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Free Movement of Enriched Foodstuffs and Food Supplements in the European Union

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Especially in the food sector the establishing of a common market has been one of the most noticeable achievements of the European Union so far. But it is also true that the free movement of foodstuffs has not yet totally been realised. The present article aims to provide an overview of the principles of free movement of foodstuffs in the European Union and the connected rights for economic operators in the food sector, with particular regard to the manufacture and the marketing of enriched foodstuffs and food supplements.

I. Introduction

As is known, one of the European Community's main tasks is to promote the economic activities of the Member States by abolishing the existing obstacles to the free movement of goods (see Art. 3, para. 1 lit. c) and Art. 28-30 of EC Treaty). In this regard, the free movement of foodstuffs in the European Union is a very important economic aspect. Differences between the food laws of the single Member States may impede the free movement of foodstuffs by creating unequal conditions for competition. Therefore the European legislator is proceeding in a quite determined way to harmonise national food legislation and to establish common concepts, principles and procedures in this sector. For example, the adoption of Regulation (EC) No. 178/2002 laying down the general principles and requirements of food law and food safety and establishing the European Food Safety Authority¹ means a very important step towards a uniform European Food Law. This regulation indeed has been followed by the adoption of numerous legal provisions at EU-level. Furthermore the Court of Justice case law contributes significantly to the application of the principle of free movement of goods.

On the other hand, the free movement of foodstuffs has not yet totally been realised. For, in practice, numerous trade hurdles still exist. Indeed, problems are rising again and again especially in trade with food supplements and enriched foods. It is therefore important to apply correctly the principles of free movement of foodstuffs in the European Union, especially as far as the companies are concerned, but also for public authority monitoring bodies.

II. Prohibition of quantitative restrictions on imports and exports

Quantitative restrictions on imports and exports between Member States and all measures having the equivalent effect are prohibited by Art. 28 and 29 of the EC Treaty. Such a prohibition or restriction on imports, exports or goods in transit may only be allowed if justified on specific grounds (e.g. protection of health and life of humans, animals or plants or defence of consumer interests,² Art. 30 of EC Treaty).

First of all, that means, that between the Member States generally, all measures are forbidden, which restrain (totally or partially) imports, exports or goods in transit³ (quantitative restrictions). Furthermore, national trading rules which are capable of hindering, directly or indirectly, actually or potentially, intra-community trade, are prohibited be-

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¹ Official Journal, 2002, L 31, p. 1; to this regard see also "Guidance on the implementation of articles 11, 12, 16, 17, 18, 19 and 20 of Regulation (EC) No. 178/2002 on general food law. Conclusions of the Standing Committee on the Food Chain and Animal Health of 20 December 2004", available on the Internet: http://europa.eu.int/comm/food/food/aw/guidance/ guidance_rev_7_en.pdf.

² The protection of consumers is an unwritten ground of justification, see e.g. Judgment of the Court of 20 February 1979 in Case 120/78, Rewe, Rec. 1979, p.649.

³ See Judgment of the Court of 12 July 1973 in Case 2/73, Geddo/Ente Nazionale Risi, Rec.1973, p. 865.

cause they are considered as measures having effect equivalent to quantitative restrictions of imports.⁴ In the food sector, technical rules are particularly likely to constitute barriers to the free movement of foodstuffs, for example, rules relating to the composition of the product,⁵ its safety,⁶ the labelling, presentation and advertising of the product,⁷ its sales name⁸ and its packaging.⁹ Equally, national measures are forbidden, which have as their specific object or effect the restriction of patterns of exports and thereby the establishment of a difference in treatment between the domestic trade of a Member State and its export trade in such a way as to provide a particular advantage for national production or for the domestic market of the state in question at the expense of the production or of the trade of other Member States (measures having equivalent effect as quantitative restrictions).¹⁰

All these measures, generally, are forbidden between Member States, even if they may apply without distinction both to domestic products and to products from other Member States.¹¹

III. Principle of mutual recognition

1. In general

The rules explained above has been interpreted and applied also by the European Court of Justice. Already in 1979, in the famous case Cassis de Dijon,¹² which involved German legislation on the minimum alcohol content of fruit liqueurs, the Court of Justice laid down the principle of mutual recognition. According to this concept, a product (e.g. a foodstuff) which is lawfully manufactured and/or marketed in one Member State (or in Turkey or in an EFTA State that is a contracting party to the Agreement on the European Economic Area 13) must be accepted in the other Member States even though it is not in line with the domestic rules (e.g. technical rules regarding the composition, the labelling and presentation, the packaging). Only in certain circumstances when it is necessary to satisfy mandatory requirements (e.g. protection of public health and consumer rights) Member States may forbid the marketing of those imported products provided that they do not guarantee an equivalent level of protection.

