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Committee on Legal Affairs

2007/0028(COD)

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OPINION

of the Committee on Legal Affairs

for the Committee on the Internal Market and Consumer Protection

on the proposal for a European Parliament and Council regulation 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
(COM(2007)0036 – C6-0065/2007 – 2007/0028(COD))

Draftsman: Jacques Toubon

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SHORT JUSTIFICATION

Under Articles 28 and 30 of the Treaty Member States of destination cannot forbid the sale on their territories of products which are 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 are proportionate. This is the so-called 'principle of mutual recognition'.

The implementation of this principle is hampered by several problems: (i) the lack of awareness of enterprises and national authorities about the existence of the mutual recognition principle; (ii) the legal uncertainty about the scope of the principle and the burden of proof, because it is often unclear to which categories of product mutual recognition applies; (iii) the risk for enterprises that their products will not get access to the market of the Member State of destination; (iv) the absence of regular dialogues between competent authorities in different Member States. It is therefore necessary to lay down procedures to ensure that national technical rules do not create illegal barriers to the free movement of goods between Member States.

The draftsman has made changes to the proposal for a regulation in order to make its scope clearer, to improve access to information for economic operators and to make the Commission's task of monitoring easier. The amendments also seek to increase the responsibility of the Community's executive arm: as the guardian of the Treaties, it has a duty to exercise its monitoring role more actively.

AMENDMENTS

The Committee on Legal Affairs calls on the Committee on the Internal Market and Consumer Protection, as the committee responsible, to incorporate the following amendments in its report:

Text proposed by the Commission¹

Amendments by Parliament

Amendment 1 Citation 1

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

Having regard to the Treaty establishing the European Community, and in particular **Article 95** thereof,

¹ Not yet published in OJ.

Amendment 2

Recital 1

(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.***

(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.

Justification

This sentence has been replaced by Recitals 1a and 1b, which spell out the ban on any national measure which is capable of hindering intra-Community trade directly or indirectly, actually or potentially.

Amendment 3

Recital 1 a (new)

(1a) Any trade rules in the Member States which are capable of hindering intra-Community trade directly or indirectly, actually or potentially, have to be deemed to be a measure having equivalent effect to quantitative restrictions on imports and, accordingly, are prohibited by Article 28 of the Treaty. Thus, standards which are applicable without distinction to national and imported products and the application of which is likely to reduce their volume of sales also constitute, in principle, measures having equivalent effect which are prohibited by Article 28 of the Treaty.

Justification

The procedure laid down in the proposal for a regulation represents an exception to the principle of mutual recognition. The purpose of Recitals 1a and 1b is to spell out the ban on any national measure which is capable of hindering intra-Community trade directly or

indirectly, actually or potentially. They constitute a warning directed at the Member States, based on the case law of the Court of Justice¹.

Amendment 4
Recital 1 b (new)

(1b) According to the Court of Justice a system which maintains the requirement, even a purely formal one, for import licences or any other similar procedure is, in principle, contrary to Article 30 of the Treaty. The fact of imposing import formalities which create a system of preventive authorisation is actually capable of hindering intra-Community trade and of hindering market access for products which are lawfully manufactured and marketed in other Member States. The obstacle is even more serious if the system exposes the products concerned to additional costs. In such circumstances this is not a simple restriction or simple prohibition of certain sales arrangements. The fact of imposing preventive authorisation must therefore be considered to constitute a barrier to trade between the Member States which falls within the scope of Article 28 of the Treaty.

Justification

The purpose of Recitals 1a and 1b is to spell out the ban on any national measure which is capable of hindering intra-Community trade directly or indirectly, actually or potentially. They constitute a warning directed at the Member States, based on the case law of the Court of Justice².

Amendment 5
Recital 2

¹ See, in particular, the judgments of 11 July 1974, *Dassonville*, 8/74, ECR p. 837, paragraph 5; 19 June 2003, *Commission v Italy*, C-420/01, ECR p. I-6445, paragraph 25; 26 May 2005, *Burmanjer and others*, C-20/3, ECR p. I-4133, paragraph 23; and 20 February 1979 *Rewe-Zentral 'Cassis de Dijon'*, 120/78, ECR p. 649.

