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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**

(presented by the Commission)

{SEC(2007) 112}
{SEC(2007) 113}

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE PROPOSAL

• Grounds for and objectives of the proposal

The Internal Market for Goods is a fundamental element of European Integration. An integrated borderless market is the best way to enhance the competitiveness of the European economy. A better functioning Internal Market is thus a critical element of the re-launched strategy for Jobs and Growth to enable the EU to compete and succeed in a globalised economy, in which our main trading partners have large and unified markets.

Articles 28 and 30 of the EC Treaty entail inter alia that Member States of destination cannot forbid the sale on their territories of products lawfully marketed in another Member State and which are not subject to Community harmonisation, unless the technical restrictions laid down by the Member State of destination are justified on the grounds described in Article 30 of the EC Treaty, or on the basis of overriding requirements of general public importance recognised by the Court of Justice's case law, and that they are proportionate. This is the so-called "principle of mutual recognition" that results from an analysis of the case law of the Court of Justice (see the famous "Cassis de Dijon"-judgment of 20 February 1979 and the Communication from the Commission on this given by the Court of Justice on 20 February 1979 in Case 120/78 (Cassis de Dijon), OJ C 256 of 3 October 1980).

The implementation of the "principle of mutual recognition" under Articles 28 and 30 of the EC Treaty is hampered by several problems:

- (1) The lack of awareness of enterprises and national authorities about the existence of the mutual recognition principle.
- (2) The legal uncertainty about the scope of the principle and the burden of proof. Firstly, it is often unclear to which categories of product mutual recognition applies.
- (3) The risk for enterprises that their products will not get access to the market of the Member State of destination.
- (4) The absence of regular dialogues between competent authorities in different Member States.

In its Communication to the Council, the European Parliament, the European Economic and Social Committee and the Committee of the Regions on the Internal Market Strategy for 2003-2006 [COM(2003)238], the Commission outlined some of the problems related to the implementation of the "mutual recognition principle" in the non-harmonised area of goods and indicated that the possibility of a new legislative instrument would be examined in order to ensure the free circulation of goods within the European Community.

This proposal is one of the deliverables of the Internal Market Strategy for 2003-2006. Its objective is to define the rights and obligations of, on the one hand, national authorities and, on the other, enterprises wishing to sell in a Member State products lawfully marketed in another Member State, when the competent authorities intend to take restrictive measures about the product in accordance with national technical rules. In particular, the proposal

concentrates on the burden of proof by setting out the procedural requirements for denying mutual recognition. Moreover, the proposal aims at reducing the risk for enterprises that their products will not get access to the market of the Member State of destination and at enhancing regular dialogues between competent authorities by establishing one or several "Product Contact Points" in each Member State. Their main task will consist of providing information on technical rules on products to enterprises and to competent authorities in other Member States, as well as providing the contact details of the latter. That will 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.

- **General context**

The combination of various information sources (complaints and infringement cases under Article 226 EC Treaty, notifications pursuant to Directive 98/34/EC, surveys, case studies, literature review and the stakeholder consultations) indicates 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 problems. The Commission has already published interpretative communications setting out how mutual recognition should actually work. It has also organized conferences, seminars and round tables to raise the awareness of businesses and national authorities. It is, however, very difficult to reach businesses through these gatherings, especially when these events are organised across different industrial sectors.

Although current policy has succeeded in eliminating an overwhelming amount of technical barriers without harmonisation measures at EC level, stakeholders indicated that current policy has reached its limits or that it has come to a standstill. Furthermore, the functioning of the mutual recognition principle has been on the political agenda since long. 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 1999.

According to the "Kok report", 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.

The results of the public consultation on the future of the Internal Market launched by the Commission in April 2006 [SEC(2006)1215 of 20.09.2006] confirm that national technical rules still constitute important barriers to free trade within the EU. Respondents 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.

- **Existing provisions in the area of the proposal**

There are no existing provisions in the area of the proposal.

- **Consistency with the other policies and objectives of the Union**

Not applicable.

2. CONSULTATION OF INTERESTED PARTIES AND IMPACT ASSESSMENT

• Consultation of interested parties

Consultation methods, main sectors targeted and general profile of respondents

The objective of the stakeholder consultation via the Commission's "Your Voice in Europe" Internet site 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. 135 replies were received which seems to be the average number of replies for a consultation on a technical issue.

The profile of respondents: representative organisations (22.7%), enterprises (19.7%), public bodies (13.6%) and consumers (31.1%).

Summary of responses and how they have been taken into account

According to the replies to the consultation with the stakeholders via the Commission's "Your Voice in Europe" Internet site, the Commission should do more, inter alia, to improve the functioning of mutual recognition in the non-harmonised area. About 60% of the respondents think that a legislative instrument is necessary whilst about 33% are of the opinion that it is not.

The responses were used for selecting the policy options in the impact assessment.

