving Member State.	

PRODUCT SPECIFICATIONS
The enterprise applies the non-harmonized European standard (HD 1004-1993). A draft European standard (prEN 1004-2002) is being discussed and elaborated within CEN.

TECHNICAL BARRIER
<p>Despite the fact that the products are produced in another EU member state, tested and approved by an accredited testing institution in the company's home country and marketed throughout the internal market, the authorities of the receiving Member State contacted the manufacturer and asked it to comply with the national technical rules. The authorities argued that the standard (HD 1004-1993) used by the testing institution was a non-complete standard and that they were not prepared to accept the certificates issued by the testing institution. They also claimed that their national rules contain additional requirements that were not met by the products.</p> <p>Furthermore, the manufacturer was required to conduct additional product testing in order to be able to document that the products lives up to the legislation of the receiving Member State. The national authorities initially demanded that this testing be conducted at a specific testing institution on their territory, but this request was overruled and the testing could therefore be done at any accredited testing institution in another EU member state. Consequently, the company has used its usual testing institution in its home country. However, the authorities of the Member State of destination maintained that all underlying analyses, data and specifications must be made available in their official language.</p>

ENTERPRISE ATTITUDE
The enterprise relied on mutual recognition and decided to challenge the proportionality of the application of the national technical rules of the receiving Member State. The dispute lasted six years. In hindsight, the enterprise assesses that, from a narrow economic perspective, it would have made more economic sense to comply with the national technical rules of the receiving Member State from

the start of the process, when an isolated perspective for the market of this Member State alone is adopted: The direct costs related to the additional testing for this national market do not match the negative implications which the lengthy case has had for the company.

However, the decision to challenge the national requirements of the receiving Member State for this particular product was a conscious decision taken at the corporate level and should be considered in the context of the company's overall strategy and activities in the EU market: The company exports its product to all EU member states and the broader perspective of the case on the market of this particular Member State was therefore considered to be a test of the possibilities respectively the limitations of the mutual recognition principle. The company considered it relevant to challenge this as the fundamental approach of the company is to manufacture products that can be marketed on all national markets within the EU and avoid adoption to specifications in national markets because this limits economies of scale in the production process.

ADDITIONAL COSTS

The company had to face direct costs related to the additional testing needed to provide documentation, and other compliance costs. Moreover, the company has had to carry a number of related costs, such as e.g. costs for legal advisory services and costs related to informing customers about the problems with the authorities of Member State B. Besides the direct economic costs, there are other costs which are difficult to measure in precise monetary terms. The largest single component of the additional costs is the expenses to additional testing at the accredited testing institution in the company's home country to document that the product (which had not been subject to any product development or changes in the meantime) complied with the technical rule of the receiving Member State.

All costs are one-off costs. The normal cost for introducing a product of this type (excluding internal costs for product development, management, administration etc.) is approximately 150,000 EUR, which covers the market introduction for the European market as a whole. The additional costs for introducing the product in the market of the Member State of destination (which is at the same time an expression of the costs related to challenging the decision of national authorities to deny market access) amounted to approximately 218,000 EUR. In order to place the size of the additional activities and costs into a larger perspective it can be mentioned that the annual turnover for the mobile working tower on the market of the receiving Member State is approximately 100,000 EUR and the total annual turnover of the company on the market of that Member State is approximately 2.2 million EUR.

There were also indirect costs for this enterprise which are difficult to estimate with sufficient precision. Firstly, the lengthy period (6 years) from the start of the discussions between the company and the national authorities which created uncertainty for the company, due to the unclear position of the product on the market of the receiving Member State. Secondly, the negative implications for customer relations and the company's brand. In the wake of the dispute between the company and the authorities of the receiving Member State, two of the major eight clients in that Member State decided to change the cooperation with the company. One client decided to terminate the cooperation with the company completely, and the other client decided to stop buying the mobile working tower. Thirdly, the case had negative implications on the company's growth rate. The company has not been able to gain the expected market share for the type of product at issue. The enterprise itself stresses that in particular the lack of clarity during the six-year period has been the main problem and that the direct monetary costs have been diminutive compared to this issue.

ENTERPRISE CASE STUDY 2: MOBILE WORKING TOWER	
Type of enterprise: SME	Type of product: Scaffolding – Mobile working Tower
Type of technical barrier: 1. Rules on performance, safety and dimensions; 2. Recognition of tests and certificates	
Estimate of costs caused by the lack of mutual recognition: 27,000 EUR for additional testing for the only type of product that the company decided to sell on this market.	

PRODUCT SPECIFICATIONS
The enterprise applies the non-harmonized European standard (HD 1004-1993). A draft European standard (prEN 1004-2002) is being discussed and elaborated within CEN.

TECHNICAL BARRIER
See Case Study 1.

ENTERPRISE ATTITUDE
This company decided to introduce only one type of product on the market of the receiving Member State, instead of its entire product range, as the compliance and additional testing costs (in addition to the other costs related to market entry) were considered too high compared to the anticipated turnover on the market.

