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COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT AND THE COUNCIL

First Report on the application of Regulation (EC) No 764/2008 of the European Parliament and of the Council of 9 July 2008 laying down procedures relating to the application of certain national technical rules to products lawfully marketed in another Member State and repealing Decision No 3052/95/EC

(Text with EEA relevance)

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1. INTRODUCTION

In accordance with Article 12(3) of Regulation (EC) No 764/2008[1] ('the Mutual Recognition Regulation' or 'the Regulation'), the Commission shall review the application of this legal instrument on a regular basis.

This first report by the Commission on the application of the Mutual Recognition Regulation is taking due account of the outcome of the three meetings of the Consultative Committee on mutual recognition held to date[2], the notifications addressed to the Commission by the Member States under Articles 6(2) and 7(2) of the Regulation, the information provided for in the yearly reports addressed by the Member States to the Commission in accordance with Article 12(1) of the Regulation[3], the input provided by the national Product Contact Points (PCP)[4], the specific input provided by stakeholders and the complaints, petitions and parliamentary questions pertinent to this area received by the Commission.

Within the non-harmonised area, the Regulation defines 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. It is generally perceived to be a helpful piece of legislation and has contributed towards an increased awareness of the principle of mutual recognition. The Regulation has eased the burden on economic operators introducing in a given Member State products previously lawfully marketed in another Member State.

The report will demonstrate that the Regulation works by and large in a satisfactory way and that there is no need for amendments at present. It also shows that that there are certain specific categories of products where the difficulties in the application of the Regulation seem to concentrate.

2. BACKGROUND

Technical obstacles to the free movement of goods within the EU are still widespread. They occur when national authorities apply national rules that lay down requirements to be met by products (e.g. relating to designation, form, size, weight, composition, presentation, labelling and packaging) to products coming from other Member States where they are lawfully produced and/or marketed. Unless those rules implement secondary EU legislation, they constitute technical obstacles to which Articles 34 and 36 TFEU apply. This is so even if those rules apply without distinction to all products, foreign and domestic alike.

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1 Regulation (EC) No 764/2008 of the European Parliament and of the Council of 9 July 2008 laying down procedures relating to the application of certain national rules to products lawfully marketed in another Member State and repealing Decision 3052/95/EC (Text with EEA relevance), OJ L 218 of 13 August 2008, p. 21-29.

2 These three meetings took place respectively in 4 March 2009, 19 November 2010 and 30 November 2011.

3 These reports cover the period from 13 May 2009 – the date from which the Mutual Recognition Regulation applies, to 31 December 2011.

4 PCP were established by Article 9 of the Regulation and their task discussed under Article 10.

2.1. The principle of mutual recognition

The principle of mutual recognition, which derives from the case-law of the Court of Justice of the European Union[5], is one of the means of ensuring the free movement of goods within the internal market. Mutual recognition applies to products which are not subject to EU harmonisation legislation, or to aspects of products falling outside the scope of such legislation.

Under the principle of mutual recognition different national technical rules continue to coexist within the internal market. However, a Member State cannot, in principle, prohibit the sale on its territory of goods which are lawfully produced and/or marketed in another Member State, even if those goods are produced to technical or qualitative specifications that differ from those required of its own goods. The Member States may depart from this principle and take measures prohibiting or restricting access by such goods to the national market only under very strict conditions.

Thus, the mutual recognition principle in the non-harmonised area consists of a rule and an exception:

- the general rule that, notwithstanding the existence of a national technical rule in the Member State of destination, products lawfully produced and/or marketed in another Member State enjoy a basic right to free movement, guaranteed by the TFEU;

- the exception that products lawfully produced and/or 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 rule on the products concerned based on the reasons outlined in Article 36 TFEU (protection of public morality or public security, protection of the health and life of humans, animals or plants, etc.) or in the mandatory requirements developed in the Court's jurisprudence and subject to the compliance with the principle of proportionality.

2.2. The Regulation (EC) No 764/2008

Until recently, a major problem for implementation of the mutual recognition principle was the lack of legal certainty about the burden of proof. It was one of the reasons for adoption of Regulation (EC) No 764/2008 laying down procedures relating to the application of certain national technical rules to products lawfully marketed in another Member State and repealing Decision No 3052/95/EC.