An open consultation was conducted over the internet from 17/02/2004 to 30/04/2004. The Commission received 135 response(s). The results are available on <http://europa.eu.int/yourvoice/consultations>.

• Collection and use of expertise

There was no need for external expertise.

• Impact assessment

- Option 1: Status quo, i.e. to continue current policy ;
- Option 2: a non-regulatory approach, i.e. to complement current policy with additional actions: the creation of a specific website with a list of products to which mutual recognition applies, a 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 systematic inclusion of the final text of all technical rules notified pursuant to Directive 98/34/EC in the TRIS database, conferences and seminars organised in the Member States and targeted at enterprises and competent authorities, specific publications explaining mutual recognition for specific categories of products, more detailed "mutual recognition clauses" and administrative cooperation through the existing committees established by secondary EC legislation.

- Option 3: the regulatory approach, i.e. the adoption of a regulation that organises mutual recognition in the non-harmonised field of products and which establishes "Product Contact Points". The scope of the regulation would consist of a list of products or aspects of products to which mutual recognition applies. It would define the rights and obligations of, on the one hand, national authorities and, on the other, enterprises wishing to sell in a Member State products lawfully marketed in another Member State, when the competent authorities intend to take restrictive measures about the product in accordance with national technical rules. The task of the "Product Contact Point(s)" in each Member State would consist of providing information on technical rules on products to enterprises and to competent authorities in other Member States, as well as providing the contact details of the latter.
- Option 4: a regulation accompanied by non-legislative actions: Option 4 is based on the 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 into the scope of the regulation, option 4 creates a website with a list of products to which mutual recognition applies, as set out under option 2.

The Commission carried out an impact assessment listed in the Work Programme, whose report is accessible on http://ec.europa.eu/enterprise/regulation/goods/mutrec_en.htm.

3. LEGAL ELEMENTS OF THE PROPOSAL

• Summary of the proposed action

The proposal tackles two aspects of ensuring the free movement of goods in the non-harmonised area: it lays down the procedure that national authorities have to follow when they intend to impose a national technical rule (i.e. in cases when mutual recognition is not being applied for any reason). The proposal also provides for the establishment of one or more Product Contact Points in each Member State, whose main task is to provide information on the technical rules applicable, or to refer the persons interested to the competent authorities/organisations.

With the adoption of the proposal, the Council Decision 3052/95/EC establishing a procedure for the exchange of information on national measures derogating from the principle of the free movement of goods within the Community (OJ L 321, 30.12.1995, p. 1.) has to be repealed.

• Legal basis

Articles 37 and 95 EC.

• Subsidiarity principle

The subsidiarity principle applies insofar as the proposal does not fall under the exclusive competence of the Community.

The objectives of the proposal cannot be sufficiently achieved by the Member States for the following reason(s).

The elimination of technical obstacles to the free movement of goods between Member States cannot be sufficiently achieved by the Member States and can, by reason of the scale of the action, be better achieved at Community level. It is necessary to establish procedures to minimise the possibility that national technical rules create unlawful obstacles to the free movement of goods between Member States. The absence of such procedures in Member States causes additional obstacles to the free movement of goods, since it discourages enterprises to sell their products, lawfully marketed in another Member State, on the territory of the Member State laying down technical rules. Surveys have shown that many enterprises, and in particular small and medium-sized enterprises (SMEs), either adapt their products in order to comply with the technical rules of the Member State of destination, or refrain from marketing them there. National authorities also lack appropriate procedures for applying their technical rules to specific products lawfully marketed in another Member State. The lack of such procedures compromises their ability to assess the conformity of products in accordance with the Treaty.

Few Member States provide for procedures to minimise the possibility that national technical rules creates unlawful obstacles to the free movement of goods between Member States. Given the fact that these obstacles concern in the first place products lawfully marketed in another Member State, Member States do not necessarily have an interest in laying down such procedures.

Community action will better achieve the objectives of the proposal for the following reason(s).

The comments from stakeholders and the review of the situation in Member States reveal that the objective of the elimination of technical obstacles to the free movement of goods cannot be sufficiently achieved by Member States and only Community action can lead to the improvement of the free movement of goods. This proposal respects the subsidiarity principle to the greatest extent, because - if applied correctly - the free movement of goods can be achieved without further harmonisation of national technical rules.

There is legal uncertainty in the Member States concerning the application of the mutual recognition principle, which causes an unpredictable application of the principle and of imposing national technical rules. It results in costs both to enterprises and to society and can lead to reduced trade within the EU by preventing enterprises to enter the market of another Member State. A general framework for the application of national technical rules, where the economic operators concerned can foresee and understand the reasons for the application of a national technical rule to their product is a qualitative indicator that the objectives can be better achieved by the Union.

The proposal defines for the entire EU the rights and the obligations of national authorities on the one hand, and of enterprises who wish to sell their already lawfully marketed product in another Member State on the other hand. The proposal concentrates in particular on the burden of proof by setting out the procedural requirements for denying mutual recognition. The impact assessment shows that there is a gap in the functioning of the free movement of goods in the area covered by the proposal which cannot be solved without a Community legislative action.

