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## Guidance document<sup>1</sup>

# The application of the Mutual Recognition Regulation to fertilisers and growing media

## 1. INTRODUCTION

This document seeks to provide ‘user-friendly’ guidance on the application of Regulation (EC) No 764/2008<sup>2</sup> (the ‘Mutual Recognition Regulation’ or ‘the Regulation’) to fertilisers and growing media. It will be updated to reflect experience and information from the Member States, authorities and businesses.

The products specifically concerned are:

- Fertilisers, that is, substances that supply plant nutrients or amend soil fertility, other than ‘EC fertilisers’<sup>3</sup>.
- Growing media, that is, materials, other than soil *in situ*, in which plants are grown.

## 2. THE REGULATORY FRAMEWORK APPLICABLE TO FERTILISERS AND GROWING MEDIA

As EU law stands, fertilisers are only partially harmonised. Regulation (EC) No 2003/2003<sup>4</sup> introduced technical and labelling requirements for “EC fertilisers”, i.e. those inorganic fertilisers which comply with the fertiliser type designations specified in the Regulation. Those EC fertilisers are allowed to freely circulate within the internal market. The Regulation, however, does not prevent Member States, from additionally allowing the placing on the

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<sup>2</sup> 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.

<sup>3</sup> Covered by Annex I to Regulation (EC) No 2003/2003; OJ L 304, 21.11.2003, p. 1.

<sup>4</sup> See note 3.

market of “national” fertilisers, i.e. products which are not designated as “EC fertilisers”, but are produced according to national provisions. While those provisions do not need to comply with the specific EU legislation in the area of fertilisers, they have nevertheless to respect the basic principles of the EU Treaty; especially the principle of free movement of goods (Articles 34-36 TFEU). Regulation (EC) No 764/2008 (“the Regulation”) has been adopted to make the principle of mutual recognition fully operational, therefore reducing discrepancies between national rules in the non harmonised area.

Growing media are not covered by any EU piece of legislation (apart from that related to EU’s official environmental label: the European Union Eco-label<sup>5</sup>, which is a voluntary scheme seeking to encourage businesses to market products and provide services with lower environmental impact).

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

The Regulation applies to administrative decisions addressed to economic operators, on the basis of a technical rule, in respect of any non-harmonised product lawfully marketed in another Member State, where the direct or indirect effect of that decision is the prohibition, modification, additional testing or withdrawal of the product (Article 2.1). Any authority intending to take such a decision must follow the procedural requirements in the Regulation.

The Regulation will apply when all the following conditions are met:

#### **3.1. The (intended) administrative decision must concern a product lawfully marketed in another Member State**

The principle of mutual recognition applies where a product, irrelevant of its actual origin (EU or third country import), lawfully marketed in one Member State, is placed on the market in another Member State. Following this principle, a Member State cannot in principle forbid the sale on its territory of products which are lawfully marketed in another Member State, even if they were manufactured according to different technical rules. Both actual and possible denials of mutual recognition are governed by the Regulation. Hence, any Member State intending to ban access to its market should follow the procedure in Article 6.

#### **3.2. The (intended) administrative decision must concern a product which is not subject to harmonised EU law**

The Regulation operates in the non-harmonised area, in relation to products for which there is either no harmonisation of laws at EU level, or for aspects not covered by partial harmonisation.

#### **3.3. The (intended) administrative decision must be addressed to an economic operator**

Any restrictive decisions taken by a national authority and addressed to any natural or legal person who is not an economic operator do not fall within the scope of the Regulation.

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<sup>5</sup> Regulation (EC) No 66/2010 of the European Parliament and of the Council of 25 November 2009 on the EU Ecolabel (Text with EEA relevance); OJ L 27, 30.1.2010, p. 1–19.

### **3.4. The (intended) administrative decision must be based on a technical rule**

Under Article 2(2) of the Regulation a technical rule is any provision of a law, regulation or other administrative provision of a Member State, not harmonised at EU level:

(1) which prohibits in its territory the marketing of a product (or type of product) lawfully placed on the market in another Member State, or compliance with which is compulsory for that product to be marketed in the Member State where the administrative decision is or will be taken, and

(2) which lays down the characteristics required of that (type of) product, such as levels of quality, performance or safety, or dimensions, including requirements as regards the name under which it is sold, terminology, symbols, testing and test methods, packaging, marking or labelling, or

(3) which imposes on the (type of) product, for the purpose of protecting consumers or the environment, any other requirement which affects the life-cycle of the product after it has been placed on the market, such as condition of use, recycling, re-use or disposal, where such conditions can significantly influence the composition, nature or marketing of the (type of) product.

### **3.5. The direct or indirect effects of the (intended) administrative decision must be any of the following:**

- (a) prohibition of the placing on the market of that (type of) product;
- (b) modification or additional testing of that (type of) product before it can be placed or kept on the market;
- (c) withdrawal of that (type of) product from the market.

