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# COMMISSION WORKING DOCUMENT

## Guidance document. The concept of 'lawfully marketed' in the Mutual Recognition Regulation (EC) No 764/2008[1]

(Text with EEA relevance)

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## 1. INTRODUCTION

On 15 June 2012, the Commission adopted its first report on the application of Regulation (EC) 764/2008 ('the Mutual Recognition Regulation')[2] 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.

## 2. THE PRINCIPLE OF MUTUAL RECOGNITION

The free movement of goods is one of the success stories of the European project. It has helped to build the internal market, from which European citizens and businesses are now benefiting and which is at the heart of EU policies.

Obstacles to the free movement of goods between Member States may be unlawfully created by the Member States' competent authorities applying, in the absence of harmonised legislation, technical rules laying down requirements to be met by products lawfully marketed in other Member States. The application of such rules to products lawfully marketed in another Member State can be contrary to Articles 34 and 36 of the Treaty on the Functioning of the European Union (TFEU), even if they apply without distinction to all products.

The principle of mutual recognition, which derives from the case law of the Court of Justice of the European Union,[3] plays an important part in the functioning of the internal market and allows the free movement of products in the absence of any EU harmonising legislation.

This guidance document makes it clear that, under the Mutual Recognition Regulation, the Member State of destination of a product[4] must allow the placing on its market of a product

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2 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, OJ L 218, 13.8.2008, pp. 21–29.

3 This principle originates in the 'Cassis de Dijon' Judgment of 20 February 1979 (*Rewe-Zentral AG v. Bundesmonopolverwaltung für Branntwein*), Case 120/78, European Court Reports 1979, p. 649. From 1980, the Commission drew up a number of guidelines regarding the application of the principle of mutual recognition arising from Court case law, in particular in the communication from the Commission concerning the consequences of the judgment given by the Court of Justice on 20 February 1979 in Case 120/78 *Cassis de Dijon* (OJ C 256, 3.10.1980).

4 For the purposes of this guidance document, a product is defined as a moveable good which is capable, as such, of forming the subject of commercial transactions: Judgment of the Court of 21 October 1999,

lawfully marketed in another Member State or in an EFTA state that is a contracting party to the Agreement on the European Economic Area ('the EEA Agreement'),[5] unless the procedural requirements for denying mutual recognition established by the Regulation were met.

A full discussion on the defences that could be used by Member States to justify national measures that impede cross-border trade (the exceptions listed in Article 36 TFEU) can be found in the Commission's Guide to the application of Treaty provisions governing the free movement of goods.[6]

## 3. THE MUTUAL RECOGNITION REGULATION (EC) NO 764/2008

The Mutual Recognition Regulation, in force since May 2009, aims to give effect to the principle of mutual recognition. Applying exclusively to products or particular features of them not subject to harmonisation measures at EU level, it defines the rights and obligations of national competent authorities and those of enterprises wishing to sell in a Member State products lawfully marketed in another Member State, when the authorities intend to take restrictive measures regarding the product in accordance with national technical rules. In particular, the Mutual Recognition Regulation focuses on the burden of proof by setting out the procedural requirements for denying mutual recognition.

The Mutual Recognition Regulation applies in all the Member States as well as in the EFTA states that are contracting parties to the Agreement on the European Economic Area (EEA).

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*Peter Jägerskiöld v. Torolf Gustafsson*, Case C-97/98, European Court Reports 1999, p. I-7319. According to Court of Justice case law, goods taken across a frontier for the purposes of commercial transaction are subject to Article 34 TFEU, whatever the nature of those transactions: see in particular ground 20 of the Judgment of the Court of 28 March, 1995, *The Queen v. Secretary of State for Home Department, ex parte Evans Medical Ltd and Macfarlan Smith Ltd*, Case C-324/93, European Court Reports 1995, p. I-563.

5 At the time of drafting this document, the EFTA states that are contracting parties to the Agreement on the European Economic Area are Iceland, Liechtenstein and Norway. Thus, the European Economic Area (EEA) comprises the Member States of the EU, plus these three countries. The Mutual Recognition Regulation was incorporated into the EEA agreement by Decision of the EEA Joint Committee No 126/2012 of 13 July 2012 amending Annex II (Technical regulations, standards, testing and certification) to the EEA Agreement (OJ L 309, 8.11.2012, pp. 4-5). Some special adaptations apply: the Regulation only applies to products covered by Article 8(3) of the Agreement and does not apply to Liechtenstein in relation to products covered by Annex I, Chapters XII and XXVII of Annex II and Protocol 47 to the Agreement, in cases where the application of the Agreement between the European Community and the Swiss Confederation on trade in agricultural products extends to Liechtenstein. However, the Decision only entered into force on 1.4.2013 due to delays in the notification of the 'fulfilment of constitutional requirements' by Norway and Iceland. Thus, any reference in this guidance document to 'Member States' should be understood as encompassing these three countries as well.