However, it is important to emphasise that the principle of mutual recognition is only applicable when rules are not harmonised. When a matter is regulated by Community Law any national measure relating thereto must be assessed in the light of the specific harmonising measure and not by Art. 28-30 of the EC Treaty.¹⁴ In other words, when there are uniform Community rules, Member States shall not, for reasons related to their composition, manufacturing specifications, presentation or labelling, prohibit or restrict trade in foodstuffs which comply with Community Law.

- 5 See Judgment of the Court of 14 July 1988 in Case C-90/86, Zoni, Rec. 1988, p. 4285; Judgment of the Court of 5 April 2001 in Case C-123/00, Bellamy, Rec. 2001, p. I-2795.
- 6 See Judgment of the Court of 24 October 2002 in Case C-121/2000, Hahn, Rec. 2002, p. I-9193.
- 7 See Judgment of the Court of 15 July 2004 in Case C-239/02, Douwe Egberts, Rec. 2004, p. I-7007.
- 8 See Judgment of the Court of 5 December 2000, Case C-448/98, Guimont, Rec. 2000, p. I-10663.
- 9 See Judgment of the Court of 10 November 1982 in Case 261/81, Rau/De Smedt, Rec. 1982, p. 3961.
- 10 See Judgment of the Court of 8 November 1979 in Case 15/79, Groenveld, Rec. 1979, p. 3409; Judgment of the Court of 9 June 1992 in Case C-47/90, Delhaize, Rec. 1992, p. I-3669; Judgment of the Court of 16 May 2000 in Case C-388/95, Rioja, Rec. 2000, p. 3123; Judgment of the Court of 20 May 2003 in Case C-108/01, Prosciutto di Parma, Rec. 2003, p. I-5121; Judgment of the Court of 20 May 2003 in Case C-469/00, Ravil, Rec. 2003, p. 5053; see also on this topic; Klaus/Meyer, Qualitätsprodukte auf dem Siegeszug oder: die Entwicklung der EuGH-Rechtsprechung zum Schutz der Ursprungsbezeichnungen bis zu den neuen Urteilen "Prosciutto di Parma" und "Grana Padano", Deutsche Molkerei Zeitung 2003, Heft 22, 23, 24; Capelli/Klaus, La tutela delle indicazioni geografiche nell'ordinamento comunitario e in quello internazionale, Diritto Comunitario e degli Scambi Internazionali 2004, p. 191.
- 11 See Judgment of the Court of 21 June 2001 in Case C-30/99, Commission/Ireland, Rec. 2001, p. 4619.
- 12 See Judgment of the Court of Judgment 20 February 1979 in Case 120/78, Rewe, Rec. 1979, p. 649; see also Commission's interpretative communication on facilitating the access of products to the markets of other Member States: the practical application of mutual recognition (Official Journal, 2003, C 265, p. 2).
- 13 To this regard see point 2.2. of Commission's interpretative communication on facilitating the access of products to the markets of other Member States: the practical application of mutual recognition, cit. above.
- 14 See, in particular, Judgment of the Court of 13 December 2001 in Case C-324/99, DaimlerChrysler AG, Rec. 2001 p. I-9897.

⁴ See Judgment of the Court of 11 July 1974 in Case 8/74, Dassonville, Rec. 1974, p. 837; The European Court of Justice confirmed this case law in numerous judgments, see for example Judgment of the Court of 23 September 2003 in Case C-192/01, Commission v Denmark, Rec. 2003, p. I-9693; Judgment of the Court of 29 April 2004 in Case C-387/99, Commission/Germany, Rec. 2004, p. I-3751.

2. Application of the principle of mutual recognition for the marketing

As far as enriched foodstuffs and food supplements are concerned, their manufacturing and marketing has only partially been harmonised at EU level.

