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ENTERPRISE AND INDUSTRY DIRECTORATE-GENERAL

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Guidance document[1]

The application of the Mutual Recognition Regulation to food supplements

1. INTRODUCTION

This document seeks to clarify how Regulation (EC) No 764/2008[2] (the 'Mutual Recognition Regulation' or 'the Regulation') applies to the marketing of food supplements within the EU[3]. It will be updated to reflect experience and information from the Member States, authorities and businesses.

2. THE REGULATORY FRAMEWORK APPLICABLE TO FOOD SUPPLEMENTS

Directive 2002/46/EC[4] partially harmonises the rules on the placing of food supplements on the market. It covers all food supplements, with certain requirements — in particular on labelling information — applying to all food supplements regardless of their composition.

As regards composition, we can distinguish two major types of food supplements:

– supplements containing vitamins and minerals

– supplements containing substances other than vitamins and minerals.

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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, p. 21.

3 This document is based on the Commission's report on the use of substances other than vitamins and minerals in food supplements [COM(2008)824 of 5 December 2008], published at http://ec.europa.eu/food/food/labellingnutrition/supplements/index_en.htm.

4 Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements, OJ L 183, 12.7.2002, p. 51. For further information about the Directive and its application, please consult http://ec.europa.eu/food/food/labellingnutrition/supplements/index_en.htm.

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

The Regulation applies to administrative decisions addressed to economic operators, on the basis of a technical rule, in respect of any 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 set out in the Regulation.

The Mutual Recognition 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 lawfully marketed in one Member State is placed on the market in another Member State. It says that a Member State cannot 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.

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

Under the Regulation[5] 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

[5] Article 2 (2) of the Regulation.

(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 the Regulation[6].

4. THE APPLICATION OF THE MUTUAL RECOGNITION REGULATION TO FOOD SUPPLEMENTS

The Mutual Recognition Regulation applies to food supplements only if all the conditions set out under points 4.1 to 4.5 are met:

4.1. The (intended) administrative decision must concern food supplements lawfully marketed in another Member State

The Regulation applies only to food supplements lawfully marketed in another Member State (Article 2(1)).

That means that food supplements which have not previously been marketed in the EU fall outside the scope of the Regulation. They will have to comply with all the 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 concern an element of the product which is not subject to harmonised EU law

Several elements of, and requirements for, food supplements are already harmonised at EU level:

- Vitamins and minerals, and specific chemical forms of these, permitted for use in food supplements are harmonised by Directive 2002/46/EC[7]. However, the maximum and minimum amounts of vitamins and minerals present in food supplements per daily portion consumed have not yet been harmonised. Regulation (EC) No 764/2008 will therefore apply to these aspects until they have

[6] Article 2(1) of the Regulation.

[7] A transitional period where, under certain conditions indicated in Article 4(6) of Directive 2002/46/EC, vitamins and minerals not included in the EU lists could be allowed to be used in food supplements at national level ended on 31 December 2009.

been harmonised by EU legislation. This Regulation will also apply to the purity criteria for substances listed in Annex II, where these are not specified in other items of EU legislation (for example in the additive legislation).

- Labelling, presentation and advertising are harmonised by Articles 6 to 9 of Directive 2002/46/EC as well as by the general labelling provisions in Directive 2000/13/EC[8].

- Regulation (EC) No 1924/2006[9] lays down conditions for the use of nutrition and health claims on the packaging of such things as food supplements. Though the Regulation has been in force since 1 July 2007, it includes a transitional period for products which were on the market when it entered into force but which do not comply with its provisions. This Regulation is very important in a sector like this, in which claims, and in particular health claims, are a favoured means of communication with consumers. The decisive criterion for the use of a health claim is that the health effect claimed for a nutrient or substance absolutely must be based on scientific evidence.

- The general principles of food safety are laid down in Regulation (EC) No 178/2002[10]. They cover not only any product defined as a 'foodstuff' but also any substance introduced into the food chain for the purposes of manufacturing a foodstuff, irrespective of the existence of specific provisions for that substance. Accordingly, all the provisions of Regulation (EC) No 178/2002 apply directly to the manufacture and ingredients of food supplements.