ADDITIONAL COSTS
The costs for additional testing for the only type of product that the company decided to sell on the market of the receiving Member State amounted to 27,000 EUR.
The other costs for this enterprise cannot be estimated with sufficient precision: the company decided not to sell a major part of its product range on that market.

ENTERPRISE CASE STUDY 3: ALUMINIUM KETTLE

Type of enterprise: Multinational

Type of product: Aluminium kettle

Type of technical barrier: Rules on performance, safety and dimensions.

Estimate of costs caused by the lack of mutual recognition: 100% of estimated annual turnover for that type of product on this national market. 1.37% of annual worldwide turnover for this product.

PRODUCT SPECIFICATIONS

This case concerns an aluminium water kettle for normal household use. The product specifications were developed following the screening of all national rules of the Member States where the product was sold at the moment of product launch. This screening started with consulting the Council of Europe guidelines and all possible national rules on aluminium kettles. It was established that only two other Member States had national legislation in this area. On this basis it was decided that the water kettle should adhere to the European voluntary standard on aluminium purity for food contact materials and to the European voluntary safety standard for kettles EN13750. The allocated overhead cost of this activity amounts to approximately 2.000 EUR.

The enterprise incurred some difficulties in identifying the exact requirements of the regulation of one of both other Member States having national rules in this area because the documentation was only available in the official language of that Member State. Eventually a translator was hired, and it was then established that this particular Member State had the strictest rules since its regulations are, compared to the rules of the second Member State, not only measuring material quality but also migration of substances, e.g. Al, into water. Therefore the retailer chose to test according to the rules of the first of both other Member States having national rules in this area. The cost of this activity was approximately 2.500 EUR.

Following a risk assessment it was decided to launch the product world-wide. No specific cost was incurred during this activity regarding mutual recognition.

TECHNICAL BARRIER

Although the aluminium water kettle was lawfully sold in all Member States, this receiving Member State restricts the sale of this type of product on grounds of health according to national rules regulating aluminium content in potable water. The company had not identified this national rule in its usual legal screening process. When it became aware of this rule, it sought approval from the receiving Member State before placing it on that market. The enterprise was asked to perform an additional test according to the national rules of the Member State of destination regarding aluminium contents in potable water – a regulation that applies to water pipes and thus was not identified in the original survey of national rules. It was a time consuming process for the company to establish the nature of the problem – also here language barriers played a role. A locally employed legal generalist had to communicate with the authorities.

The authorities of the receiving Member State were given a sample kettle, which they had tested according to the local rules of water pipes. The test showed that the aluminium content in eatables cooked in the kettle in fact exceeded the requirements of the receiving Member State. The retailer has not received other reasons for the denial of market access, than that the kettle does not adhere to the

local rules. To prove that the kettle does comply with the strictest rules regarding food contact materials the retailer has sponsored an additional test at a test centre established in another Member State. The next step was to give the test protocol and the documentation that the product was lawfully marketed in that other Member State to the authorities of the receiving Member State. However, the product has still not reached the market of that Member State.

ENTERPRISE ATTITUDE

The company wishes to fully exploit economies of scale and therefore always develops a new product with the intention of selling the same product on all markets globally. This situation is fundamentally different from the situation for a typical smaller enterprise that wants to export its products to other Member States. The small enterprise has often established the product on the home market first before contemplating selling the product elsewhere.

This company decided to meet the strictest national rules in order to ensure that a product can be marketed on all markets. For the retailer it is also a cost efficient strategy eliminating costs of communicating with national authorities in destination Member States, that otherwise would have to accept a product with less strict rules applied to it. The strategy also enables the retailer to place products on the market faster than otherwise, because fewer obstacles are met. The strategy is, however, at times difficult to apply in practice: Besides the difficulty of finding accurate information about specific product and material requirements for all the national market where the firm operates, it is at times difficult to assess which national rules are the strictest, as the rules of two Member States sometimes contradict each other. The enterprises therefore carefully screens the national rules and enforcement policies in all Member States in order to identify necessary product changes at the earliest possible point of time and to update the information needed for the development of new products, for instance rules on materials and composition. This activity is a fixed annual cost for the company, as it has to be performed regardless of the load of new legislation. When measuring the expenses of a single product, the total costs of the continuous legal surveillance process count as an overhead. The total costs are allocated to each product, that 'uses' this service.