With regard to the enrichment of foods (despite of the use of food additives, an argument not considered by the present explanations) there are only specific harmonised rules on certain substances that may be added for specific nutritional purposes to dietary foodstuffs. The Directive 91/321/EEC on infant formulae and follow-on formulae¹⁵ and the Directive 96/5/EC on processed cereal-based foods and baby foods¹⁶ include positive lists of nutritional substances that may be added to the foods intended for infants and young children up to three years of age covered by these two specific directives. Furthermore, Directive 2001/15/EC¹⁷ applies to all other dietary food groups that are covered by Council Directive 89/398/EEC¹⁸ on foodstuffs intended for particular nutritional uses. The use of the substances in Directive 2001/15/EC is permitted

19 COM (2003) 671 final.

for either all foods for particular nutritional uses covered by the directive or only foods for special medical purposes. The lists include the following categories of nutrients: vitamins, mineral substances, amino acids and other nitrogen compounds, choline and inositol. Anyway, there are no specific uniform rules on the enrichment of foodstuffs for common use as yet. At the moment, there is only a proposal for a regulation of the European Parliament and of the Council on the addition of vitamins and minerals and of certain other substances to foods.¹⁹ For this reason, the principle of mutual recognition is still applicable to the marketing of enriched foodstuffs for common use.

As far as food supplements are concerned, Directive 2002/46/EC,²⁰ as a first stage, has only laid down specific common rules regarding the labelling, presentation and advertising of food supplements as well as rules for vitamins and minerals used as ingredients of food supplements. Indeed, in order to ensure a high level of protection for consumers, only vitamins and minerals in the forms listed in Directive 2002/46/EC may be used for the manufacture of food supplements in the European Union (Art. 4, para. 1 Directive 2002/46/EC).²¹ Anyway, it is important to emphasise that until 31 December 2009, Member States may allow the use (in their territory) of vitamins and minerals not listed in Directive 2002/46/EC provided that (a) the substance in question has been used in one or more food supplements marketed in the Community on the date of entry into force of this Directive (12 July 2002) and (b) the European Food Safety Authority has not given an unfavourable opinion in respect of the use of that substance, or its use in that form, in the manufacture of food supplements (Art. 4, para. 6 Directive 2002/46/EC). Several Member States (for example Italy²²) have adopted lists of those (forms of) vitamins and minerals still allowed in food supplements manufactured and marketed in their territory. Therefore, also as far as the use of vitamins and minerals in food supplements is concerned, at the moment different national rules still exist. Furthermore, harmonised maximum and minimum amounts of vitamins and minerals present in food supplements per daily portion of consumption as recommended by the manufacturer are still missing at EU level.²³ In addition, no specific rules have been laid down by Community Law for other nutrients than vitamins and minerals or substances with a nutritional or physiological effect

¹⁵ Commission Directive 91/321/EEC of 14 May 1991 on infant formulae and follow-on formulae (Official Journal 1991, L 175, p. 35).

¹⁶ Commission Directive 96/5/EC on processed cereal-based foods and baby foods for infants and young children (Official Journal 1996, L 49, p. 17).

¹⁷ Commission Directive 2001/15/EC of 15 February 2001 on substances that may be added for specific nutritional purposes in foods for particular nutritional uses (Official Journal 2001, L 52, p. 19).

¹⁸ Council Directive 89/398/EEC of 3 May 1989 on the approximation of the laws of the Member States relating to foodstuffs intended for particular nutritional uses (Official Journal 1990, L 275, p. 42).

²⁰ 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 (Official Journal 2002, L 183, p. 51).

²¹ The Court of Justice has revealed no factor of such a kind as to affect the validity of Directive 2002/46/EC, see Judgment of the Court of 12 July 2005 in Case C-154/04, Alliance for Natural Health and others, as yet unpublished; to this regard see also Capelli/Klaus, La direttiva sugli integratori alimentari è conforme al diritto comunitario, nota alla sentenza della Corte di giustizia del 12 luglio 2005 nei procedimenti riuniti C-154/04 e C-155/04 (Alliance for Natural Health ed altri), Diritto Comunitario e degli Scampi Internazionali, 2004, p. 437.