6 Document available online at: http://ec.europa.eu/enterprise/policies/single-market-goods/files/goods/docs/art34-36/new_guide_en.pdf. Art. 36 TFEU is discussed from p. 26 on.

Although the principle of mutual recognition also applies to EU-Turkey relations,[7] the Mutual Recognition Regulation as such does not.[8]

The Mutual Recognition Regulation lays down the rules and procedures to be followed by the competent authorities of a Member State when taking or 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.

## 4. THE CONCEPT OF LAWFULLY MARKETED

The Mutual Recognition Regulation itself does not define the concept 'lawfully marketed' for products falling within its scope, i.e. not subject to harmonisation. Furthermore, there is no jurisprudence of the Court of Justice on this concept.

Nevertheless, the concepts of 'making available' and 'placing on the market' are defined by Regulation (EC) No 765/2008[9]. Thus, 'making available on the market' means any supply of a product for distribution, consumption or use on the Union market in the course of a commercial activity, whether in return for payment or free of charge[10] and 'placing on the market' means the first making available of a product on the Union market[11].

For products which are subject to the Mutual Recognition Regulation, the Commission consequently considers that the concept of 'marketing' means any supply of a product for distribution, consumption or use in another Member State or in an EFTA state that is a contracting party to the EEA Agreement, in the course of a commercial activity, whether in return for payment or free of charge.

Correspondingly, the Commission takes the view that the concept of 'lawful marketing' means that the supply, as referred to in the previous paragraph, should take place in:

– another Member State, in accordance with the applicable national legislation; or

– an EFTA state that is a contracting party to the EEA Agreement in accordance with the applicable national legislation.

– Additionally, with regard to products intended for (or which may be used by) consumers, products placed on the EU market are subject to the requirements and safety criteria laid down by the Directive on general product safety.[12]

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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), which provide for the elimination of measures having an effect equivalent to quantitative restrictions between the EU and Turkey. Under Article 66 of Decision 1/95, Articles 5 to 7 must, for the purpose 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 Turkey as well.

8 See above. Nevertheless, Turkey has adopted a national Regulation on Mutual Recognition in the Non-Harmonised Area, in force as of 1 January 2013.

9 Regulation (EC) No 765/2008 of the European Parliament and of the Council, of 9 July 2008, setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93, OJ L 218, 13.8.2008, pp. 30–47.

10 Article 2(1) of Regulation (EC) No 765/2008.

11 Article 2(2) of Regulation (EC) No 765/2008.

12 Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety, OJ L 11, 15.1.2002, pp. 4–17.

– As regards products imported from third countries, they must lawfully be marketed in a Member State or in an EFTA state that is a contracting party to the EEA Agreement in order to benefit from mutual recognition.

An economic operator imports into an EU or EFTA state that is a contracting party to the EEA agreement products from a third country. Once released for **free circulation**[13], these products are considered as Community goods. **From that moment on** those products may be marketed in another EU or EFTA state that is a contracting party to the EEA agreement under the terms of the Mutual Recognition Regulation.

## 5. OBLIGATIONS UNDER THE MUTUAL RECOGNITION REGULATION

An essential principle of EU law is that a product that is subject to the Mutual Recognition Regulation enjoys the basic right of free movement of goods guaranteed by the TFEU, provided that the Member State of destination has not taken a reasoned decision of refusal, based on proportionate technical rules.[14]

The basic right of free movement of products is not an absolute right: mutual recognition is subject to the right of the Member State of destination to assess the need to apply a technical rule, as set out in the Mutual Recognition Regulation.

Therefore, the Mutual Recognition Regulation gives the opportunity to economic operators to provide information to responsible authorities of the receiving Member State as regards the lawful marketing of the product in another Member State or in an EFTA state that is a contracting party to the EEA Agreement.