ADDITIONAL COSTS
<p>The basic problems encountered by this enterprise were difficulties in finding information on national regulations, the unclear communication process when dealing with national authorities on mutual recognition issues and the complete lack of information on exceptions to mutual recognition. Some of these costs are included in the overheads.</p> <p>The estimated yearly quantity to be sold in the Member State of destination is 1500 pieces corresponding to a turnover of 6.000 EUR. The costs so far for getting the approval to sell the product in that Member State amounts to approximately 6.000 EUR including test costs there and in the other Member State as well as time spent by the retailer's employees in three different Member State (including the receiving Member State). This means that the costs incurred for the retailer so far, more or less equal to the estimated annual turnover.</p> <p>Due to the relatively small turnover in Member State C it is not an economically viable option to market a separate version of the product for Member State C for logistical reasons alone. Therefore, the retailer pressed for a legal resolve of the case, so that the aluminium kettles complying with the national rules of another Member State could be sold in Member State C – the only other option is to not market the product in Member State C. The retailer's policy has so far been not to seek confrontations with national authorities. It is the firm's assessment that testing the limits of the mutual recognition principle, through e.g. legal confrontations, may have other negative implications for the firm, for instance on the customers perception of the company's stance on health issues.</p> <p>If the market were of a greater importance for the retailer, it might have decided to retail a separate product. The retailer today markets separate versions of products if it is economically viable, which mainly means that the separate versions are only sold on the large markets.</p> <p>Abstaining from marketing the product in the receiving Member State is not the main concern of the company. However, it has other concerns: to fully exploit economies of scale, its catalogue is the identical version used all over Europe and it would be costly to produce a separate version of the catalogue for this particular Member State, in which the kettle was not included. If the product can not be marketed here, a work-around concerning the catalogue has to be found. In the worst case the water kettle may be excluded from the product range in all of Europe. As display through the catalogue marketing channel usually raises turnover with 30-50%, that would imply a loss of turnover of 100,000 – 200,000 EUR.</p>

ENTERPRISE CASE STUDY 4: LABELLING OF TEXTILE PRODUCTS	
Type of enterprise: Multinational	Type of product: Textile products
Type of technical barrier: Rules on labelling.	
Estimate of costs caused by the lack of mutual recognition: No estimate could be given.	

PRODUCT SPECIFICATIONS

Directive 96/74/EC on textile names requires the labelling of the fibre composition of textile products. It stipulates checks on whether the composition of textile products is in conformity with the information supplied. All products containing at least 80% by weight of textile fibres, including raw, semi-worked, worked, semi-manufactured, semi-made, made-up products are covered in the Directive. A list of exceptions is provided in Annex III (e.g. disposable articles, flags). The labelling indicating the fibre composition is mandatory in all stages of the industrial processing and commercial distribution of a product. Names and Descriptions of the fibres are listed in Annex I which contains 41 fibre names and their description. Article 14(1) of the Directive specifies that Member States may not, for reasons connected with names or composition specifications, prohibit or impede the placing on the market of textile products which satisfy the provisions of this Directive.

Consequently, technical barriers that do not relate to names or composition specifications fall within the scope of the mutual recognition principle.

TECHNICAL BARRIER

The national rules in the receiving Member State require that a woven label must be attached to a piece of textile. This label must include clear text with all details in the official language of the receiving Member State, be stitched to the textile product in a permanent way, be resistant to treatments and always remain readable. Different requirements apply for products made within the EU and for products made outside the EU. These specific information requirements are not an isolated case as several other EU member states provide for similar obligations. However, for particular materials, such as e.g. downs and feather, separate specifications for the information on the label exist where the company must state that a sterilization process has been carried out. These separate specifications mean that for down and feather products such as jackets and coats the retailer is unable to apply one extensive label with all the required information but need to treat the batch for this receiving Member State separately. Moreover, the label must include details about the manufacturer (name and address). The company is therefore unable to use its international packaging centre which handles the distribution to all stores in Europe.

According to the company, almost all manufacturers and retailers meet these different information requirements by developing rather long and extensive labels where all the required information is included in several languages. The underlying rationale is that textile manufacturers and retailers seek to obtain a cost-efficient production process where they only need to stitch the label onto each single piece of clothing once instead of treating each batch of clothing to a specific national market separately, which makes the handling process more time consuming and entails more administrative work.

ENTERPRISE ATTITUDE

The company prefers harmonization to mutual recognition. This view is founded in the company's wide international presence where the existence of harmonized rules and regulations for products allows the company to exploit economies of scale as harmonized rules enable the company to optimize the business processes for production, distribution and sale as the volume increases and there are less products that have to be treated separately in e.g. packaging.

For types of products covered by the mutual recognition principle the general policy of the company is to try to follow the strictest national rules in order to have products that can be accepted in all markets. However, the practical experience is that this strategy cannot always be applied because it is not always possible to identify the one strictest regulation as the requirements of national authorities differ between countries in such a manner that the company needs to adopt the products in order to be present on these national markets.

Despite the fact that the annual turnover for the example chosen (down jackets) is relatively small on the market of this receiving Member State (100,000 EUR), the company has chosen to comply with the national labelling requirements. Due to the strategic importance of maintaining the information about the supplier and manufacturer of the jackets, the retailer has chosen not to comply with the obligation in the receiving Member State that information about the manufacturer's name and address must be included on the label.