Any such (intended) decision must be taken in accordance with Article 2(1) of the Regulation.

## **4. THE APPLICATION OF THE MUTUAL RECOGNITION REGULATION TO FERTILISERS AND GROWING MEDIA**

The Mutual Recognition Regulation should apply to fertilisers and growing media only if all conditions set out under points 4.1 to 4.4 are met:

### **4.1. The (intended) administrative decision must concern fertilisers and/or growing media lawfully marketed in another Member State**

The Regulation should apply only to “national” fertilisers and growing media lawfully marketed in another Member State (Article 2(1)). That means that fertilisers or growing media which have not previously been marketed on the territory of the EU fall outside the scope of the Regulation. They will have to comply with the technical rules applicable in the Member State where they are put on the market for the first time in the EU.

## **4.2. The (intended) administrative decision must be addressed to an economic operator**

Under Article 2(1), the Regulation applies to administrative decisions addressed to economic operators, whether taken or intended, on the basis of a ‘technical rule’, in respect of fertilisers and growing media lawfully marketed in another Member State, where the direct or indirect effect of that decision is the prohibition, modification, additional testing or withdrawal as set out under point 4.1.

An economic operator is, in essence, a person in the supply chain for the product concerned, from manufacturer/importer to retailer. End users, even *professional users*, as those growing crops or raising animals, do not fall within the scope of the Mutual Recognition Regulation.

Thus - and without prejudice to Art. 36 TFEU – any restrictive decisions taken by competent authorities and addressed to any natural or legal person who is not an economic operator are not covered by the Mutual Recognition Regulation.

## **4.3. The (intended) administrative decision must be based on a technical rule**

### *4.3.1. The notion of ‘technical rule’*

The Mutual Recognition Regulation applies to (intended) administrative decisions taken on the basis of a ‘technical rule’ (Article 2(2)).

As regards fertilisers and growing media specifically, a technical rule is any provision of a law, regulation or other administrative provision of a Member State:

- (a) which prohibits the marketing of any “national” fertiliser or growing media lawfully marketed in another Member State in the territory of the Member State where the administrative decision is or will be taken or compliance with which is compulsory when that fertiliser or growing media is marketed in the territory of that Member State, and
- (b) which lays down either:
  - the characteristics required for that (type of) fertiliser or growing media, such as levels of quality, performance or safety, or dimensions, including requirements as regards the name under which it is sold, terminology, symbols, testing and test methods, packaging, marking or labelling; or
  - any other requirement which is imposed on that (type of) fertiliser or growing media for the purposes of protecting consumers or the environment, and which affects its life-cycle after it has been placed on the market, such as conditions of use, recycling, reuse or disposal, where such conditions can significantly influence the composition, nature or marketing of the fertiliser or growing media.

### *4.3.2. Prior authorisation procedures*

EU law does not in principle preclude Member States from establishing appropriate measures, if they deem this necessary to control and/or restrict the placing on the market of “national” fertilisers or growing media for public health reasons or

environmental protection. Member States usually establish those measures through prior authorisation procedures in accordance with which, before a product may be placed on a given Member State's market, the competent authority of that Member State should give its formal approval following an application.

The Court of Justice has repeatedly held<sup>6</sup> that any national legislation which makes the marketing of products subject to a prior authorisation procedure restricts the free movement of goods. Nevertheless, such procedures could be justified if national rules pursue a public-interest objective recognised by EU law and comply with the principle of proportionality (Recital (11) of the Regulation).

The Court of Justice has set a number of conditions under which the prior authorisation procedure might be justified:

- it must be based on objective, non-discriminatory criteria which are known in advance to the undertakings concerned, in such a way as to circumscribe the exercise of the national authorities' discretion, so that it is not used arbitrarily;
- it should not essentially duplicate controls which have already been carried out under other procedures, either in the same State or in another Member State;
- prior authorisation will be necessary only where subsequent control must be regarded as being too late to be genuinely effective and to enable it to achieve its aim;
- the procedure should not, on account of the cost and time element, be such as to deter operators from pursuing their business plan.

#### 4.3.3. *Is a prior authorisation a technical rule?*

The obligation to submit fertilisers or growing media for prior authorisation before they can be marketed in a Member State falls outside the scope of the Regulation (Recitals (12) of the Regulation). Such an obligation does not in itself constitute a technical rule within the meaning of the Regulation since it does not lay down the characteristics required of that (type of) fertiliser or growing media. Thus, any decision to exclude or remove fertilisers or growing media from the market solely on the grounds that they do not have prior authorisation does not constitute a decision to which the Regulation applies.

When, however, an application for such mandatory prior authorisation of a product is made, any intended decision to reject the application on the basis of a technical rule should be taken in accordance with the Regulation, so that the applicant can enjoy the procedural protection the Regulation provides.