The Regulation neither covers, nor was intended to, the whole area of application of the principle of mutual recognition. Instead, it lays down the rules and procedures to be followed by the competent authorities of a Member State when taking or

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[5] The principle originated in the famous *Cassis de Dijon* judgment of the Court of Justice of 20 February 1979 (Case 120/78 *Rewe-Zentral* [1979] ECR 649) and was the basis for a new development in the internal market for goods. While at the beginning not expressly mentioned in the case-law of the Court of Justice, it is now fully recognised (see, for example, Case C-110/05 *Commission* v *Italy* [2009] ECR I-519, paragraph 34).

intending to take a decision, in accordance with national technical rules, which would hinder the free movement of a product lawfully marketed in another Member State and subject to Article 34 TFEU.

Therefore, national authorities must apply the Regulation if the administrative decision to be taken:

(1) concerns a product lawfully marketed in another Member State;

(2) concerns a product which is not subject to harmonised EU law;

(3) is addressed to economic operators;

(4) is based on a technical rule; and

(5) has the direct or indirect effect that the product is:

  (a) prohibited from being placed on the market;

  (b) modified or subject to additional testing before it can be placed or kept on the market; or

  (c) withdrawn from the market.

The Regulation places the burden of proof on the national authorities that intend to deny market access. They must set out in writing the precise technical or scientific reason for their intention to deny the product access to the national market. The economic operator is given the opportunity to defend its case and to submit solid arguments to the competent authorities.

The Regulation also reduces the risk for enterprises that their products will not get access to the market of the Member State of destination by establishing one or several Product Contact Points in each Member State.

The philosophy of the Regulation follows the twofold approach of combining transparency and efficiency: transparency of information to be exchanged between enterprises and national authorities, efficiency by avoiding any duplication of checks and testing. The preventive dialogue established between enterprises and administrations takes full advantage of the instruments for preventing and for amicably and effectively settling problems of free movement and can be considered as the core mechanism of the Regulation.

The main value of the Mutual Recognition Regulation principally is perceived in terms of how this piece of legislation has reduced information costs (for instance, making national technical rules more accessible for SMEs) and, in doing so, has facilitated the exploitation of free movement of goods and mutual recognition.[6]

[6] For all, see Pelkmans, J., "Mutual recognition: rationale, logic and application in the EU internal goods market", Paper presented in the XIIth Travemuender Symposium, 24 – 26 March 2010 on: Oekonomische Analyse des Europarechts: Primaerrecht, Sekundaerrecht und die Rolle des EuGH.

The Mutual Recognition Regulation is of application in all the 27 Member States. Its adoption under the EEA Agreement is still pending at the moment of drafting this report. Whereas the principle of mutual recognition also applies in EU-Turkey relations[7], the Mutual Recognition Regulation as such does not.[8]

3. APPLICATION OF REGULATION (EC) No 764/2008 DURING 2009 – 2012

During the period in question, the Commission monitored the application of the Regulation in the Member States, mainly but not only through the notifications and reports addressed by the Member States. It also organized the meetings of the Consultative Committee.

The Commission has also undergone specific actions to increase public awareness of the principle of mutual recognition and the Mutual Recognition Regulation in the single market.

3.1. Establishing Product Contact Points (PCP)

Articles 9(1) and (2) required, respectively, the designation of PCP by the Member States and the publication and regularly updating by the Commission of a list with their contact details.

3.2. Establishing the list of products

In turn, Article 12(4) required from the Commission the publication of a non-exhaustive list of products which are not subject to EU harmonisation legislation.

The contact details of the PCP were published in the Official Journal.[9] Together with the database containing the list of products which are not subject to EU harmonisation legislation they are now also available online[10], aiming to facilitate the exchange of information between economic operators, PCP and the competent authorities of the Member States.

3.3. Notifications from Member States

Articles 6(2) and 7(2) of the Regulation establish the obligation for the national authorities to notify to economic operators and to the Commission, respectively, decisions referred to in Article 2(1)[11] and other decisions establishing the temporary

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7 The obligation to apply the principle of mutual recognition to products lawfully manufactured and/or marketed in Turkey is based on Articles 5 to 7 of Decision 1/95 of the EC-Turkey Association Council of 22 December 1995 on implementing the final phase of the Customs Union (OJ L 35 of 13 February 1996) that provide for the elimination of measures having an effect equivalent to quantitative restrictions between the EU and Turkey. Pursuant to Article 66 of Decision 1/95, Articles 5 to 7 must, for purposes of their implementation and application to products covered by the Customs Union, be interpreted in conformity with the relevant judgments of the Court of Justice of the European Union. Therefore, principles resulting from the Court of Justice's case-law on issues that relate to Articles 34 and 36 TFEU, particularly the "Cassis de Dijon" case, apply to the EU Member States and Turkey.