The proposal therefore complies with the subsidiarity principle.

- **Proportionality principle**

The proposal complies with the proportionality principle for the following reason(s).

The scope of the proposal is limited to cases where technical obstacles could arise and do arise and it does not involve the areas where the free movement functions well and where there is no barrier caused by a national technical rule.

The proposal is limited to the most essential provisions to achieve its goal.

Considering that the free movement of goods between Member States is the general principle and its exceptions should be interpreted narrowly, the financial and administrative burden was minimised by limiting the scope of the proposal to cases where technical obstacles could arise and do arise. The proposal will not apply when the free movement functions well and where there is no barrier caused by a national technical rule.

- **Choice of instruments**

Proposed instruments: regulation.

Other means would not be adequate for the following reason(s).

The form of a Regulation was chosen as the legislative instrument for the envisaged measures because other means would not be adequate. A Regulation seems to be the most appropriate instrument for achieving the objective. The procedural requirements laid down in this proposal are so precise that they can be immediately implemented in national law.

4. BUDGETARY IMPLICATION

Although the proposal as such has no budgetary implications, the implementation of the regulation will require the establishment of a list of products or aspects of products to which mutual recognition applies and the creation of a website with a list of products to which mutual recognition applies. The establishment of this and the creation of the website will have budgetary implications, which are set out in the legislative financial statement.

5. ADDITIONAL INFORMATION

- **Repeal of existing legislation**

The adoption of the proposal will lead to the repeal of existing legislation.

- **Review/revision/sunset clause**

The proposal includes a review clause.

- **Correlation table**

The Member States are required to communicate to the Commission the text of national provisions transposing the Regulation as well as a correlation table between those provisions and this Regulation.

- **European Economic Area**

The proposed act concerns an EEA matter and should therefore extend to the European Economic Area.

- **Detailed explanation of the proposal**

Articles 2 and 3 define the scope of the proposal, which essentially applies to restrictive decisions taken in respect of any industrially manufactured product or agricultural product, including fish products, lawfully marketed in another Member State, on the basis of a technical rule which is not the subject of harmonisation at Community level, where the direct or indirect effect of that decision is that the product cannot be put on the market in its current form.

Articles 4, 5 and 6 are the core of the proposal, and outline the minimal necessary requirements to be followed by the national authorities before intending to implement a national technical rule (i.e. when mutual recognition is not applied for any reason) in a specific case. The burden of proof is placed on the national authority that is intending to apply a technical rule that restricts the access of the product to the national market.

Articles 7 and 8 define the tasks of the Product Contact Points. Their main task involves providing information on technical rules to enterprises and to the competent authorities of other member States.

Article 9 provides for the possibility to establish a telematics network, in accordance with Decision 2004/387/EC on the interoperable delivery of pan-European eGovernment services to public administrations, businesses and citizens (IDABC).

A reporting scheme is laid down in Article 10.

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

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Articles 37 and 95 thereof,

Having regard to the proposal from the Commission¹,

Having regard to the opinion of the European Economic and Social Committee²,

Having regard to the opinion of the Committee of the Regions³,

Acting in accordance with the procedure laid down in Article 251 of the Treaty⁴,

Whereas:

- (1) The internal market comprises an area without internal frontiers in which the free movement of goods is ensured under the Treaty, which prohibits measures having equivalent effect to quantitative restrictions on imports. That prohibition covers any national measure which is capable of hindering, directly or indirectly, actually or potentially, intra-Community trade in goods.
- (2) Obstacles to the free movement of goods between Member States may be unlawfully created by the national authorities, in the absence of harmonisation of legislation, as a consequence of applying, to goods coming from other Member States where they are lawfully marketed, technical rules laying down requirements to be met by such goods, such as those relating to designation, form, size, weight, composition, presentation, labelling and packaging. The application of such technical rules to products lawfully marketed in another Member States can be contrary to Articles 28 and 30 of the EC Treaty, even if those national rules apply without distinction to all products.

¹ OJ C , , p. .

² OJ C , , p. .

³ OJ C , , p. .

⁴ OJ C , , p. .