ADDITIONAL COSTS

These separate specifications for particular materials mean that for down and feather products such as jackets and coats the retailer is unable to apply one extensive label with all the required information but need to treat the batch of this specific receiving Member State separately. The company is therefore unable to use its international packaging centre which handles the distribution to all stores in Europe. While this element is the most costly in the production process, meeting the requirements of the different countries also include other costs, such as the internal administrative time for companies that are not established in this receiving Member State to handle the procedure, the cost of adjusting the production line (manufacturing and packaging) for the enterprise and its suppliers, and logistical costs. It was, however, impossible to estimate these costs in more precise terms.

However, it is not the monetary costs that are the issue of greatest concern for this enterprise, but the legislation's requirement that the label must include details about the manufacturer (name and address). Most of the textile products marketed by this enterprise are manufactured by suppliers in Asia, and from the enterprise's point of view the contact details of the supplier represents strategically important information which it wishes to treat as confidential information. The rationale is that the company does not wish to disclose this information as its collaboration with the manufacturer is a competitive parameter. Significant resources have been invested in the identification and selection of the right suppliers. If the identity of the suppliers becomes known to competitors they will have the opportunity to contact the suppliers to explore the possibilities for collaboration, which the enterprise considers as a competitive threat.

ENTERPRISE CASE STUDY 5: BICYCLES	
Type of enterprise: Multinational	Type of product: Bicycles
Type of technical barrier: Rules on performance, safety and dimensions.	
Estimate of costs caused by the lack of mutual recognition: 98,000 and 148,000 EUR each year, which represents between 0.7% and 1% of the turnover of this company on the market of this (large) Member State.	

TECHNICAL BARRIER
In some Member States, bicycles are allowed without any lighting equipment. In other Member States, the law requires lights but with different technical specifications. The receiving Member State in this case also imposes a number of technical specifications. The most serious problem for this company is the obligation that the rear light and the headlight be operated by a dynamo, for safety considerations. The argument is that a dynamo driven light is more reliable than a battery driven light. An additional obligation is that each bicycle should be equipped with two brakes. However, this requirement is less problematic for the manufacturer than the dynamo lightening.

ENTERPRISE ATTITUDE
In order to place bicycles on the market of the receiving Member State, the cycles are being adjusted by providing them with dynamo driven lightening and two brakes.

ADDITIONAL COSTS
<p>The cost of these adjustments adds approximately 2 EUR on to the price of each bike sold on the market of the receiving Member State. As the prices of the producer's bicycles, due to their higher quality, are already at the high end of the market, it is the assessment of the manufacturer that the increased cost only has a very marginal influence on the total sale. Furthermore, the requirements in the receiving Member State as well as on other markets do not constitute barriers to increased export. The enterprise is of the opinion that its limited export to other highly regulated markets has more to do with the limited demand for high quality bikes than with barriers created by specific technical specifications. The main costs for the company in terms of additional activities are costs related to marketing and the need for marketing material with pictures of the revised models to the market of the receiving Member State. The costs of producing this extra material are assessed to be between 50 – 100.000 EUR per year. In addition to this there are some, limited, management costs related to keeping up-to-date with regulatory developments, which are estimated to 1-2 weeks per year equalling 2.000 EUR.</p> <p>The total cost of the national rules in the Member State of destination for the manufacturer is between 98,000 and 148,000 EUR each year, i.e. between 0.7% and 1% of its turnover on that market.</p>

ENTERPRISE CASE STUDY 6: BICYCLES

Type of enterprise: SME

Type of product: Bicycles

Type of technical barrier: Rules on performance, safety and dimensions and authorisation procedure

Estimate of costs caused by the lack of mutual recognition: 103,400 EUR each year, which represents 4.75% of its annual turnover.

TECHNICAL BARRIER

As an importer, the company mainly faces three problems. The first is a new requirement stating that all bikes must be equipped with bells. Although this requirement is considered annoying, the enterprise considers that it is still possible in practice to cope with it. The second problem is the need to have particular stickers on the bikes. The third, and final problem, is the need to have bikes type approved.

ENTERPRISE ATTITUDE

This company is an importer of bicycles and sells 15,000 bikes annually on average in the receiving Member State, which amounts to an annual turnover of 2,176,000 EUR. It does not rely on mutual recognition and adapts the bicycles to the national rules on its territory.

ADDITIONAL COSTS

The importer needs to do two things in order to place the bike on the market of the receiving Member State. First, he needs to have all the bicycles type approved. The total cost per bike is 510 EUR for each model. This includes both the fee for the test as well as the cost of getting the bikes to the test. As each model, on average, is sold in more than 350 units, the additional price for the testing is about 1.5 EUR. The second activity is to upgrade the bikes so they fulfil the requirements as to stickers and bells. The importer estimates the cost for this to be approximately 4.40 EUR for each bike.

The importer thinks these costs are reasonable compared with the size and turnover of the company. However, the importer is of the opinion that the costs may be considerably higher for more inexperienced importers. Due to his experience he is able to find bicycles that fulfil the requirements of the Member State of destination, except for the small adjustments with the bell and the stickers.

The total costs of the national rules of this Member State for the importer are 103,400 EUR each year, which represents 4.75% of its annual turnover. It is the view of the importer that competition on the bike market is so strong that it is not possible to increase the price further.

