Basic information

2007/0028(COD) COD - Ordinary legislative procedure (ex-codecision procedure) Regulation	Procedure completed
Application of certain national technical rules to products lawfully marketed in another Member State Repealing Decision 3052/95/EC 1993/0489(COD) Repealed by 2017/0354(COD) **Subject** 2.10 Free movement of goods 2.10.03 Standardisation, EC/EU standards and trade mark, certification, compliance 4.60.08 Safety of products and services, product liability	

Key players

European Parliament

Committee responsible	Rapporteur	Appointed
IMCO Internal Market and Consumer Protection	STUBB Alexander (PPE-DE)	20/03/2007

Committee for opinion	Rapporteur for opinion	Appointed
INTA International Trade	The committee decided not to give an opinion.	
ENVI Environment, Public Health and Food Safety	The committee decided not to give an opinion.	
ITRE Industry, Research and Energy	BŘEZINA Jan (PPE-DE)	03/05/2007
JURI Legal Affairs	TOUBON Jacques (PPE-DE)	10/04/2007

Council of the European Union

Council configuration	Meetings	Date
Competitiveness (Internal Market, Industry, Research and Space)	2852	2008-02-25
Competitiveness (Internal Market, Industry, Research and Space)	2832	2007-11-22
Competitiveness (Internal Market, Industry, Research and Space)	2801	2007-05-21
Agriculture and Fisheries	2881	2008-06-23

European Commission

Commission DG	Commissioner

	Internal Market, Industry, Entrepreneurship and SMEs	VERHEUGEN Günter

Key events

Date	Event	Reference	Summary
14/02/2007	Legislative proposal published	COM(2007)0036	Summary
13/03/2007	Committee referral announced in Parliament, 1st reading		
21/05/2007	Debate in Council		
22/11/2007	Debate in Council		
27/11/2007	Vote in committee, 1st reading		Summary
04/12/2007	Committee report tabled for plenary, 1st reading	A6-0489/2007	
19/02/2008	Debate in Parliament		
21/02/2008	Decision by Parliament, 1st reading	T6-0063/2008	Summary
21/02/2008	Results of vote in Parliament		
25/02/2008	Debate in Council		
23/06/2008	Act adopted by Council after Parliament's 1st reading		
09/07/2008	Final act signed		
09/07/2008	End of procedure in Parliament		
13/08/2008	Final act published in Official Journal		

Technical information

Procedure reference	2007/0028(COD)
Procedure type	COD - Ordinary legislative procedure (ex-codecision procedure)
Procedure subtype	Legislation
Legislative instrument	Regulation
Amendments and repeals	Repealing Decision 3052/95/EC 1993/0489(COD) Repealed by 2017/0354(COD)
Legal basis	EC Treaty (after Amsterdam) EC 095 EC Treaty (after Amsterdam) EC 037
Stage reached in procedure	Procedure completed
Committee dossier	IMCO/6/46215

Documentation gateway

European Parliament

Document type	Committee	Reference	Date	Summary

Committee draft report		PE390.733	25/06/2007	
Committee opinion	JURI	PE390.524	12/09/2007	
Committee opinion	ITRE	PE390.375	17/09/2007	
Amendments tabled in committee		PE396.499	16/10/2007	
Committee report tabled for plenary, 1st reading/single reading		A6-0489/2007	04/12/2007	
Text adopted by Parliament, 1st reading/single reading		T6-0063/2008	21/02/2008	Summary

Council of the EU

Document type	Reference	Date	Summary
Draft final act	03613/2008/LEX	09/07/2008	

European Commission

Document type	Reference	Date	Summary
Legislative proposal	COM(2007)0036	14/02/2007	Summary
Document attached to the procedure	SEC(2007)0112	14/02/2007	
Document attached to the procedure	SEC(2007)0113	14/02/2007	
Commission response to text adopted in plenary	SP(2008)1767	31/03/2008	
Follow-up document	COM(2012)0292	15/06/2012	Summary
Commission document (COM)	COM(2013)0592	16/08/2013	Summary

Additional information

Source	Document	Date
National parliaments	IPEX	
European Commission	EUR-Lex	

Final act

Regulation 2008/0764
OJ L 218 13.08.2008, p. 0021 Summary

Application of certain national technical rules to products lawfully marketed in another Member State

2007/0028(COD) - 16/08/2013 - Follow-up document

This Commission working document is a guidance document on the concept of “lawfully marketed” in the Mutual Recognition Regulation (EC) No 764 /2008.

The Mutual Recognition Regulation is designed to ensure observance of the principle of mutual recognition within the internal market and in the EFTA state that are contracting parties to the EEA Agreement, in particular through initiation of a dialogue process where market access is impeded.