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<sup>6</sup> Judgment of the Court of Justice of 22 January 2002, Canal Satélite Digital SL, Case C-390/99, paragraph 43; Judgment of the Court of 10 November 2005, Commission v Portuguese Republic, Case C-432/03, paragraph 52; Judgment of the Court of 15 July 2004, Nicolas Schreiber, C-443/02, paragraphs 49-50.

#### 4.3.4. *'Positive lists' for fertilisers and growing media*

Some Member States refer through their relevant prior authorisation procedures to 'positive lists' sorting certain fertiliser and/or growing media types. According to these lists, products that comply with the types listed may be placed on the national market of the Member State of destination.

EU law does not in principle preclude Member States from establishing such a positive list, if they deem this necessary to control and/or restrict the placing on the market of "national" fertilisers or growing media for public health reasons or environmental protection. Nevertheless, according to constant case law of the European Court of Justice national legislation should make provision for a procedure designed to allow a given type to be added to those lists and/or an individual registration or authorisation procedure for products (product types) not listed, but already legally marketed or manufactured in another Member State. Such a procedure must be one which is readily accessible, can be completed within a reasonable period, and, if it leads to a refusal, the decision of refusal must be open to challenge before the courts (cf. Case C-244/06, *Dynamic Medien*, para. 50).

#### 4.3.5. *'Negative lists' for fertilisers and growing media*

In some other cases prior authorisation procedures rely on existing 'negative lists' where some substances are blacklisted. In application of this system, Member States refuse to authorise the marketing of fertilisers and/or growing media uniquely on the grounds that they present unauthorised components without justifying the refusals by reference to a real risk to public health. In accordance with the Court's case-law (cf. Case C-24/00, *Commission v French Republic*, para. 43), it is for the Member State, in each case, to state the public health risks incurred.

Additionally, it derives from the same case-law that Member States are not entitled to prohibit the marketing of fertilisers or growing media lawfully marketed in another Member State on the sole grounds that no benefit accrues from their use and without reference to any considerations of public health or protection to the environment.

#### 4.3.6. *Language requirements for labelling*

Member States may require that the label, the markings on the package and the accompanying documents must appear in at least the national language(s) of the Member State of destination as mentioned in recital 10 of Regulation (EC) No 764/2008.

### 4.4. **The (intended) administrative decisions must prohibit the marketing of a fertiliser or growing media lawfully marketed in another Member State**

The direct or indirect effect of the (intended) administrative decision should be any of the following:

- prohibition of the placing on the market of that (type of) fertiliser or growing media;

- modification or additional testing of the (type of) fertiliser or growing media before it can be placed or kept on the market;
- withdrawal of that (type of) fertiliser or growing media from the market.

## **5. EVALUATION PROCEDURES AND REQUESTS FOR INFORMATION**

When a competent authority submits a product to an evaluation to determine whether or not to adopt an administrative decision, Member State may request economic operators some relevant information concerning the characteristics of the product (Art. 4 of the Regulation). However, the request should remain proportionate: it should not essentially duplicate controls which have already been carried out under other procedures, either in the same State or in another Member State.

Member States can not refuse certificates or test reports issued by a conformity assessment body accredited for the appropriate field of conformity-assessment activity in accordance with Regulation (EC) No 765/2008 on grounds related to the competence of that body (Art. 5 of the Regulation).

## **6. CONCLUSION: TACKLING RISKS TO HEALTH AND ENVIRONMENT**

Mutual recognition is based on the freedom of movement of goods through mutual confidence between Member States and on the assumption that Member States are applying equivalent criteria for the protection of the environment and human health.

However, the Member State of destination might have legitimate reasons to forbid or stop within its territory the marketing of fertilisers or growing media even if lawfully marketed in another Member State. EU legislation provides enough possibilities to directly ban dangerous products (the general product safety Directive<sup>7</sup>, the food safety Regulation<sup>8</sup>, and the official food and feed controls Regulation<sup>9</sup>). In addition, Article 36 TFEU lists the defences that could be used by Member States to justify national measures that impede cross-border trade, among others the protection of health and life of humans, animals or plants. The Court of Justice interprets narrowly the list of derogations in Article 36 TFEU, which all relate to non-economic interests. Moreover, any measure must respect the principle of proportionality and not ‘constitute a means of arbitrary discrimination or a disguised restriction on trade between Member States’<sup>10</sup>.

The burden of proof in justifying the measures adopted according to Article 36 TFEU lies with the Member State and not with the economic operators.

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<sup>7</sup> 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, p. 4–17.

<sup>8</sup> 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, p. 1–24.

<sup>9</sup> 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, p. 1–141.

<sup>10</sup> Case 34/79 Henn and Darby [1979] ECR 3795, paragraph 21, as well as Joined Cases C-1/90 and C-176/90 Aragonesa de Publicidad Exterior and Publivía [1991] ECR I-4151, paragraph 20.