EUROPEAN COMMISSION

ENTERPRISE AND INDUSTRY DIRECTORATE-GENERAL

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Guidance document[1]

The application of the Mutual Recognition Regulation to narcotic drugs and psychotropic substances

1. INTRODUCTION

This document seeks to provide a 'user-friendly' guidance to issues regarding the Mutual Recognition Regulation (EC) No 764/2008[2] (the 'Mutual Recognition Regulation' or 'the Regulation') and in particular to clarify the application of and procedures referred to in the Regulation to the area of psychotropic substances.

This guidance document does not cover drug precursors. This is an area that is fully harmonised and therefore falls outside the scope of the principle of mutual recognition. These chemicals are regulated by Regulation (EC) No 273/2004[3] as regards intra-EU trade and by REACH (Regulation (EC) No 1907/2006). It does not cover either controlled substances under the UN Conventions[4], which have no medical or scientific purpose, or controlled substances under Council Decision 2005/387/JHA[5], insofar as those substances cannot be lawfully marketed in the EU.

This document will be updated to reflect experience and information from the Member States, authorities and businesses.

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1 This document is not legally binding. Neither the European Commission nor any person acting on its behalf may be held responsible for the use to which information contained in this publication may be put, nor for any errors which may appear despite careful preparation and checking. This guidance document does not necessarily reflect the view or the position of the European Commission.

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, p. 21.

3 OJ L 47, 18.2.2004, p. 1–10.

4 The 1961 Single Convention on Narcotic Drugs and the 1971 Convention on Psychotropic Substances.

5 Council Decision 2005/387/JHA of 10 May 2005 on the information exchange, risk-assessment and control of new psychoactive substances, OJ L 127, 20.5.2005, p. 32–37.

2. FREE MOVEMENT OF GOODS AND MUTUAL RECOGNITION

2.1. 2.1 Controlled substances with medical or scientific purpose within the meaning of the United Nations Conventions.

These products are covered by Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use on medicinal products[6] and Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products[7] (the 'EU pharmacovigilance system'). Consequently the Mutual Recognition Regulation does not apply.

2.2. 2.2 Not controlled substances

2.2.1. With medical or scientific purpose

The EU pharmacovigilance system applies.

2.2.2. Without medical or scientific purpose

- Restrictive measures taken on the grounds of public health or public safety

Depending on the substance (e.g. alcohol, caffeine based-products, tobacco), such measures can be taken in accordance with Regulation 178/2002[8] and Regulation 882/2004[9], i.e. food law, or with Articles 8(3) and 12 of Directive 2001/95[10] on general product safety. Consequently the Mutual Recognition Regulation does not apply according to Article 3(2).

- Restrictive measures taken on other grounds

The Mutual Recognition Regulation would apply in those cases, for instance when a psychoactive substance lawfully marketed in another Member State is denied for reasons based on the denomination, size, composition, etc.

3. THE MUTUAL RECOGNITION REGULATION (EC) 764/2008

The Regulation operates in the non-harmonised area, and in particular for products for which there is no harmonisation of laws at EU level, or for aspects of product falling outside the scope of EU harmonisation measures.

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6 OJ L 311, 28.11.2001, p. 67–128.

7 OJ L 311, 28.11.2001, p. 1–66.

8 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, OJ L 31, 1.2.2002.

9 Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules, OJ L 165, 30.4.2004.

10 Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety (Text with EEA relevance), OJ L 11, 15.1.2002.

The Mutual Recognition Regulation lays down procedures relating to the application of certain national technical rules on products lawfully marketed in another Member State. The main aim is to make the mutual recognition principle fully operational.

Pursuant to Article 2 of the Regulation it should apply to administrative decisions addressed to economic operators on the basis of a technical rules in respect of any product lawfully marketed in another Member State.

As regards narcotic drugs and psychotropic substances, the Mutual Recognition Regulation should apply in particular cases and on a case by case basis. In particular, when competent authorities of a Member State intend to adopt a decision that could prohibit the marketing of those substances lawfully marketed in another Member State on other than safety or health grounds, the Regulation should apply. This is the case, for example, when a psychoactive substance lawfully marketed in another Member State is denied for reasons based on the denomination, size, composition, etc.