ENTERPRISE CASE STUDY 7: BICYCLES	
Type of enterprise: Multinational	Type of product: Bicycles
Type of technical barrier: Rules on performance, safety and dimensions.	
Estimate of costs caused by the lack of mutual recognition: No estimate could be given.	

PRODUCT SPECIFICATIONS
These bicycles are developed under one of the strictest national voluntary standards within the EC. But as this norm does not cover all parts of the product, models are developed in line with another voluntary national standard for the missing parts.

TECHNICAL BARRIER
<p>The company faces difficulties in exporting its bicycles to five Member States. In each of these countries, standard bicycle models have to be modified to meet the specific national regulations.</p> <p>This case concerns the most cumbersome and questionable national rule, according to the company, namely the requirement that each model of bicycle put on the national market must be previously tested in an accredited laboratory on the territory of the receiving Member State. If the model complies with the test criteria, it is attributed a specific certification number, which must be engraved on the frames of the bikes.</p> <p>The company considers that there is no added value in this test, since the criteria tested are all included in the national voluntary standard under which its models are systematically developed and tested.</p>

ENTERPRISE ATTITUDE
The company does not rely on mutual recognition. It sends a model to the receiving Member State to be tested and attributed a number. The length of the test varies from 2 to 4 weeks. Then the production process can start and bicycles are engraved a specific certification number on the frames. Changes in the production process require extra management resources.

ADDITIONAL COSTS
The company has not been able to specify the additional costs related to these additional activities

ENTERPRISE CASE STUDY 8: FOOD COMPLEMENTS

Type of enterprise: SME

Type of product: Food complements

Type of technical barrier: Rules on performance, safety and dimensions.

Estimate of costs caused by the lack of mutual recognition: No information available.

PRODUCT SPECIFICATIONS

This enterprise is a medium sized company manufacturing food complements, mainly natural herbal supplements. About 80% of its production is sold outside the Member State where the products are lawfully manufactured and marketed.

Although the types of products manufactured by the company fall within the definition of food supplements laid down in Directive 2002/46/EC, there is no full harmonisation of the national rules applicable to the composition of these products. Consequently, the composition of the products is subject to mutual recognition in case of intra-EU trade, while the labelling is governed by Directive 2000/13/EC relating to the labelling, presentation and advertising of foodstuffs.

ENTERPRISE ATTITUDE

According to the enterprise, there are in its case three important elements that contribute to the acceptance of the products by the authorities in other Member States, although the composition of the products did not fully comply with the rules there:

1. The definition of food complements in Directive 2002/46/EC: this avoids any further lengthy discussions with national authorities about the question whether the products constitute pharmaceutical products for human use or food complements;
2. A scientifically solid legal framework in the Member State of origin of the product: the rules that are in place have been drafted and are regularly amended in the light of scientific development. This scientific credibility of this legislation facilitates the discussions with the authorities of the Member State of destination.
3. The notification system in the Member State of origin of the product: when a new food complement is put on the market, the manufacturer must notify it to his national authorities who can object to the marketing of the product constitutes a risk for human health. The advantage of this system from a mutual recognition perspective is that the product is known to the local authorities who even deliver, upon request, a certificate for export purposes. When they do not react upon a notification, the authorities implicitly do not have any objections against the marketing of the products, which comforts the manufacturer that his products are lawfully marketed. The notification system allows authorities in other Member States to get more information on the product and its compliance with the rules applicable on the territory of the manufacturer.

As regards mutual recognition, the enterprise usually works in the following way:

- a. Analysis of national rules: The enterprise starts with analysing the legislation of the Member State of destination in order to identify on which points the composition of the products does not comply

with the local rules.

b. Notification: next, the company prepares a file with more specific information on the product and notifies it to the authorities of the Member State of destination. In that regard, it should be noted that one of the particularities of the food supplements legislation is that most Member States also provide for a notification system to inform the local authorities that the product is being marketed. This notification system is included in Directive 2002/46/EC, which specifies that, “to facilitate efficient monitoring of food supplements, Member States may require the manufacturer or the person placing the product on the market in their territory to notify the competent authority of that placing on the market by forwarding it a model of the label used for the product.” (Article 10)

c. Internal assessment: However, when there is no notification system or no explicit authorisation scheme, the enterprise evaluates the situation on the basis of several factors, which include informal contacts with national authorities, advice from a local lawyer, the attitude and the cooperation of the local distributor, the financial risk if the product would have to be withdrawn from the national market of the receiving Member State, etc. This evaluation can lead to the decision to abandon product launch, or to adapt the composition of the product unconditionally to the local rules of the receiving Member State, or “to accept the challenge of mutual recognition”.

d. Waiting for possible reactions of national authorities: When the product is put on the local market without any changes in its composition, the enterprise then awaits the possible reactions of the local authorities. It starts the discussion with them only when they indicate that the product should be withdrawn from the market.