² See the judgments of 8 February 1983, *Commission v United Kingdom*, known as 'UHT milk', 124/81, ECR p. 203, paragraph 9 and 5 July 1990, *Commission v Belgium*, C-304/88, ECR p. I-2801, paragraph 9; see also the judgment of 26 May 2005, *Commission v France*, C-212/03, ECR p. I-4213, paragraph 16, and the judgment of 23 October 1977, *Franzén*, C-189/95, ECR p. 5909, paragraph 71.

(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.***

(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.

Justification

The final sentence of this recital is covered by the new Recitals 1a and 1b.

Amendment 6
Recital 7a (new)

(7a) 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 and of rules on Information Society services¹ obliges Member States to communicate to the Commission and the other Member States any draft technical rules concerning industrially manufactured products and agricultural (including fish) products and a statement of the grounds which make the enactment of such technical rules necessary. It is necessary, however, to ensure that, following the adoption of a national technical rule, the principle of mutual recognition is correctly applied in individual cases to specific products. This Regulation lays down a procedure for the application of the principle of mutual recognition in individual cases, through the obligation for the national authorities to

specify the technical or scientific grounds on which the specific product in its current form cannot be authorised on the national market, in accordance with Articles 28 and 30 of the Treaty. National authorities are not required under this Regulation to state the grounds for the technical rule itself.

¹ OJ L 204, 21.7.1998, p. 37. Directive last amended by Council Directive 2006/96/EC (OJ L 363, 20.12.2006, p. 81).

Justification

La directive 98/34 et le règlement doivent être deux systèmes complémentaires, le règlement ne doit pas remettre en cause les procédures de notifications existantes.

En outre, en communiquant à la Commission toute règle technique à l'état de projet relative à un produit industriel, un produit agricole ou de la pêche et en lui notifiant les éléments qui le poussent à prendre cette mesure technique, l'Etat membre par la directive 98/34 s'assure ainsi que les contraintes pesant sur les autorités nationales ensuite seront les plus légères possible : il ne devra pas rejustifier la règle technique en elle-même. Le présent règlement renforce le système ex ante en obligeant les Etats membres à notifier tout projet de règle technique aux opérateurs économiques concernés par l'intermédiaire des points de contact "produit". Il assure donc une information à l'interlocuteur direct avant que l'entrave ne soit créée et encourage le dialogue entre les entreprises et les Etats membres.

Amendment 7 Recital 8 a (new)

(8a) A distinction must be drawn between the obligation to provide the consumer with specific information concerning the product by affixing certain specifications to the product or by appending to it documents such as instructions for use, and the obligation to provide such information in a given language. This is why the obligation to provide specific information concerning a product by affixing certain specifications to the product or by appending documents to it constitutes a 'technical rule' for the purposes of this Regulation, whereas the obligation to provide mandatory labelling information and instructions for use at

least in the language(s) of the area in which those products are to be marketed does not constitute a technical rule within the meaning of this Regulation.

Justification

The reason for this recital is the concern not only to ensure proper information for operators and consumers but also to clarify the scope of this regulation in accordance with the case law of the Court of Justice. In its COLIM NV judgment (C-33/97) the Court of Justice spelled out what was and was not covered by the idea of a 'technical rule', and this must therefore be clarified in a recital so as to ensure the satisfactory application of this regulation.

Amendment 8
Recital 8 b (new)

(8b) Procedures entailing prior authorisation do not constitute a technical rule within the meaning of this Regulation.

Justification

There are national procedures for authorising the marketing of products (medical products). Under Community law, where any prior authorisation procedure is concerned there is no obligation to have a standstill period, and this regulation therefore does not apply.

Amendment 9
Recital 9

(9) Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety 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.