- (3) It is necessary to establish procedures to minimise the possibility that such national technical rules create unlawful obstacles to the free movement of goods between Member States. The absence of such procedures in Member States causes additional obstacles to the free movement of goods, since it discourages enterprises from selling their products, lawfully marketed in another Member State, on the territory of the Member State laying down technical rules. Surveys have shown that many enterprises, and in particular small and medium-sized enterprises (SMEs), either adapt their products in order to comply with the technical rules of the Member State of destination, or refrain from marketing them there.
- (4) National authorities also lack appropriate procedures for applying their technical rules to specific products lawfully marketed in another Member State. The lack of such procedures compromises their ability to assess the conformity of products in accordance with the Treaty.
- (5) The Council Resolution of 28 October 1999 on mutual recognition⁵ noted that economic operators and citizens do not always make full and proper use of the mutual recognition principle because they are not sufficiently aware of the principle and its operational consequences. It called upon the Member States to develop appropriate measures in order to provide economic operators and citizens with an effective framework for mutual recognition, inter alia by dealing effectively with requests from economic operators and citizens and by replying rapidly to those requests.
- (6) The European Council of 15 and 16 June 2006 emphasised the importance of a simple, transparent and easy-to-apply regulatory environment and of strengthening consumer and business confidence in the internal market.
- (7) The smooth functioning of the internal market for goods requires adequate and transparent means for solving the problems that result from applying national technical rules to specific products lawfully marketed in another Member State.
- (8) It is not appropriate, in the light of the principles of proportionality and subsidiarity, to harmonise all national technical rules for most or all product categories.
- (9) Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety⁶ specifies that only safe products may be placed on the market. It entitles the authorities to ban any dangerous product with immediate effect or, for the period needed for the various safety evaluations, checks and controls, to ban temporarily a product that could be dangerous. It is necessary, therefore, to exclude from the scope of this Regulation measures taken by the national authorities pursuant to national laws implementing Directive 2001/95/EC.
- (10) 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 safety⁷ establishes inter alia a rapid alert system for the notification of

⁵ OJ C 141 of 19.05.2000, p. 5.

⁶ OJ L 11 of 15.01.2002, p. 4.

⁷ OJ L 31, 1.2.2002, p. 1. Regulation as last amended by Commission Regulation (EC) No 575/2006 of 7 April 2006 (OJ L 100, 8.4.2006, p. 3).

a direct or indirect risk to human health deriving from food or feed. It obliges the Member States to immediately notify the Commission under the rapid alert system of any measure they adopt which is aimed at restricting the placing on the market or forcing the withdrawal from the market or the recall of food or feed in order to protect human health and requiring rapid action. Measures taken by the national authorities pursuant to Article 50(3)(a) of Regulation (EC) No 178/2002 should therefore be excluded from the scope of this Regulation.

- (11) 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 rules⁸ lays down general rules for the performance of official controls to verify compliance with rules aiming, in particular, at preventing, eliminating or reducing to acceptable levels risks to humans and animals, either directly or through the environment, and guaranteeing fair practices in feed and food trade and protecting consumer interests, including feed and food labelling and other forms of consumer information. It lays down a specific procedure to ensure that the economic operator remedies a situation of non-compliance. It is necessary, therefore, to exclude from the scope of this Regulation measures taken by the national authorities pursuant to Article 54 of Regulation (EC) No 882/2004.
- (12) Directive 2004/49/EC of the European Parliament and of the Council of 29 April 2004 on safety on the Community's railways and amending Council Directive 95/18/EC on the licensing of railway undertakings and Directive 2001/14/EC on the allocation of railway infrastructure capacity and the levying of charges for the use of railway infrastructure and safety certification (Railway Safety Directive)⁹ provides for an authorisation procedure for the placing in service of existing rolling stock, leaving scope for the application of certain national rules. Measures taken by the national authorities pursuant to Article 14 of that Directive should therefore be excluded from the scope of this Regulation.
- (13) Council Directive 96/48/EC of 23 July 1996 on the interoperability of the trans-European high-speed rail system¹⁰ and Directive 2001/16/EC of the European Parliament and of the Council of 19 March 2001 on the interoperability of the trans-European conventional rail system¹¹ provide for gradual harmonisation of systems and operations through the progressive adoption of Technical Specifications for Interoperability. Systems and equipment that are within the scope of those Directives should therefore be excluded from the scope of this Regulation.
- (14) It is for the national authority to show in each case that the application of national technical rules to specific products lawfully marketed in another Member State falls within the permitted exceptions.

⁸ OJ L 191, 28.5.2004, p. 1. Regulation as last amended by Commission Regulation (EC) No 776/2006 of 23 May 2006 (OJ L 136, 24.5.2006, p. 3).

⁹ OJ L 164, 30.4.2004, p. 44-; corrected version in OJ L 220, 21.6.2004, p. 16.

¹⁰ OJ L 235, 17.9.1996, p. 6. Directive as last amended by Directive 2004/50/EC of the European Parliament and of the Council (OJ L 164, 30.4.2004, p. 114).

¹¹ OJ L 110, 20.4.2001, p. 1. Directive as last amended by Directive 2004/50/EC.