Nevertheless, the company has encountered difficulties getting several of their products accepted in other Member States. In certain Member States, it took a considerable amount of time and human resources to overcome the hurdles of national rules.

The company considers that the most important problems with mutual recognition are the general lack of awareness of enterprises and national authorities of the mutual recognition principle, the legal uncertainty that surrounds its implementation and the need for more organised and efficient dialogue between enterprises and authorities.

In addition, the fear of high costs in case of legal proceedings can prevent an SME to rely on mutual recognition in a specific case. Another barrier for mutual recognition, according to the enterprise, is the difficulty to get access to information on national technical rules and the lack of transparency by national authorities on their national rules and on their implementation and interpretation.

Mutual recognition can be successful if a number of conditions are fulfilled. The company stresses the importance of the determination of the relevant enterprise to go ahead with selling its product and, in case of problems, to challenge the proportionality of certain national rules. The enterprise stresses the importance, for the marketing of the product, of the interpretation and the understanding of national technical rules by distributors and their willingness or reluctance to sell the product if it does not comply with local rules.

It also emphasises the importance of information exchange and trust-building between the enterprise and the authorities of the receiving Member State. It believes that more should be done to make authorities and companies familiar with mutual recognition. It recommends that the TRIS-system currently used under Directive 98/34/EC begin to include the final and official text of the national rules so that the accessibility of national rules is improved for enterprises.

**ENTERPRISE CASE STUDY 9:
TESTING OF CHILDREN'S CLOTHING**

Type of enterprise: Multinational

Type of product: Textile - children's clothing

Type of technical barrier: additional tests

Estimate of costs caused by the lack of mutual recognition: 1% of the retailer's normal costs for quality assurance of textiles

PRODUCT SPECIFICATIONS

The company prefers harmonization compared to having the cross-border trade of products regulated by the mutual recognition. This view is founded in the company's wide international presence where the existence of harmonized rules and regulations for products allows the company to exploit economies of scale as harmonized rules enable the company to optimize the business processes for production, distribution and sale as the volume increases and there are less products that have to be treated separately in e.g. packaging.

For types of products that fall under the mutual recognition principle the general policy of the company is to try to follow the strictest national rules in order to have products that can be accepted in all markets. However, the practical experience is that this strategy cannot always be applied because it is not always possible to identify the one strictest regulation as the requirements of national authorities differ between countries in such a manner that the company needs to adopt the products in order to be present on these national markets.

TECHNICAL BARRIER

The testing regime applied in the receiving Member State is a private testing method offered by a private association. According to the retailer this testing method is generally well recognized in the textiles industry. It prevents the use of substances which are harmful to the health, controls numerous chemicals which may be detrimental to health, and also includes precautionary test parameters designed to protect good health. The system is used for the testing of babies' and children's clothing, bed linen, mattresses, blankets and pillows, textile toys and the linings of prams, towelling goods, decorative fabrics and all other types of textiles.

The authorities of the receiving Member State require the testing of the clothes' chemical reactions when exposed to e.g. body sweat and saliva in order to prevent allergic and dermatological problems, which are all aspects included in the private test. The receiving Member State is the only market in Europe where this type of testing is required by the public authorities. Moreover, it is the experience of the company that test certificates are generally not necessary to gain the confidence of the consumer and sell the products. The retailer considers that there is therefore no immediate positive benefit from the testing done exclusively for the market of the receiving Member State.

ENTERPRISE ATTITUDE

The company accepted the additional testing regime applied in the receiving Member State. It did not rely on mutual recognition.

The company is considering withdrawing its product range in children's clothing from stores in the receiving Member State, due to the testing costs, their impact on the prices and the corresponding lower turnover on that market.

ADDITIONAL COSTS

As testing is normally not carried out for the children's clothing product range, the testing carried out for the market of the receiving Member State is an additional activity and cost which the company must cover in order to market its children's clothing products on that market. At present this means that 220 pieces of clothing must be tested on an annual basis which amounts to approximately 44,000 EUR in annual testing costs alone. The level of the annual costs are relatively stable as testing is required every time the company wishes to market a new piece of clothing on the market of the receiving Member State.

There are some additional, internal administrative costs in the company as the testing requires management and planning, but it is not possible to estimate these costs in more precise terms. The retailer's normal costs for quality assurance of textiles amounts to 0.45% of the total costs of the products, but the additional costs for the receiving Member State mean that these costs increase to 1.45% of the total costs. It should be mentioned that the annual turnover for the children's clothing product range on the market of the receiving Member State is approximately 1,840,000 EUR. Since the turnover for this product range is relatively small the retailer is considering withdrawing the clothing from the market of the receiving Member State.

**SECTOR CASE STUDY:
OFF-ROAD MACHINERY**

PRODUCT SPECIFICATIONS

Off-road machinery is self-propelled machinery with a maximum design speed higher than 6 km/h, running on tyres, endless non-metallic tracks or drums falling within the scope of the machinery directive. The intended purpose of off-road machinery is to work on construction sites, agricultural areas etc. but not to carry goods or persons on public roads. However, the use of public roads is necessary for the quick and efficient transport of machinery to its place of work.