When the competent authority of the Member State of destination requires an evaluation of the conformity of a product lawfully marketed in another Member State or in an EFTA state that is a contracting party to the EEA Agreement with its own technical rules, this should be done following the terms of the Mutual Recognition Regulation. The Regulation addresses the collecting of information on the product in its Article 4. Under this Article, the authority may request from the economic operator, with due regard to the principle of proportionality, relevant information concerning the characteristics of the product and/or relevant and readily available information on the lawful marketing of the product in another Member State.

## 6. MEANS OF EVIDENCE

The Mutual Recognition Regulation does not specify the means of evidence that may be used by economic operators to demonstrate that a product has been lawfully marketed in another Member State or in an EFTA state that is a contracting party to the EEA Agreement. This avoids imposing any additional administrative burden and does not limit in any way the means of evidence that an economic operator may present as part of the information mentioned by Article 4(b) to the authorities of the Member State of destination.

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13 Article 79 of the Council Regulation (EEC) No 2913/92 establishing the Community Customs Code states that 'Release for free circulation shall confer on non-Community goods the customs status of Community goods. It shall entail application of commercial policy measures, completion of the other formalities laid down in respect of the importation of goods and the charging of any duties legally due'.

14 The Directive on general product safety permits Member States to take rapid restrictive measures with regard to products which are dangerous or are likely to be dangerous, pursuant to Articles 8, 11 or 12 and 18 of the Directive.

It must also be noted that Member States follow very different systems for placing products on the market and controlling this activity through *ex ante* (prior authorisation procedures) or *ex post* (market surveillance) mechanisms — in most cases a product can be lawfully marketed without having to be approved first.

Hence, **any piece of evidence** such as a product invoice, product label, catalogue with evidence of a date, sale or tax records, registrations, licences, notifications to/from the authorities, certifications, extracts from public records, etc. **should be deemed suitable to demonstrate the actual marketing of the product in another Member State or in an EFTA state that is a contracting party to the EEA Agreement.**

### 6.1. Rights and obligations

Under Article 4(b) of the Mutual Recognition Regulation, the competent authority of the Member State of destination may request from the economic operator concerned relevant information on the previous lawful marketing of the product in another Member State or in an EFTA state that is a contracting party to the EEA Agreement.

More specifically:

– If the economic operator has proof of conformity with the national legislation of the other Member State or the EFTA state that is a contracting party to the EEA Agreement where the product is actually marketed (such as written confirmation from the competent authority of the Member State of origin[15]), the Commission considers that it would be useful for this proof to be transmitted to the competent authority of the Member State of destination.

– It would also be useful if the economic operator were to provide the references of the applicable provisions of law in another Member State or EFTA state that is a contracting party to the EEA Agreement. If this is not possible, however, the competent authority in the Member State of destination should consider obtaining such information directly from the authorities of these States through the Product Contact Point (see section 7 below).

The competent authority of the Member State of destination may request translation of the documents provided by the economic operator when necessary. Nonetheless, it would be excessive for a Member State to require a translation certified or authenticated by a consular or administrative authority,[16] or to impose an excessively short deadline for providing the translation, unless there are special circumstances warranting this. The Commission also considers that the competent authority of the Member State of destination should identify those parts of the documents which need to be translated. The authority should also avoid asking for translations when the documents in question are available in another language which the authority is able to understand.

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15 Proof from the competent authority of the Member State where the EEA product is lawfully marketed is only one of several possibilities: it cannot be required by the competent authority of the Member State of destination. See ground 63 of the Judgment of 8 May 2003 (*ATRAL v. Belgian State*, Case C-14/02), where the Court specified that imposing as a condition the attestation of conformity of EEA products with technical standards or rules which guarantee a level of protection equivalent to that required by the Member State of destination is contrary to Article 34 TFEU.

16 See, in this respect, the Judgment of the Court of 17 June 1987, *Commission of the European Communities v. Italian Republic*, Case 154/85, European Court Reports 1987, p. 2717.

### 6.2. Failure to notify the economic operator

The Commission considers that a request for information by the competent authority of the Member State of destination (and/or the examination of the product by the competent authority) cannot cause the marketing of a product in the Member State of destination to be suspended indefinitely, or for a long period of time, pending a reasoned decision on marketing by the competent authority,[17] except where an emergency measure is adopted following an alert under Directive 2001/95/EC[18] or Regulation 178/2002.[19] Therefore, as stated by Article 6(4) of the Mutual Recognition Regulation:

> 'When the competent authority fails to notify the economic operator of a decision as referred to in Article 2(1) within the period specified in paragraph 2 of this Article, the product shall be deemed to be lawfully marketed in that Member State insofar as the application of its technical rule as referred to in paragraph 1 of this Article is concerned.'