- (15) Any national decision to which this Regulation applies should specify the methods of appeal available so that economic operators can bring a case before the competent national court or tribunal.
- (16) Decisions of national courts or tribunals assessing the legality of cases in which products lawfully marketed in another Member State are not granted access to the national market on account of the application of a technical rule should be excluded from the scope of this Regulation.
- (17) It is important for the internal market for goods to ensure the accessibility of national technical rules, so that enterprises, and in particular SMEs, can gather reliable and precise information about the law in force in the Member State of destination.
- (18) It is therefore necessary to implement principles of administrative simplification, inter alia through the establishment of a system of Product Contact Points. This should be designed to ensure that enterprises can gain access to information in a transparent and correct manner, so that the delays, costs and dissuasive effects which arise from national technical rules can be avoided.
- (19) In order to facilitate the free movement of goods, it should be possible for Product Contact Points to provide high-quality information about national technical rules and their implementation. Since the creation of Product Contact Points should not interfere with the allocation of functions among competent authorities within each national regulatory system, it should be possible for the number of Product Contact Points per Member State to vary according to regional or local competencies.
- (20) Member States should be able to entrust the role of Product Contact Point, not only to existing services within the public administration, but also to chambers of commerce, professional organisations or private bodies, in order not to increase the administrative costs for enterprises and competent authorities alike.
- (21) Member States should ensure that the Product Contact Points can obtain and provide, on request, detailed information about any decision to which this Regulation applies, unless the disclosure of such information would undermine the protection of commercial interests of an economic operator, including intellectual property.
- (22) Member States and the Commission should work closely together to facilitate the training of staff employed in Product Contact Points and to encourage Product Contact Points to make information on the application of national technical rules available in other Community languages.
- (23) In view of the development and establishment of a pan-European eGovernment service and the underlying interoperable telematic networks, the possibility of establishing an electronic system for the exchange of information between Product Contact Points should be envisaged, in accordance with Decision 2004/387/EC of the European Parliament and of the Council of 21 April 2004 on the interoperable delivery of pan-European eGovernment services to public administrations, businesses and citizens (IDABC)¹².

¹²

OJ L 144, 30.4.2004, p. 62; corrected version in OJ L 181, 18.5.2004, p. 25.

- (24) Reliable and efficient monitoring and evaluation mechanisms should be established in order to provide information on the implementation of this Regulation.
- (25) The monitoring scheme established by Decision 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 Community¹³ has proved largely unsuccessful in that its implementation has not provided the Commission with sufficient information to identify sectors where harmonisation might be appropriate. Nor has it brought about a rapid resolution of certain free movement problems. Decision 3052/95/EC should therefore be repealed.
- (26) Since the objective of the action to be taken, namely the elimination of technical obstacles to the free movement of goods between Member States, cannot be sufficiently achieved by the Member States and can therefore, by reason of the scale of the action, be better achieved at Community level, the Community may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve this objective.
- (27) The measures necessary for the implementation of this Regulation should be adopted in accordance with Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission¹⁴,

HAVE ADOPTED THIS REGULATION:

Chapter 1

Subject-matter and scope

Article 1

This Regulation lays down the rules and procedures to be followed by the national authorities when taking or intending to take a decision, as referred to in Article 2(1), affecting the free movement of a product lawfully marketed in another Member State.

It also provides for the establishment, in each Member State, of Product Contact Points for the provision of information inter alia on the national technical rules applicable.

¹³ OJ L 321, 30.12.1995, p. 1.

¹⁴ OJ L 184, 17.7.1999, p. 23. Decision as amended by Decision 2006/512/EC (OJ L 200, 22.7.2006, p. 11).

Article 2

1. This Regulation applies to decisions taken in respect of any industrially manufactured product or agricultural product, including fish products, lawfully marketed in another Member State, on the basis of a technical rule, where the direct or indirect effect of that decision is any of the following:
 - (a) to ban that product or type of product;
 - (b) to refuse to allow the product or type of product to be placed on the market;
 - (c) to require modification of the product or type of product before it can be placed or kept on the market;
 - (d) to require the withdrawal of that product or type of product from the market.

For the purposes of point (c) of the first subparagraph, modification of the product or type of product means any modification of one or more of the characteristics of a particular product or a particular type of product as listed in a technical specification within the meaning of Article 1(3) of Directive 98/34/EC of the European Parliament and of the Council¹⁵.

2. For the purposes of this Regulation, a technical rule means a law, regulation or administrative provision of a Member State, which is not the subject of harmonisation at Community level, compliance with which is compulsory for the marketing or use of a product or type of product in the territory of a Member State, and which lays down either of the following:
 - (a) the characteristics required of that product or type of product, such as levels of quality, performance, safety or dimensions, including the requirements applicable to the product or product type as regards the name under which it is sold, terminology, symbols, testing and test methods, packaging, marking or labelling and conformity assessment procedures;
 - (b) any other requirement which is imposed on the product or type of product for the purposes of protecting consumers or the environment, and which affects the life cycle of the product after it has been placed on the market, such as conditions of use, recycling, reuse or disposal, where such conditions can significantly influence the composition or nature of the product or type of product, or its marketing.

Article 3

1. This Regulation shall not apply to decisions of a judicial nature delivered by national courts or tribunals.
2. This Regulation shall not apply in the case of measures taken by the national authorities of the Member States pursuant to:

¹⁵ OJ L 204, 21.7.1998, p. 37.