8 Nevertheless, Turkey has recently undertaken to launch the internal procedure for the adoption of its own Draft Regulation on Mutual Recognition in the Non-Harmonised Area.

9 The contact details of the PCP were initially published in the OJ C 185 of 7 August 2009, p. 6-12.

10 http://ec.europa.eu/enterprise/intsub/a12/

11 That is, those administrative decisions whose direct or indirect effect is the prohibition of the placing on the market of that product or type of product; the modification or additional testing of that product or type of product before it can be placed or kept on the market; or the withdrawal of that product or type of product from the market.

suspension of the marketing of a product. In the period between the entry of the Regulation into force on 13 May 2009 and 31 December of 2011, the Commission has received 1524 notifications pursuant to Article 6(2) and none pursuant to Article 7(2).

Of these notifications, 90% refer to articles of precious metals, whereas the rest to variety of products: foodstuffs (or food additives/medicines), energy drinks and electrical equipment.

The notifications have to date come from seven Member States. However, 1378 of the total notifications come from one Member State and concern articles of precious metals.

In the Commission's opinion, and as further developed under 3.4 below, this points to the fact that Member States do not notify all decisions falling under Articles 6(2) and 7 of the Regulation they take.

The high number of notifications concentrating in the precious metals area can be explained, in the Commission's opinion, by the existence in many Member States of permanent and long time ago established control bodies (assay offices) specifically devoted to the assaying (testing), hallmarking and control of articles of precious metals.

It must be recalled that the Commission has presented in the past two different proposals concerning the harmonisation of national laws relating to articles of precious metal. The first one[12] was introduced in 1975 and withdrawn in 1977. The most recent[13] was introduced in 1993. A number of Member States (those following a compulsory hallmarking system) were adamant in their opposition to these proposals and, even after the introduction of an amended proposal in 1994, opposition continued among a considerable number of Member States. Over the following years no agreement could be reached and consequently the proposal was withdrawn on 24 March 2005.

In light of the subsequent rulings of the Court of Justice in this area[14], it was rendered clear that articles of precious metals imported from one Member State and marketed in another, which have been lawfully struck in a Member State with a hallmark stamped by a body which offers guarantees of independence, and which offers appropriate information to consumers, should be allowed to be marketed. No differences should be made between approved hallmarks struck on articles

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12 Proposition de directive du Conseil concernant le rapprochement des legislations des etats membres relatives aux ouvrages en metaux precieux, COM/1975/607/final, 1 December 1975; published in the OJ C 11 of 16 January 1976, p. 2-11.

13 Proposal for a Council Directive on articles of precious metal, COM(93) 322 final, 14 October 1993; modified by Amended Proposal for a European Parliament and Council Directive on articles of precious metal, COM(94) 267 final, 30 June 1994.

14 The main cases being the judgment of the Court of Justice of 22 June 1982, Criminal proceedings against Timothy Frederick Robertson and others, Case C-220/81; the judgment of the Court of Justice of 15 September 1994, Criminal proceedings against Ludomira Neeltje Barbara Houtwipper, Case C-293/93 [1994] ECR I-04249]; and the judgment of the Court of Justice of 21 June 2001, Case C-30/99, Commission v. Ireland [2001] ECR I-04619.

manufactured in the Member State of destination and those hallmarks of the same type struck on articles imported from other Member States.[15]

Therefore, in the absence of harmonised EU legislation, free movement of articles of precious metals between the Member States can be achieved by following the mutual recognition route charted by the *Houtwipper* judgment.[16] In consequence, the Commission does not consider proposing further harmonisation in this area for the moment.

As concerns foodstuffs, food additives and medicines, in light of the partial harmonisation within this area, there might be differences in national legislation (e.g. the classification of some products as medicinal products or foodstuffs, in various Member States, the use of substances other than vitamins or minerals in the manufacture of food supplements, etc.) which may be factors affecting the free movement of those products. Further harmonization efforts in those sectors are envisaged.