(9) Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety specifies that only safe products may be ***marketed, and lays down the obligations of producers and distributors with regard to product safety***. 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. ***Under that Directive the authorities are also entitled to take the requisite steps so as to apply appropriate measures, such as those referred to in Article 8(1)(b)-(f) of the Directive, with the***

requisite speed in cases where products pose a serious risk. Measures taken by the national authorities pursuant to national laws implementing Article 8(1)(d)-(f) and Article 8(3) of Directive 2001/95/EC should therefore be excluded from the scope of this Regulation.

Justification

This amendment clarifies the content of Directive 2001/95/EC on product safety.

Amendment 10
Recital 10

(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 safety establishes inter alia a rapid alert system for the notification of 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.

(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 safety establishes inter alia a rapid alert system for the notification of 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 ***Member States'*** authorities pursuant to Article 50(3)(a) ***and Article 54*** of Regulation (EC) No 178/2002 should therefore be excluded from the scope of this Regulation.

Justification

It is necessary to refer to Article 54 of Regulation (EC) No 178/2002, which provides for emergency measures to withdraw products from the market in the event of the Commission failing to act with regard to food safety.

Amendment 11

Recital 11 a (new)

(11a) This Regulation is without prejudice to Community directives which harmonise measures concerning the protection of human, animal or plant health and which lay down procedures for monitoring compliance with such measures.

Justification

There is a specific procedure concerning the protection of human, animal and plant health which continues to apply, because monitoring is already harmonised within the European Union. Any specific procedure which has already been harmonised is excluded from the scope of the proposal for a regulation (see judgment C-249/92) and is thus not covered by the rules concerning the inversion of the burden of proof, the standstill period, etc.

Amendment 12
Recital 14

(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.

(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 ***and that less restrictive measures cannot be used. The written notice sent to the economic operator by the national authority should enable the former to submit comments, in good faith, on all the relevant aspects of the intended decision to limit access to the market. The authority should consequently inform the economic operator concerned of the technical and scientific reasons for the intended decision, in accordance with the principle of proportionality. If there is no response from the economic operator by the end of the time allowed, there is nothing to prevent the national authority taking more restrictive measures.***

Justification

It is essential to balance obligations between the operator and the Member State of destination. Consequently, it has to be ensured that if the economic operator has not responded within the time allowed the State may impose an additional national technical rule.

Amendment 13
Recital 23

(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).

(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 **provided for**, 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).

Justification

It is not enough to envisage the establishment of such a system: it must be provided for. See also the amendment to Article 9.

Amendment 14
Article 2, paragraph 1, subparagraph 1, introductory part

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:

1. This Regulation applies to decisions taken in respect of any **new or used** 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:

Amendment 15
Article 2, paragraph 1, subparagraph 1, point (c)

(c) to require modification of the product or type of product before it can be placed or kept on the market;

(c) to require modification of the product or type of product before it can be placed or kept on the market, **or to permit its use or, in the case of vehicles, its registration or**

use;

Amendment 16
Article 3, paragraph 2, point a

(a) Article 8(d), **(e) or** (f) of Directive 2001/95/EC;

(a) Article 8**(1)**(d)-(f) **and Article 8(3)** of Directive 2001/95/EC;

Justification

The amendment spells out the measures for withdrawal from the market applicable to all product categories in the event of serious risk.

Amendment 17
Article 3, paragraph 2, point (b)

(b) Article 50(3)(a) of Regulation (EC) No 178/2002;

(b) Article 50(3)(a) **and Article 54** of Regulation (EC) No 178/2002;

Justification

The amendment hereby excludes from this regulation Article 54 of Regulation (EC) No 178/2002, which provides for emergency measures to withdraw products from the market in the event of the Commission failing to act with regard to food safety.

Amendment 18
Article 4, paragraph 1, subparagraph 2 a (new)

National authorities shall not be required to state the grounds for the technical rule itself where this has already been done under Directive 98/34/EC.