- (a) Article 8(d), (e) or (f) of Directive 2001/95/EC;
 - (b) Article 50(3)(a) of Regulation (EC) No 178/2002;
 - (c) Article 54 of Regulation (EC) No 882/2004;
 - (d) Article 14 of Directive 2004/49/EC.
3. This Regulation shall not apply to systems and equipment falling within the scope of Directive 96/48/EC and Directive 2001/16/EC.

Chapter 2

Application of a technical rule

Article 4

1. Where a national authority intends to adopt a decision as referred to in Article 2(1), it shall send the economic operator identified in accordance with Article 5 written notice of its intention, specifying the technical rule on which the decision is to be based and setting out sufficient technical or scientific evidence that the intended decision is justified on one of the grounds of public interest listed in Article 30 of the Treaty or by reference to another overriding requirement in the public interest, and that it is appropriate for securing the attainment of the objective pursued and does not go beyond what is necessary in order to attain that objective.

The economic operator concerned shall, following receipt of such notice, be allowed at least twenty working days in which to submit comments.

2. Any decision as referred to in Article 2(1) shall be notified to the economic operator concerned and shall state the reasons on which it is based, including the reasons for rejecting any arguments put forward by the operator.

It shall also specify the remedies available under the provisions in force in the Member State concerned and the time limits applying to such remedies.

3. Where, after giving written notification in accordance with paragraph 1 of this Article, the national authority decides not to adopt a decision as referred to in Article 2(1), it shall inform the economic operator concerned accordingly.

Article 5

The written notice referred to in Article 4(1) shall be sent to the producer within the meaning of Article 2(e) of Directive 2001/95/EC, when his identity and contact details appear on the packaging or labelling of the product, or in the accompanying documents.

The written notice shall be sent to the distributor within the meaning of Article 2(f) of Directive 2001/95/EC, when his identity and contact details appear on the packaging or labelling of the product, or in the accompanying documents.

When the identity and contact details of the producer and distributor appear neither on the packaging or labelling of the product nor in the accompanying documents, the written notice shall be sent to any other producer or distributor within the meaning of the provisions referred to in the first and second paragraphs.

Article 6

Any decision as referred to in Article 2(1) may be challenged before the national courts.

Chapter 3

Product Contact Points

Article 7

1. Each Member State shall designate one or more Product Contact Points in its territory and shall communicate their contact details to the other Member States and to the Commission.
2. The Commission shall publish and regularly update the list of Product Contact Points.

Article 8

1. Product Contact Points shall provide, upon request, the following information:
 - (a) the technical rules applicable to a specific type of product in the national territory;
 - (b) the contact details of the national authorities enabling them to be contacted directly, including the particulars of the authorities responsible for supervising the implementation of the particular technical rules in the national territory;
 - (c) the remedies generally available in the national territory in the event of a dispute between the competent authorities and a producer or a distributor;
 - (d) the contact details of any associations or organisations other than the national authorities, from which producers or distributors may obtain practical assistance in the national territory.
2. Product Contact Points shall respond within twenty working days of receipt of any request to transmit the information referred to in paragraph 1.

3. The Product Contact Point in the Member State in which the producer and distributor concerned have lawfully marketed the product in question shall be informed of written notices and decisions under Article 4, unless the disclosure of such information would undermine the protection of commercial interests of that economic operator, including intellectual property rights. That Product Contact Point shall have the right to submit its observations to the national authority concerned.

Article 9

The Commission may establish a telematic network for the implementation of the exchange of information between Product Contact Points under this Regulation, in accordance with the procedure provided for in Article 11(2).

Chapter 4

Final Provisions

Article 10

1. Member States shall send to the Commission, upon its request, an in-depth report on the implementation of this Regulation, including detailed information about any written notices or decisions sent pursuant to Article 4(1), (2) or (3).
2. The Commission shall, within five years following the date specified in Article 13, submit a report on the implementation of this Regulation to the European Parliament and the Council.

Article 11

1. The Commission shall be assisted by a committee, composed of representatives of the Member States and chaired by a representative of the Commission.
2. Where reference is made to this paragraph, the advisory procedure laid down in Article 3 of Decision 1999/468/EC shall apply, in compliance with Article 7(3) and Article 8 thereof.

Article 12

Decision 3052/95/EC is repealed.

Article 13

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

For the European Parliament
The President

For the Council
The President

LEGISLATIVE FINANCIAL STATEMENT

1. NAME OF THE PROPOSAL:

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

2. ABM / ABB FRAMEWORK

Policy Area(s) concerned and associated Activity/Activities: ABB2 – Internal Market for Goods and Sectoral Policies.

