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.