Off-road machinery falls within the scope of the machinery directive 89/392/EEC as amended and codified in Directive 98/37/EC. However, it is also subject to national road traffic regulations and to specific approval procedures based on national road requirements.

TECHNICAL BARRIER

The investigation of the national regulatory systems for off-road machinery revealed that some Member States call for comprehensive and time-consuming procedures based on strict regulations for the road approval of off-road machinery, in particular third party certification. Other Member States pose, by far, less challenging requirements and some Member States do not even have any procedures and focus only on a few features of importance.

With regard to functions of high importance for road safety, such as braking, steering etc., very often the requirements – as far as Member States have some regulation – do not differ that much. But different values, criteria and required testing procedures induce the multiplication of the workload necessary for the road approval. The national regulatory systems ask for different signalling, warning and lighting equipment to increase visibility of off-road machinery, which – as disclosed in some studies – is highly important for road safety. The purpose of these national rules is always and everywhere the same but national solutions differ from each other.

ADDITIONAL COSTS

The model applied is based on the difference between the total costs related to a company's efforts to meet the requirements of all national regulatory regimes in the Member States and the costs of meeting the requirements in just one Member State. In any case, the Member State taken as a benchmark was the one that has induced higher costs than the others. This means that the excess costs have been estimated conservatively.

A survey revealed that three categories of costs are regarded as most important at the manufacturers level:

- The first category comprises the workload and input additionally necessary in a manufacturing company during the product innovation process by the design of variants to meet the different requirements of the Member States' national regulatory systems and the costs induced by the additional logistic effort in all of the manufacturing process necessary to control the production of variants to meet all requirements. As a share of turnover these excess costs reached 0.31%.
- The second category comprises the costs induced by the delay in the introduction of a new product in the internal market. On average, the companies reported a delay of 15 weeks. The imputed interest

rates in the capital locked-up amounts to 0.06% of the manufacturing companies' turnover.

- The third category of costs is linked directly to the introduction of the products into the market, in particular road approval procedure and third-party testing. The excess costs are induced by the multiple testing, conformity assessment and in particular multiple third-party certification. The excess costs – caused by the execution of more than one activity – amounted to 0.08% of companies' turnover.

It was assumed that all costs for homologation procedures at the distributors' level are excess costs because under a harmonised regulation usually a dealer does not have to carry out any comprehensive road approval procedure for machines manufactured in the EU which comprises testing, conformity assessment, assemblage of safety equipment etc. The total excess costs amount to 0.12% of the dealers' turnover.

The indicators derived from the companies that participated in the survey were applied to calculate total excess costs for all of the off-road industry. At the manufacturers' and at the dealers' level, the costs of the current situation add up to €74.3 million; a share of 0.5% of the off-road machinery industry's turnover. As a rough estimation, the amount of excess is around one tenth of the industry's profits.

Excess costs induced by regulatory differences for off-road machinery (December 2001) (source: http://ec.europa.eu/enterprise/mechan_equipment/machinery/gesam.pdf)						
Level of invest- igation	Indicators		Agricul- tural machinery (1)	Construc- tion machinery (2)	Others	Total
Manufac- turers	Size of the market in millions of €		6,351	7,030	2,100	15,481
	Excess costs as a share of total turnover	Innovation and manufacturing	0.31%	0.31%	0.31%	
		Capital costs	0.06%	0.06%	0.06%	
		Roading approval	0.12%	0.06%	0.06%	
	Excess costs in millions of €		31.1	30.3	9.0	70.4
Distributors	Turnover as a share of market size (3)		15%	25%	25%	
	Excess costs as a share of turnover		0.12%	0.12%	0.12%	
	Excess costs in millions of €		1.2	2.1	0.6	3.9
Total excess costs in millions of €			32.3	32.4	9.6	74.3
(1) Without tractors						
(2) Industrial trucks (as far as roading approval is important), mobile cranes						
(3) Only distributors turnover in markets for which manufacturers do not carrying out the homologation.						

CONSEQUENCES OF THESE BARRIERS

The burden is not the same for all companies. In particular firms that experience higher costs are those that are more innovative than their competitors (there are manufacturers with product life cycles of well under three years), have to manufacture a high number of variants or manufacture a small number of units only, especially SMEs. For instance, the delivery of a small number of specialised machines into another Member State can raise homologation costs up to 5% of the concerned turnover. An analysis of the behaviour of SMEs disclosed that the costs of road approval are nearly twice as high as for big companies as a share of total turnover. This burden hampers SMEs efforts to become European players and indeed most of the smaller firms with a turnover of €15 million and less only export into Member States with loose regulatory systems. There are nearly no small firms that export off-road machinery into Member States with high requirements and third-party certification.