3.4. The yearly reports from the Member States

Under Article 12(1) of the Regulation, each Member State must address the Commission on a yearly basis a report on the application of this Regulation. That report should include at least the information on the number of written notices sent pursuant to Article 6(1) and the type of products concerned; sufficient information concerning any decisions taken pursuant to Article 6(2), including the grounds on which those decisions were based and the type of products concerned; and the number of decisions taken pursuant to Article 6(3) – intended negative decisions finally not adopted, and the type of products concerned.

To date, the Member States have presented the Commission with three such reports: a first report covering the application of the Regulation from May 2009 to May 2010, a second one covering such a period from 2010 to 2011, and a supplementary report covering the period until 31st December 2011. From that moment on, the reports will be requested upon calendar year basis.

In addition to the information indicated above, the following items were suggested by the Commission:

- an analysis of types of products and/or sectors in which the Regulation was applied most often;
- information on the structure and functioning of the product contact points (the staffing, number and nature of inquiries, problems encountered, etc.);
- an assessment of any difficulties experienced in the process of applying the Regulation and proposals for possible improvements; and

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15 For further specific information on this issue, see the guidance document "The application of the Mutual Recognition Regulation to articles of precious metals" referred to in point 4.1 below.

16 Case C-293/93. See note 14.

- an evaluation of the impact of the Regulation on the practical functioning of the mutual recognition principle; and

The following main conclusions can be drawn from these reports:

(1) The opinions of the Member States have been almost unanimously positive as regards the effectiveness of the Regulation in raising the awareness of the principle of mutual recognition among those businesses involved in intra-EU trade.

(2) The majority of decisions, requests for information and complaints received by the national administrations concern specific categories of goods: articles of precious metals, foodstuffs, food additives and food supplements, construction products, fertilisers, automobile spare parts, electrical products, and spring water.

(3) They confirm that the national authorities are not always communicating to the Commission the negative decisions actually adopted by them. This situation may be due to several reasons:

– in some decentralized Member States, regional or local bodies are able to adopt – and indeed they do, negative decisions that, in turn, are notified neither to the central government (which prepares the yearly reports) nor to the Commission;

– there seem still to be some misunderstandings as to the scope of the Regulation[17] as well as to its relationship with other pieces of EU legislation[18]; thus, several negative decisions actually adopted by some Member States seem to have not been considered as those decisions referred to in Article 2(1) of the Regulation and therefore not communicated to the Commission.

Also, some uncertainty about how and when to apply mutual recognition in practice is often mentioned by business, PCP and national administrations alike. Further dissemination of information, as detailed under point 4 below, seems the adequate way to tackle this problem. Nevertheless, the Commission must reiterate what is provided for in Articles 6(2) and 7(2) of the Regulation that whenever a decision under the Mutual Recognition Regulation is adopted by the national authorities, they are bound to notify it to the Commission at the same time as to the economic operator.

3.5. Meetings of the Consultative Committee on Mutual Recognition

During the three meetings to date held by the Consultative Committee established by Article 13 of the Regulation, the Commission and the representatives of the Member States[19] have discussed matters relating to the application of this legislative instrument.

The main discussion topics during these first three meetings have been the guidance documents prepared by the Commission (see 4.1 below), the role of the PCP, the list of products falling under the Regulation, issues dealing with the information obligations, difficulties perceived during the application of the Regulation and the

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17 Especially regarding prior authorisation procedures (and, therefore, not covered by the Regulation) in some Member States.

18 Mainly with Directive 2001/95/EC (the General Safety Products Directive).

19 And, since 2011, also from the EFTA.

assessment of the possibilities under the telematic network mentioned under Article 11 of the Regulation concerning the exchange of information between PCP and/or the competent authorities of the Member States.

4. DISSEMINATION OF INFORMATION

The Commission elaborated guidance documents on the application of the Regulation in particular sectors and was taking other steps aiming at improving the way that both, mutual recognition principle and the Mutual Recognition Regulation, operate.