3. BUDGET LINES

3.1. Budget lines (operational lines and related technical and administrative assistance lines (ex- B..A lines)) including headings:

02.03.01

3.2. Duration of the action and of the financial impact:

Continuous

3.3. Budgetary characteristics:

Budget line	Type of expenditure		New	EFTA contribution	Contributions from applicant countries	Heading in financial perspective
02.03.01	Non-comp	Diff	NO	YES	NO	1a

4. SUMMARY OF RESOURCES

4.1. Financial Resources

4.1.1. Summary of commitment appropriations (CA) and payment appropriations (PA)

EUR million (to 3 decimal places)

Expenditure type	Section no.		2007	2008	2009	2010	2011	2011 and later	Total
Operational expenditure¹⁶									
Commitment Appropriations (CA)	8.1.	a	0.2	0	0	0	0	0	0.2
Payment Appropriations (PA)		b	0.1	0.1	0	0	0	0	0.2

¹⁶ Expenditure that does not fall under Chapter xx 01 of the Title xx concerned.

Administrative expenditure within reference amount¹⁷

Technical & administrative assistance (NDA)	8.2.4.	c	0	0.5	0.05	0.05	0.05	0.05	0.7
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TOTAL REFERENCE AMOUNT

Commitment Appropriations		a+c	0.2	0.5	0.05	0.05	0.05	0.05	0.9
Payment Appropriations		b+c	0.1	0.6	0.05	0.05	0.05	0.05	0.9

Administrative expenditure not included in reference amount¹⁸

Human resources and associated expenditure (NDA)	8.2.5.	d	0	0	0	0	0	0	0
Administrative costs, other than human resources and associated costs, not included in reference amount (NDA)	8.2.6.	e	0.05	0.05	0.15	0.25	0.15	0.15	0.8

Total indicative financial cost of intervention

TOTAL CA including cost of Human Resources		a+c +d +e	0.25	0.55	0.20	0.30	0.20	0.20	1.7
TOTAL PA including cost of Human Resources		b+c +d +e	0.15	0.65	0.20	0.30	0.20	0.20	1.7

Co-financing details: No co-financing

4.1.2. Compatibility with Financial Programming

The proposal is compatible with existing financial programming. Its financial consequences will be financed by credits already foreseen for the budgetary line concerned in the official financial programming of the Commission.

4.1.3. Financial impact on Revenue

The proposal has no financial implications on revenue

4.2. Human Resources FTE (including officials, temporary and external staff) – see detail under point 8.2.1.

Annual requirements	2007	2008	2009	2010	2011	2012 and later
Total number of human resources	1.4	1.4	1.4	1.4	1.4	1.4

¹⁷ Expenditure within article xx 01 04 of Title xx.

¹⁸ Expenditure within chapter xx 01 other than articles xx 01 04 or xx 01 05.

5. CHARACTERISTICS AND OBJECTIVES

5.1. Need to be met in the short or long term

The proposal requires, as an accompanying measure, the establishment of a detailed list of products or aspects of products to which mutual recognition applies and the subsequent creation of a website on which the list will be published. It may be necessary eventually to organise seminars about the implementation of the regulation. In addition, the proposal provides for the establishment of a consultative committee.

The general objectives of the proposal are set out in the explanatory memorandum.

5.2. Value-added of Community involvement and coherence of the proposal with other financial instruments and possible synergy

The creation of the internal market for goods is one of the objectives of the European Community. 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 as quantitative restrictions on imports of goods is one of the main principles of the EC Treaty (Articles 3(1)(a) and 28 to 30).

A comparison of the options points to a regulatory approach 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 the 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.

5.3. Objectives, expected results and related indicators of the proposal in the context of the ABM framework

In the context of the enlarged single market, action at EU level carries an evident added value, providing European businesses with a large, single market and allowing economies of scale. At the same time, the smooth functioning of this market requires for its very supra-national nature an EU-level intervention, while limiting the EC intervention to the strict necessary.

The main objective of the proposal is to ensure the free movement of goods in the non-harmonised area. It should impose the minimum economic burden consistent with achieving this objective, and it should be applied effectively and easily. The impact assessment comprises a more detailed and technical description of the objectives and the expected results.

5.4. Method of Implementation (indicative)

Centralised Management - directly by the Commission

Relevant comments: The establishment of a detailed list of products or aspects of products to which mutual recognition applies and the subsequent creation of a website on which the list will be published requires the procurement of services.

6. MONITORING AND EVALUATION

6.1. Monitoring system

The establishment of a detailed list of products or aspects of products to which mutual recognition applies and the subsequent creation of a website on which the list will be published will be monitored by the Commission, in cooperation with the representatives of the Member States in the committee established by the Regulation. In addition, Product Contact Points may be requested, if necessary, to participate in this monitoring.

6.2. Evaluation

6.2.1. Ex-ante evaluation

Surveys and existing literature show that a detailed list of products or aspects of products to which mutual recognition applies does not yet exist.

6.2.2. Measures taken following an intermediate/ex-post evaluation (lessons learned from similar experiences in the past)

Not applicable.

6.2.3. Terms and frequency of future evaluation

The terms and the frequency of future evaluation activities will be determined in accordance with the applicable rules.