On 15 June 2012, the Commission adopted its first report on the application of Regulation (EC) 764/2008 and proposed that the Consultative Committee on Mutual Recognition should closely monitor, among other areas, the **difficulties faced by economic operators when trying to demonstrate that a product has been lawfully marketed in another Member State**.

To address this concern, this guidance document seeks to **provide user-friendly guidance on the concept of ‘lawfully marketed’** in the Mutual Recognition Regulation. It will be updated to reflect experience and information from the Member States, authorities and businesses.

In discussions of the concept of ‘lawfully marketed’, most problems arise either from the difficulties economic operators face at the beginning of this dialogue, when trying to find adequate means of evidence, or once the dialogue has already started, from the additional requirements asked for by the authorities after some documents have already been provided.

As regards **adequate means of evidence**, the issue is mostly a question of information, as economic operators are not always aware that they can rely on almost any document produced during their usual commercial activities in another Member State or in an EFTA state that is a contracting party to the EEA Agreement to demonstrate that their products have been lawfully marketed there.

As regards **additional requirements**, the relevant State bears the burden of proof that the stated aim of the measure or requirement cannot be achieved by any other means that has a less restrictive effect on trade.

Application of certain national technical rules to products lawfully marketed in another Member State

2007/0028(COD) - 21/02/2008 - Text adopted by Parliament, 1st reading/single reading

The European Parliament adopted a resolution based on the report by Alexander **STUBB** (EPP-ED, FI), amending, under first reading of the co-decision procedure, the proposal for a 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.

The main amendments are as follows:

Subject-matter: MEPs consider that the regulation should state its principal aim more clearly. The text now states that the aim of this Regulation is to strengthen the functioning of the internal market by improving the free movement of products.

Scope: this Regulation applies to administrative decisions addressed to the economic operator and taken or intended to be taken, on the basis of a technical rule as defined in this regulation, in respect of any product, including agricultural and fish products, lawfully marketed in another Member State, where the direct or indirect effect of that decision is any of the following: a) the prohibition of the placing on the market of the product or type of product; b) the modification or additional testing of the product or type of product before it can be placed or kept on the market; c) the withdrawal of that product or type of product from the market.

The definition of technical rule has been amended by Parliament, and includes a rule which prohibits the marketing of a product or type of product in the territory of that Member State. Parliament specified that the Regulation will not apply to decisions of a judicial nature taken by national courts or tribunals; and to decisions of a judicial nature taken by law enforcement authorities in the course of the investigation or prosecution of a criminal offence as regards the terminology, symbols or any material reference to unconstitutional or criminal organisations or offences of a racist or xenophobic nature.

Parliament also clarified the relationship between the regulation and other provisions of Community law and stated that the former shall not apply to systems and interoperability constituents falling within the scope of Directives 96/48/EC and 2001/16/EC.

Procedure for the application of a technical rule of the Member State of destination: where the competent authority of the Member State of destination submits a product or type of product to an evaluation, it may request from the economic operator with due regard to the principle of proportionality: a) relevant information on the characteristics of the product or type of product in question; or b) relevant and readily available information on the lawful marketing of the product in another Member State. MEPs also introduced an article on mutual recognition of the level of competence of accredited conformity assessment bodies.

Assessment of the need to apply a technical rule of the Member State of destination: Parliament specified that any intended decision shall be based on the characteristics of the product or type of product in question. The economic operator concerned shall, following receipt of a notice, be allowed at

least twenty working days in which to submit comments. Such notice shall specify the time limit within which to submit comments. Any decision shall be taken and notified to the economic operator concerned and the Commission within twenty working days following the expiry of the deadline for receipt of comments from the economic operator. When duly justified by the complexity of the issue, the competent authority may extend once the time period referred to above by a maximum of twenty working days. This extension shall be duly reasoned and shall be notified to the economic operator before the initial period has expired.

Any decision may be challenged before national courts or tribunals or other instances of appeal. When, following the procedure laid down, the competent authority fails to notify to the economic operator a decision within the time period specified, the product shall be deemed to be lawfully marketed in that Member State in so far as the application of its technical rule is concerned.

Temporary suspension of the marketing of a product: Parliament introduced a new Article on this and stated that during the application of the procedure, the competent authority shall not temporarily suspend the marketing of the product or type of product in question, except where certain conditions are met, for example, that the product poses a serious risk to the safety and health of the users. A suspension of the marketing of a product adopted in accordance with this Article may be challenged before the national courts or tribunals or other instances of appeal.

Information to the economic operator: Parliament inserted this Article specifying to whom the request for information, the written notice and the decision should be sent. The economic operator is in the first instance the manufacturer of the product, when he is established in the Community, or the person who has placed the product on the market or is requesting to the competent authority that the product be placed on the market. The Article specifies the persons to contact when the manufacturer cannot be identified.