- Some of these food supplements or their ingredients may be considered as 'novel food' or 'novel ingredients'; within the meaning of Regulation (EC) No 258/97, this covers all foods and food ingredients which had not been used for human consumption to a significant degree within the Union prior to the Regulation's entry into force. This definition covers foods and food ingredients: with a new or intentionally modified primary molecular structure; consisting of or isolated from micro-organisms, fungi or algae; consisting of or isolated from plants; and food ingredients isolated from animals obtained by non-traditional propagating or breeding practices. Regulation (EC) No 258/97[11], interprets the concept of 'novel food' broadly. It explains how a plant extract which was not on the internal market, or not being produced, at the date of entry into force of the Regulation

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8 Directive 2000/13/EC of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs, OJ L 109, 6.5.2000, p. 29. For further details, see http://ec.europa.eu/food/food/labellingnutrition/foodlabelling/index_en.htm.

9 Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods, OJ L 404, 30.12.2006, p. 9. For further information, see http://ec.europa.eu/food/food/labellingnutrition/claims/index_en.htm.

10 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. For further information, see http://ec.europa.eu/food/food/foodlaw/principles/index_en.htm, http://ec.europa.eu/food/food/foodlaw/guidance/index_en.htm and http://ec.europa.eu/food/food/foodlaw/procedures/index_en.htm.

11 Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients, OJ L 43, 14.2.1997, p. 1. For further details, see http://ec.europa.eu/food/food/biotechnology/novelfood/index_en.htm.

will, in principle, be considered a 'novel ingredient', even though the plant from which it is extracted would not be considered 'novel'.

In accordance with Article 2(2)(a), the Mutual Recognition Regulation will not apply where the (intended) administrative decision is based on any of the above regulations or directives.

GENERAL OVERVIEW		
Characteristics of the product	**Food supplements containing vitamins and minerals**	**Food supplements containing substances other than vitamins and minerals**
Vitamins and minerals and specific chemical forms of these, permitted for use in food supplements	**Harmonised** by Directive 2002/46/EC	N/A
Purity criteria for substances listed in Annex II of Directive 2002/46/EC	**Not yet harmonised** → Regulation (EC) No 764/2008 applies to supplements lawfully marketed in another Member State, unless already specified in other EU legislation (e.g. in the additives legislation)	N/A
Maximum amounts of vitamins and minerals present in food supplements per daily portion of consumption	**Not yet harmonised** → Regulation (EC) No 764/2008 applies to supplements lawfully marketed in another Member State	N/A
Other rules on the composition of food supplements	**If novel ingredient: harmonised** by Regulation (EC) No 258/97. **If food additives other than colours and sweeteners: harmonised** by Directive 95/2/EC.	**If no novel ingredients: not yet harmonised** → Regulation (EC) No 764/2008 applies to supplements lawfully marketed in another Member State.
Name under which products are sold	**Harmonised** by Directives 2002/46/EC and 2000/13/EC	**Harmonised** by Directives 2002/46/EC and 2000/13/EC
Labelling, presentation and advertising	**Harmonised** by Directives 2002/46/EC and 2000/13/EC	**Harmonised** by Directives 2002/46/EC and 2000/13/EC
Nutrition and health claims	**Harmonised** by Regulation (EC) No 1924/2006	**Harmonised** by Regulation (EC) No 1924/2006

4.3. The (intended) administrative decision must be addressed to an economic operator

Pursuant to 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 food supplements lawfully marketed in another Member State, where the direct or indirect effect of that decision is the prohibition, modification, additional testing or withdrawal of such products.

Thus, any restrictive decisions taken by competent authorities (including the police) and addressed to any natural or legal person who is not an economic operator (e.g. private citizens) do not fall within the scope of the Mutual Recognition Regulation.