Justification

Given that Recital 7a explains the relationship between the regulation and Directive 98/34, the operative part of the regulation needs to include a reference to that relationship.

Amendment 19
Article 4, paragraph 3 a (new)

3a. The national authority shall inform the Commission of the decision to commence the procedure laid down by this article and of all action taken following that decision.

Justification

To enable the Commission to carry out its monitoring function, it must be informed of the decision to commence the procedure and of all action taken following that decision.

Amendment 20

Article 5 a (new)

Article 5a

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 and that less restrictive measures cannot be used. The written notice shall enable the economic operator to submit comments, in good faith, on all the relevant aspects of the intended decision to limit access to the market. The national authority shall consequently inform the economic operator concerned of the technical and scientific reasons for the intended decision, in accordance with the principle of proportionality. If there is no response from the economic operator, the national authority may take measures after the expiry of the time limit.

Or. fr

Justification

It is essential to balance obligations between the operator and the Member State of destination. Consequently, it has to be ensured that if the economic operator has not responded within the time allowed the State may impose an additional national technical rule.

Amendment 21
Article 8 a (new)

Article 8a

1. Each Member State shall collect the information referred to in Article 8(1) in its own database.

2. The Commission shall ensure that the databases are interconnected and shall use the information for the purposes of:

- checking the information and checking that the technical rules in question comply with Community law;

- making this information accessible, via the Internet, to economic operators and to the Member States.

3. The Member States shall ensure that all the information supplied to the Commission is kept up to date.

Or. fr

Justification

The Commission must ensure that the databases are interconnected, to check that the national technical rules comply with Community law and to make the information relating thereto accessible to economic operators.

Amendment 22
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).

No later than 31 December 2009 the Commission *shall* 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).

Justification

This amendment makes it mandatory for the Commission to establish a telematic network within a reasonable period of time.

Amendment 23
Article 10, paragraph 2 a (new)

2a. The Commission shall draw up, publish and regularly update an indicative list of products which are not subject to Community harmonisation.

Justification

Such an indicative list of non-harmonised products may be drawn up on the basis of the customs code and customs nomenclature, and on the basis of the judgments of the Court of Justice, which is the final arbiter as to whether a product belongs to the harmonised sector or not.

Amendment 24
Article 13, paragraph 1 a (new)

Notwithstanding the first paragraph of this article, Articles 7 and 8 shall apply with effect from the first day of the month following a period of one year after the date of publication of this Regulation.

Justification

Since this text is a regulation, its provisions are immediately applicable. This amendment is intended to postpone the point at which the regulation takes effect, since the establishment of Product Contact Points and the development of a network enabling operators to consult the list of non-harmonised products will require substantial financial investment, training in the use of those tools for officials and the introduction in practice of the inversion of the burden of proof.

PROCEDURE

Title	Application of certain national technical rules to products lawfully marketed in another Member State
References	COM(2007)0036 - C6-0065/2007 - 2007/0028(COD)
Committee responsible	IMCO
Opinion by Date announced in plenary	JURI 13.3.2007
Drafts(wo)man Date appointed	Jacques Toubon 10.4.2007
Discussed in committee	25.6.2007
Date adopted	11.9.2007
Result of final vote	+: 24 -: 0 0: 0
Members present for the final vote	Marek Aleksander Czarnecki, Bert Doorn, Monica Frassoni, Giuseppe Gargani, Lidia Joanna Geringer de Oedenberg, Othmar Karas, Piia-Noora Kauppi, Klaus-Heiner Lehne, Katalin Lévai, Alain Lipietz, Hans-Peter Mayer, Manuel Medina Ortega, Hartmut Nassauer, Aloyzas Sakalas, Francesco Enrico Speroni, Daniel Stroj, Rainer Wieland
Substitute(s) present for the final vote	Janelly Fourtou, Jean-Paul Gauzès, Barbara Kudrycka, Michel Rocard, Jacques Toubon
Substitute(s) under Rule 178(2) present for the final vote	Albert Deß, María Sornosa Martínez