4.1. The guidance documents

A series of guidance documents (9 for the moment now) offering practical information on the application of the Regulation to some particular issues have been prepared by the Commission at the request and with the input of the members of the consultative committee. They concern:

- The relationship between Directive 98/34/EC and the Mutual Recognition Regulation,
- The application of the Mutual Recognition Regulation to articles of precious metals,
- The relationship between Directive 2001/95/EC and the Mutual Recognition Regulation,
- The application of the Mutual Recognition Regulation to food supplements,
- The application of the Mutual Recognition Regulation to narcotic drugs and psychotropic substances,
- The application of the Mutual Recognition Regulation to prior authorisation procedures,
- The application of the Mutual Recognition Regulation to weapons and firearms,
- The application of the Mutual Recognition Regulation to fertilisers and growing media, and
- The application of the Mutual Recognition Regulation to non-CE –marked construction products.

These indicative, non-legally binding, documents have also been made public through the Commission's web page on mutual recognition.[20] They seek to provide 'user-friendly' guidance on the application of the Regulation and will be updated to reflect experience and information from the Member States, authorities and businesses.

[20] http://ec.europa.eu/enterprise/policies/single-market-goods/free-movement-non-harmonised-sectors/mutual-recognition/

4.2. Guide to the application of Treaty provisions governing Free Movement of Goods

The application of the principle of mutual recognition requires a basic knowledge of the principles of the free movement of goods. The Commission published the document "Free movement of goods. Guide to the application of Treaty provisions governing the free movement of goods" in which it describes in particular the principle of mutual recognition and summarises the most pertinent case law of the Court of Justice on the subject. It is available on the Commission's web page on free movement in the non-harmonised sector.[21]

4.3. Conferences, seminars and round tables

Since 2009 the Commission has organised or taken part in 12 seminars on mutual recognition in the internal market and the application of the Mutual Recognition Regulation. The main participants were academia and specific business sectors from the areas most often concerned by mutual recognition. National administrations seemed to be in favour of holding such seminars more regularly.

5. COMPLIANCE WITH THE REGULATION

During the period covered by this report, there have been neither specific judgments by the Court of Justice nor infringement procedures centred on the application of the Mutual Recognition Regulation.

Due to the nature of the regulation as a directly applicable legislative act of the European Union, it is immediately and directly enforceable in all Member States. As specified in the Regulation, any decision to which it applies should specify the remedies available so that an economic operator can bring proceedings before the competent national court or tribunal. Thus, in the Commission's opinion, the matters regarding the correct application of the Regulation in concrete situations, while not precluding any possible Commission's action, should be dealt with by the competent national bodies.

6. CONCLUSIONS

In the light of the above, certain aspects of the Mutual Recognition Regulation require continued monitoring and could be subject to further clarification.

Apart from the specific categories of goods mentioned in points 3.3 and 3.4 above, the following issues constitute areas where the European Commission proposes that close and regular monitoring through the consultative committee on mutual recognition takes place:

- difficulties to demonstrate that a product has been lawfully marketed in another Member State;
- difficulties in indentifying which legal provisions apply and which are the relevant national authorities in charge;

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[21] http://ec.europa.eu/enterprise/policies/single-market-goods/free-movement-non-harmonised-sectors/index_en.htm

- different testing methods relied upon by the Member States and their possible compatibility through mutual recognition; and

- the role of prior authorisation procedures.

After having taken into account the information obtained regarding the application of the Regulation, the Commission does not consider it necessary, at this stage, to submit any proposal for its amendment.

Nevertheless, the Commission would also like to underline its commitment to continue monitoring the particularly important area of mutual recognition in the single market by: a) improving information and developing training; b) taking advantage of the instruments for preventing and for amicably and effectively settling problems of free movement and c) resorting, if need be, to existing possibilities afforded under EU law to eliminate unlawful barriers.

In this sense, the Commission proposes the continuation during the period 2012-2017 of the examination and discussion within the Consultative Committee of the topics in the areas mentioned above with the objective of analyzing the functioning of the existing EU legal framework for mutual recognition. If discrepancies in the operation of the Mutual Recognition Regulation between Member States assume greater practical significance, an intervention by the Commission may be warranted.

Finally, it must be highlighted that mutual recognition in general and the application of the Regulation in particular, cannot always offer a solution for ensuring the free movement of goods in the single market. Harmonisation remains one of the most effective instruments, both for economic operators and for the national administrations.

The Commission, in accordance with Article 12(3) of the Regulation will, therefore, continue to monitor the application and the effects of the Regulation and evaluate any eventual need for future amendments in its next report on the application of Regulation (EC) No 764/2008.

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The Commission would ask the European Parliament, the Council and the European Economic and Social Committee to take note of this report.