The barriers to the free circulation of off-road machines have an impact on dealership structure. There are only few dealers that have representatives in more than one Member State. Most of the dealers are sales representatives for areas defined by the manufacturers. Although full area protection is no longer possible in the internal market, the different national regulatory systems hamper cross-border competition among dealers. Even potential clients situated close to intra-EU borders do not procure off-road machines from neighbouring Member States because of difficult approval procedures.

Rental companies and farm machinery cooperatives are gaining importance in the market for off-road machinery. Among the underlying reasons for this development, the interest of users, e.g., farms, construction companies etc., to increase the level of utilisation of machines is of major importance. This tendency contributes much to an efficient allocation of working capital. Under the current framework conditions for self-propelled working machines, rental companies cannot exploit much synergies by shifting off-road machinery cross-border, which usually is restricted to off-road machines for which road approval is not a necessity.

The road approval of off-road machinery is the responsibility of the Member States. Few Member States impose extremely high requirements and most of the big manufacturers sell machines that meet the tough regulations throughout the internal market. For this reason, there is a certain level of road safety all over Europe insofar as machines are manufactured by firms with a pan-European distribution network. But importers often deliver cheaper off-road machines from third countries into those markets that do not require all safety features necessary in other Member States. This is perceived as a general threat to road safety.

There were no statistics available that allowed an evaluation of the impact of a loose regulatory system on accidents of off-road machinery on the road in comparison with Member States with high requirements. Available studies on the impact of off-road machines on road safety show that the visibility of off-road machines is poor and in combination with the slow movement on the road, both of these factors are of importance for accidents. Moreover, maintenance of lighting and other safety equipment is not always satisfactory and contributes to risks caused by off-road machinery on the road. In some countries initiatives have been taken to improve the situation. This will lead to more strict regulation and to a growing number of national peculiarities that will have to be met by the manufacturers. The barriers to free circulation will become even higher.

Annex 4: Global administrative costs

Mutual recognition in the non-harmonised area of goods - Option 4 (combination of a regulatory and a non-regulatory approach)						Tariff (€ per hour)		Time (hour)		Price (per action or equip)	Freq (per year)	Nbr of entities	Total nbr of actions	Total cost	Regulatory origin (%)			
No.	Ass. Art.	Orig. Art.	Type of obligation	Description of required action(s)	Target group	i	e	i	e						Int	EU	Nat	Reg
1	4		Inspection	Retrieving relevant information from existing data	Public authorities	50	0	5,00	0,00	250,0	80	27	2.160	540.000		100%		
2	4		Inspection	Producing new data	Public authorities	50	0	5,00	0,00	250,0	80	27	2.160	540.000		100%		
3	5		Notification of (specific) activities	Submitting the information (sending it to the designated recipient)	Public authorities	50	0	1,00	0,00	50,0	80	27	2.160	108.000		100%		
4	7		Other	Adjusting existing data	Public authorities	50	0	20,00	0,00	1.000,0	1	27	27	27.000		100%		
5	8		Information labelling for third parties	Training members and employees about the information obligations	Public authorities	50	30	140,00	350,00	17.500,0	5	27	135	2.362.500		100%		
6	8		Information labelling for third parties	Retrieving relevant information from existing data	Public authorities	50	20	1.000,00	1.000,00	70.000,0	5	27	135	9.450.000		100%		
7	8		Information labelling for third parties	Producing new data	Public authorities	50	20	680,00	680,00	47.600,0	5	27	135	6.426.000		100%		
8	12		Notification of (specific) activities	Retrieving relevant information from existing data	Public authorities	50	0	-3,00	0,00	-150,0	80	27	2.160	-324.000		100%		
9	12		Notification of (specific) activities	Producing new data	Public authorities	50	0	-5,00	0,00	-250,0	80	27	2.160	-540.000		100%		
10	12		Notification of (specific) activities	Submitting the information (sending it to the designated recipient)	Public authorities	50	0	-1,00	0,00	-50,0	80	27	2.160	-108.000		100%		

**Total administrative costs
(€) 18.481.500**

Regulatory act refers to legislative and statutory acts

For the reference of the proposal / act, use EU-Lex format ('cut and paste' of the reference given by http://europa.eu.int/eur-lex/lex/RECH_menu.do?ihmlang=en).

No. = gives a number for each action.

Ass. Art.= article and § detailing the obligation assessed on that line.

Orig. Art. = if the act assessed is the transposition of an act adopted at another level, insert here the article and § of the 'original' act corresponding to the obligation assessed on that line

(for ex., article of the EC directive at the origin of one specific obligation imposed by national law)

i = internal tariff (administrative action carried by the enterprise itself). e = external tariff (administrative action contracted out).

Price per action = $(TA_i * T_{li}) + (TA_e * T_{le})$. Total Nbr of actions = Frequency * Number of entities. Total cost per action = $P * Q$.

For equipment, yearly cost based on the depreciation period must be put in the 'price' column; the 'tariff' and 'time' columns must be left empty column

For one-off costs, put '1' in the frequency column in italics

When the act amends existing provisions and diminishes the number of hours or frequency, negative figures corresponding to the burden reduction should be typed in the corresponding columns