Product Contact Points: MEPs introduced amendments specifying that Contact Points must provide information to both the economic operators and the competent authorities of the Member States. They shall respond within fifteen working days of receipt of any request for information or assistance. The information provided will include the technical rules applicable to a specific type of product in the territory where those Product Contact Points are established and information as to whether that type of product is subject to a requirement for prior authorisation under the laws of their Member State, together with information about the principle of mutual recognition and the application of the Regulation in the territory of that Member State. Product Contact Points shall not charge any fee for information or assistance.

Reporting obligations and review: MEPs introduced a yearly reporting obligation for Member States. In light of the information provided by Member States, the Commission shall analyse the decisions taken and make an assessment of their justification. The Commission shall, within three years following entry into force of the Regulation, and every five years thereafter, carry out a review and submit a report on the application of the Regulation to the European Parliament and the Council. It shall, if relevant, accompany the report with appropriate proposals with a view to improving the free movement of goods. It shall also publish and regularly update a non-exhaustive list of products which are not subject to harmonisation at Community level. It shall make this list accessible through a website.

Application of certain national technical rules to products lawfully marketed in another Member State

2007/0028(COD) - 14/02/2007 - Legislative proposal

PURPOSE: i) to lay down the procedures for national authorities in cases where they wish to deny the principle of “mutual recognition” to a product and ii) to establish “Product Contact Points” in the Member States.

PROPOSED ACT: Regulation of the European Parliament and of the Council.

BACKGROUND: the internal market not only furthers European integration it also enhances the overall competitiveness of the European Union. Primary EU legislation forbids Member States from refusing products which have been lawfully marketed in another Member State and which are not subject to Community harmonisation – unless they are forbidden on the ground of public health and safety. The 1979 Cassis de Dijon judgement sets out, clarifies and gives added authority to the principle of mutual recognition.

However, in recent years, the principle of mutual recognition is being undermined for the following reasons:

- both enterprises and national authorities lack awareness of the mutual recognition principle;
- the scope of the principle remains unclear. For example, it is often unclear to which categories of product mutual recognition applies;
- enterprises still risk the possibility that their products will not gain access to the Member State market which they are targeting;
- lack of regular dialogue between Member State national authorities.

Although current policy has succeeded in eliminating an overwhelming amount of technical barriers without the need for harmonisation at an EU level, stakeholders are indicating that current policy has reached its limits and that progress has come to a standstill.

CONTENT: the purpose of this proposal, therefore, is to define the rights and obligations of national authorities, on the one hand, and the rights and obligations of enterprises wishing to sell their products to another EU Member State, on the other. It intends to do so:

- firstly, by laying down procedures which the national authorities will be obliged to follow in cases where they choose to deny a product entry on to their market but which has been lawfully marketed in another EU Member State; and
- secondly, by establishing Product Contact Points which enterprises can contact for further information.

More specifically the Commission is proposing:

- the laying down of rules and procedures to be followed by the national authorities if they intend to ban, refuse, modify or withdraw a product which has been lawfully marketed in another EU Member State;
- the establishment, in each Member State, of “Product Contact Points” in order to provide information on national technical rules;
- that the Regulation apply to any industrially manufactured product or agricultural product (including fish products) which have been lawfully marketed in another Member State;
- the establishment of a telematic network for the exchange of information between the Product Contact Points.

For further details of the financial implications of this proposal, please refer to the financial statement.

Application of certain national technical rules to products lawfully marketed in another Member State

2007/0028(COD) - 09/07/2008 - Final act

PURPOSE: to lay down the procedures for national authorities which would hinder the free movement of a product lawfully marketed in another Member State, and to establish Product Contact Points in Member States.

LEGISLATIVE ACT: Regulation (EC) No 764/2008 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 No 3052/95/EC

CONTENT: the aim of this Regulation is to strengthen the functioning of the internal market by improving the free movement of goods. Obstacles to the free movement of goods between Member States may be unlawfully created by the Member States' applying to products lawfully marketed in other Member States, technical rules laying down requirements to be met by those products. These might include rules relating to designation, form, size, weight, composition, presentation, labelling and packaging. The application of such rules to products lawfully marketed in another Member State can be contrary to the Treaty, even if they apply without distinction to all products.

This Regulation lays down the rules and procedures to be followed by the competent authorities of a Member State when taking a decision which would hinder the free movement of a product lawfully marketed in another Member State and subject to Article 28 of the Treaty. It also provides for the establishment of Product Contact Points in the Member States to contribute to the achievement of the aim of the Regulation.