4.4. The (intended) administrative decision must be based on a technical rule

4.4.1. The notion of 'technical rule'

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

For food supplements, a technical rule is any provision of a law, regulation or other administrative provision of a Member State:

- which is not subject to EU harmonisation (see point 4.2);
- which prohibits in its territory the marketing of food supplements lawfully marketed in another Member State, or where 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
- which lays down the characteristics required of that (type of) food supplement, 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.

4.4.2. Is a prior authorisation a technical rule?

The obligation to submit food supplements for prior authorisation may constitute an infringement of Directive 2002/46/EC for food supplements containing vitamins and minerals, or an impediment to the free movement of goods under Articles 34 to 36 TFEU (ex Arts. 28 – 30 of the EC Treaty)[12].

However, this does not in itself constitute a technical rule within the meaning of the Regulation since it does not, as such, lay down the characteristics required of that (type of) food supplement. Thus, any decision to exclude or remove food supplements from the market solely on the grounds that they do not have prior authorisation does not constitute a decision to which the Regulation applies.

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[12] See, for example, judgment of the Court of Justice of 5 February 2004, Commission of the European Communities v French Republic, Case C-24/00.

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.

4.4.3. Does a national rule requiring a notification to the national authorities constitute a technical rule?

Article 10 of Directive 2002/46/EC specifies that Member States may require the manufacturer or the person placing the product on the market to notify the competent authority by submitting a model of the label used for the product.

Such notification is, as such, already the subject of harmonisation at EU level.

4.4.4. The classification of the product as a medicinal product

Some substances, in particular certain herbal extracts, are used both in food supplements and for manufacturing proprietary medicinal products, e.g. traditional herbal medicinal products. As a result, there have been borderline cases which have given rise, or could give rise, to situations where a given product is authorised for marketing as a food in some Member States, but as a medicinal product in others.

These classification problems are discussed in more detail in the Commission's report on the use of substances other than vitamins and minerals in food supplements[13].

In most cases, however, classification problems will arise not from technical rules but from a case-by-case assessment of the product, taking into account all its characteristics. In such cases, the Mutual Recognition Regulation will not apply.

4.5. The (intended) administrative decisions must prohibit the marketing of a food supplement lawfully marketed in another Member State

4.5.1. The restrictive effect of the decision

Under the Regulation, the direct or indirect effect of the (intended) administrative decision is or would be any of the following:

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

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13 COM(2008)824 of 5.12.2008, published at http://ec.europa.eu/food/food/labellingnutrition/supplements/index_en.htm. See also the judgments of the Court of Justice of 15 January 2009 (Hecht-Pharma GmbH v Staatliches Gewerbeaufsichtsamt Lüneburg, Case C-140/07), 15 November 2007 (Commission of the European Communities v Federal Republic of Germany, Case C-319/05) and 9 June 2005 (HLH Warenvertriebs GmbH (C-211/03) and Orthica BV (C-299/03 and C-316/03 to C-318/03) v Bundesrepublik Deutschland).

This means that any such restriction will be governed by the Mutual Recognition Regulation.

4.5.2. Direct or indirect risk to human health deriving from food

Regulation (EC) No 178/2002 establishes a rapid alert system for the notification of a direct or indirect risk to human health deriving from food. It obliges the Member States to notify the Commission immediately of any measure aimed at restricting the placing on the market of, withdrawing from the market of, or recalling food or feed in order to protect human health, and which requires rapid action.

Article 3(2)(b) of the Mutual Recognition Regulation consequently excludes from its scope all measures taken by the competent authorities of the Member States pursuant to Article 50(3)(a) and Article 54 of Regulation (EC) No 178/2002.

Regulation (EC) No 882/2004[14] lays down a specific procedure to ensure that economic operators remedy any situation of non-compliance with food law. Measures taken by the competent authorities of the Member States pursuant to Article 54 of that Regulation are therefore excluded from the scope of the Mutual Recognition Regulation.

[14] 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; corrected version in OJ L 191, 28.5.2004, p. 1.