## 7. THE ROLE OF THE PRODUCT CONTACT POINTS

The main task of the Product Contact Points (PCPs) is to provide information on technical rules for products to economic operators and competent authorities in other Member States or in an EFTA state that is a contracting party to the EEA Agreement and to provide the contact details for these authorities. The Mutual Recognition Regulation thus addresses difficulties affecting dialogue between national administrations in the non-harmonised area. With the establishment of the PCPs, contacts between national authorities as regards the non-harmonised field of products within the EU have been greatly simplified.

Contacts between national administrations are often also necessary for getting more information about the product and the technical rules in another Member State or in an EFTA state that is a contracting party to the EEA Agreement, including whether it is lawfully marketed there. The burden for both individual economic operators and national authorities is thus alleviated by the information activities of the PCPs.

The Mutual Recognition Regulation establishes several tasks for PCPs relating to information provided at the request of economic operators or competent authorities in other Member States or in an EFTA state that is a contracting party to the EEA Agreement. In particular, Article 10(3) of the Regulation establishes that:

> 'Product Contact Points in the Member State in which the economic operator concerned has lawfully marketed the product in question may provide the economic operator or the competent authority as referred to in Article 6 with any relevant information or observations.'

Thus, while not imposing any obligation on the PCPs, the Mutual Recognition Regulation opens the door for these bodies to assist economic operators or the authorities in another

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[17] In the exceptional situation of a prior authorisation procedure, marketing may take place only after the authorisation has been obtained. It must be underlined that, as explained by recital 12 of the Mutual Recognition Regulation, 'A requirement that the placing of a product on the market be subject to prior authorisation should, as such, not constitute a technical rule, so that a decision to exclude or remove a product from the market exclusively on the grounds that it does not have valid prior authorisation should not constitute a decision to which this Regulation applies'.

[18] See footnote 13.

[19] 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.

Member State or in an EFTA state that is a contracting party to the EEA Agreement by providing them with relevant information, if available, on the lawful marketing of a product.

**Case 1: Administrative cooperation**

An economic operator has placed a product on the market in a Member State or in an EFTA state that is a contracting party to the EEA Agreement where no specific obligations exist as regards its marketing and is now trying to introduce it in another Member State as well. The authorities of the country of destination would like to ascertain whether any legal procedures or market surveillance activities have been undertaken in the State where the product was actually marketed on account of its perceived lack of safety.

The competent authorities of the Member State or the EFTA state that is a contracting party to the EEA Agreement where the economic operator tries to introduce its product should then contact the PCP of the State of origin, directly or through their own PCP. This PCP in turn will provide them with the contact details of the relevant authorities and/or forward to them the request.

**Administrative cooperation** allows 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.

**Case 2: Disproportionate requirements**

To recognise some types of products as 'lawfully marketed' in other Member States, the authorities of Member State A accept only official certifications produced by the administration of the Member State of origin. They do not consider at all any other kind of document, dismissing them as 'easilyforged'.

For products marketed in Member States where such certifications exist, this requirement does not pose any problem, as those certifications would immediately confirm that they are 'lawfully marketed' there. In contrast, for products marketed in those Member States that do not produce such certifications (for instance because they rely solely on market surveillance mechanisms), this condition would amount to an impossible obstacle.

In conclusion, **such a condition is disproportionate** and amounts to a measure having an effect equivalent to quantitative restrictions, thus in breach of Article 34 TFEU.

**Case 3: Prior authorisation procedures**

Some economic operators believe that, once a product has already been lawfully marketed in a Member State, it should not require authorisation in the Member State of destination. That is not necessarily the case.

Indeed, **such national procedures may still apply** in the Member State of destination and, even if considered a restriction on the free movement of goods, they could be justified if they pursue a public interest objective recognised by EU law and if they comply with the principle of proportionality.

## 8. CONCLUSIONS

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.

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, in their examination and assessment of a product, in particular whether it is lawfully marketed in another Member State, authorities should be aware that, under Article 5 of the Regulation and the established case law of the Court of Justice of the EU, the Member State or the EFTA state that is a contracting party to the EEA Agreement shall show that the measure (or requirement) is necessary and, where appropriate, that the marketing of the products in question poses a risk and that the measure (or requirement) conforms to the principle of proportionality. In conclusion, 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.