Scope: the Regulation applies to administrative decisions addressed to economic operators, on the basis of a technical rule, in respect of any product, including agricultural and fish products, lawfully marketed in another Member State, where the direct or indirect effect of that decision is any of the following:

a) the prohibition of the placing on the market of that product or type of product;

b) the modification or additional testing of that product or type of product before it can be placed or kept on the market;

c) the withdrawal of that product or type of product from the market.

Procedure for the application of a technical rule of the Member State of destination: where the competent authority of the Member State of destination submits a product or type of product to an evaluation, it may request from the economic operator with due regard to the principle of proportionality:

a) relevant information on the characteristics of the product or type of product in question; or

b) relevant and readily available information on the lawful marketing of the product in another Member State.

Assessment of the need to apply a technical rule: where a competent authority intends to adopt a decision, it shall send the economic operator written notice of that intention, specifying the technical rule on which the decision is to be based and setting out technical or scientific evidence to the effect that:

a) the intended decision is justified on one of the grounds of public interest set out in Article 30 of the Treaty or by reference to other overriding reasons of public interest; and

b) the intended decision is appropriate for the purpose of achieving the objective pursued and does not go beyond what is necessary in order to attain that objective. The economic operator concerned shall be allowed at least 20 working days in which to submit comments.

Product Contact Points: Member States shall designate Product Contact Points, which shall, at the request of, inter alia, an economic operator or a competent authority of another Member State, provide the following information:

a) the technical rules applicable to a specific type of product in the territory in which those Product Contact Points are established and information as to whether that type of product is subject to a requirement for prior authorisation under the laws of their Member State, together with information concerning the principle of mutual recognition and the application of the Regulation in the territory of that Member State;

b) the contact details of the competent authorities within that Member State by means of which they may be contacted directly, including the particulars of the authorities responsible for supervising the implementation of the technical rules in question in the territory of that Member State;

c) the remedies generally available in the territory of that Member State in the event of a dispute between the competent authorities and an economic operator.

Product Contact Points must not charge any fee for the provision of this information. They shall respond within 15 working days of receiving any request for information.

Telematic network: the Commission may establish a telematic network for the implementation of the provisions of the Regulation concerning the exchange of information between Product Contact Points and/or the competent authorities of the Member States.

Reporting obligations: each Member State shall send the Commission on a yearly basis a report on the application of this Regulation. In the light of this information, the Commission shall analyse the decisions taken and assess the grounds on which they were based. By 13 May 2012, and every five years thereafter, the Commission shall review the application of this Regulation and shall submit a report thereon to the European Parliament and to the Council. The Commission may, where appropriate, accompany the report with proposals with a view to improving the free movement of goods.

APPLICATION: from 13/05/2009.

ENTRY INTO FORCE: 02/09/2008.

Application of certain national technical rules to products lawfully marketed in another Member State

2007/0028(COD) - 15/06/2012 - Follow-up document

The Commission presents a first report on the application of Regulation (EC) No 764/2008 ('the Mutual Recognition Regulation') laying down procedures relating to the application of certain national technical rules to products lawfully marketed in another Member State. It recalls that 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 demonstrates 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.

Application of the Regulation between 2009 – 2012: the Regulation establishes the obligation for national authorities to notify to economic operators and the Commission, respectively, of decisions establishing the temporary 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 a total of 1524 notifications. 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. The Commission considers that Member States do not notify all decisions taken which fall under the Regulation. The high number of notifications concentrating in the precious metals area can be by the existence in many Member States of 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 most recent proposal being adopted in 1993. A number of Member States (those following a compulsory hallmarking system) were adamant in their opposition to these proposals and the latest proposal was withdrawn on 24 March 2005. 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 ECJ's Houtwipper judgment; 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 harmonisation efforts in those sectors are envisaged.

The yearly reports from the Member States : the main conclusions to be drawn are:

- Member States are 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 ;
- 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 ;
- national authorities are not always communicating to the Commission the negative decisions actually adopted by them. This situation may be due to several reasons: (a) in some decentralized Member States, regional or local bodies are able to adopt negative decisions that, in turn,

are notified neither to the central government (which prepares the yearly reports) nor to the Commission; (b) there seem still to be some misunderstandings as to the scope of the Regulation as well as to its relationship with other pieces of EU legislation.

The Commission discusses the guidelines that it has issued.

Conclusion: 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 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 demonstrating 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;
- different testing methods relied upon by the Member States and their possible compatibility through mutual recognition;
- the role of prior authorisation procedures which are not covered by this Regulation.

The Commission does not consider it necessary, at this stage, to submit any proposal for amendment. Nevertheless, it 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 discussion within the Consultative Committee of the topics in the areas mentioned above with the objective of analysing 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.

Lastly, the report stresses that **mutual recognition 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 will continue to monitor the application of the Regulation it asks the European Parliament, the Council and the European Economic and Social Committee to take note of the report.