7. ANTI-FRAUD MEASURES

Full application of internal control standards No 14, 15, 16, 17, 18, 19, 20, 21.

The Commission shall ensure that, when actions financed under the present programme are implemented, the financial interests of the Community are protected by the application of preventive measures against fraud, corruption and any other illegal activities, by effective checks and by the recovery of the amounts unduly paid and, if irregularities are detected, by effective, proportional and dissuasive penalties, in accordance with Council Regulation (EC, Euratom) No 2988/95 of 18 December 1995 on the protection of the European Communities financial interests, and with Regulation (EC) No 1073/1999 of the European Parliament and of the Council of 25 May 1999 concerning investigations conducted by the European Anti-Fraud Office (OLAF).

8. DETAILS OF RESOURCES

8.1. Objectives of the proposal in terms of their financial cost

Commitment appropriations in EUR million (to 3 decimal places)

(Headings of Objectives, actions and outputs should be provided)	Type of output	Av. cost	2007		2008		2009		2010		2011		2012 and later		TOTAL	
			No. outputs	Total cost	No. outputs	Total cost	No. outputs	Total cost	No. outputs	Total cost	No. outputs	Total cost	No. outputs	Total cost	No. outputs	Total cost
Establishment of a list of products to which mutual recognition applies	Report containing such list		1	0.2	0	0	0	0	0	0	0	0	0	0	1	0.2
TOTAL COST				0.2	0	0	0	0	0	0	0	0	0	0	0	0.2

8.2. Administrative Expenditure

8.2.1. Number and type of human resources

Types of post		Staff to be assigned to management of the action using existing resources (number of posts/FTEs)					
		2007	2008	2009	2010	2011	2012
Officials or temporary staff ¹⁹ (XX 01 01)	A*/AD	1	1	1	1	1	1
	B*, C*/AST	0.4	0.4	0.4	0.4	0.4	0.4
Staff financed ²⁰ by art. XX 01 02		0	0	0	0	0	0
Other staff ²¹ financed by art. XX 01 04/05		0	0	0	0	0	0
TOTAL		1.4	1.4	1.4	1.4	1.4	1.4

8.2.2. Description of tasks deriving from the action

Besides the follow-up of the proposal and the assessment of the transposition of the directive into national law, the task will consist of managing:

- The establishment of a detailed list of products or aspects of products to which mutual recognition applies;
- The subsequent creation of a website on which the list will be published.

8.2.3. Sources of human resources (statutory)

Posts to be redeployed using existing resources within the managing service (internal redeployment)

8.2.4. Other Administrative expenditure included in reference amount (XX 01 04/05 – Expenditure on administrative management)

EUR million (to 3 decimal places)

Budget line (number and heading)	2007	2008	2009	2010	2011	2012 and later	TOTAL
1 Technical and administrative assistance (including related staff costs)							
Executive agencies	0	0	0	0	0	0	0
Other technical and administrative assistance							
- <i>intra muros</i>	0	0	0	0	0	0	0
- <i>extra muros</i>	0	0.5	0.05	0.05	0.05	0.05	0.7
Total Technical and administrative assistance	0	0.5	0.05	0.05	0.05	0.05	0.7

¹⁹ Cost of which is NOT covered by the reference amount.

²⁰ Cost of which is NOT covered by the reference amount.

²¹ Cost of which is included within the reference amount.

8.2.5. *Financial cost of human resources and associated costs not included in the reference amount*

EUR million (to 3 decimal places)

Type of human resources	2007	2008	2009	2010	2011	2012
Officials and temporary staff (XX 01 01)	0	0	0	0	0	0
Staff financed by Art XX 01 02 (auxiliary, END, contract staff, etc.) (specify budget line)	0	0	0	0	0	0
Total cost of Human Resources and associated costs (NOT in reference amount)	0	0	0	0	0	0

8.2.6. *Other administrative expenditure not included in reference amount*

EUR million (to 3 decimal places)

	2007	2008	2009	2010	2011	2012 and later	TOTAL
XX 01 02 11 01 – Missions	0.05	0.05	0.05	0.05	0.05	0.05	0.3
XX 01 02 11 02 – Meetings & Conferences	0	0	0.1	0.1	0	0	0.2
XX 01 02 11 03 – Committees ²²	0	0	0	0.1	0.1	0.1	0.3
XX 01 02 11 04 – Studies & consultations	0	0	0	0	0	0	0
XX 01 02 11 05 - Information systems	0	0	0	0	0	0	0
2 Total Other Management Expenditure (XX 01 02 11)	0.05	0.05	0.15	0.25	0.15	0.15	0.8
3 Other expenditure of an administrative nature (specify including reference to budget line)	0	0	0	0	0	0	0
Total Administrative expenditure, other than human resources and associated costs (NOT included in reference amount)	0.05	0.05	0.15	0.25	0.15	0.15	0.8

²²

Advisory committee.