²² See Decreto ministeriale of 17 February 2005 (published in Gazzetta Ufficiale No. 54 of 7 March 2005).

²³ Maximum amounts of vitamins and minerals present in food supplements are going to be set at Community level taking in account the criteria established in Art. 5 of Directive 2002/46/EC.

that might be present in food supplements (e.g. such as amino acids, essential, fatty acids, fibre and various plants and herbal extracts).²⁴ As these specific matters are not yet completely regulated by Community Law, the principle of mutual recognition is still applicable.

3. Extent of the principle of mutual recognition

a. In general

Especially in the food sector, Member States have always tried and still try to hinder the access of foodstuffs (e.g. food supplements or enriched food) manufactured and/or marketed in other Member States into the domestic marked claiming that these products do not fulfil the national (safety) requirements and are not equal to the level of protection that they guarantee their own citizens (human health and consumer rights). Indeed, in those situations, often national authorities refuse to allow a product to be placed on the market or order its withdrawal from the market, obliging the economic operator to refrain from marketing the product in that Member State. The result is uncertainty, which can act as an important barrier to gaining access to that market. Therefore, it is very important that economic operators as well as national authorities know to what extent products legally manufactured and marketed in a Member State may be commercialised in another Member State even if they do not fulfil all the national rules of that state.

In following the extent of the principle of mutual recognition according to the Court of Justice case law and the Commission's interpretation²⁵ will be synthesised.

b. Verification of the equivalence of the level of protection of the imported product

The economic operators' right to commercialise their products legally manufactured and marketed in one Member State also in the others is not an absolute right. The Member State of destination has the right to verify if the level of protection of the product (e.g. a food supplement or an enriched foodstuff) imported from another Member State is equivalent to that provided by its own national rules.²⁶ This supervision must be based on objective and non-discriminatory criteria which are known in advance.²⁷ Consequently, the criteria should be duly published or easily available and the supervision should be exercised in the framework of a procedure that is as short, effective and inexpensive as possible.

For example, in order to be able to verify if the imported foodstuff conforms to the rules of the Member State of origin, the authorities of the Member State of destination may ask the economic operator to provide the relevant technical information as well as some product samples. Obviously, if the economic operator has proof of the conformity such as a written confirmation from an authority of the Member State of origin, it would be useful for it to be transmitted to the relevant authority of the Member State of destination. On the other hand, national authorities of the Member State of destination, generally may not impose the official attestation of conformity as a condition for marketing the relevant product on the domestic market.²⁸ Furthermore, it cannot duplicate controls which have already been carried out in the context of other procedures, either in the same State, or in another Member State.²⁹ Rather, according to that Court of Justice case law, the following must be taken into account:³⁰ (a) the checks carried out by a

- 27 See in particular Judgment of the Court of 22 January 2002 in Case C-390/99, Canal Satélite Digital, Rec. 2002, p. I-607.
- 28 See Judgment of 8 May 2003 in Case C-14/02, ATRAL, Rec. 2003, p. I-4431. Such a restriction of free trade would only be justified, if covered by one of the exceptions provided for in Art. 30 EC Treaty or one of the overriding requirements recognised by the case-law of the Court and, in either case, it must be appropriate for securing the attainment of that objective and not go beyond what is necessary in order to attain it.
- 29 See in particular Judgment of the Court of 22 January 2002 in Case C-390/99, Canal Satélite Digital, cit. above. However, the Member State of destination may always carry out additional tests, but at its own expense, see in particular Judgment of the Court of 16 November 2000, in Case C-217/99, Commission/Belgium Rec. 2000, p. I-10251.
- 30 See point 4.1. of the Commission's interpretative communication on facilitating the access of products to the markets of other Member States: the practical application of mutual recognition, cit. above.

²⁴ Not later than 12 July 2007, the Commission shall submit to the European Parliament and the Council a report on the advisability of establishing specific rules, for those kinds of substances used in food supplements (Art. 4, para. 8 Directive 2002/46/CE).

²⁵ Commission's interpretative communication on facilitating the access of products to the markets of other Member States: the practical application of mutual recognition, cit. above.

²⁶ See also point 4. of the Commission's interpretative communication on facilitating the access of products to the markets of other Member States: the practical application of mutual recognition, cit. above.

competent authority in the Member State of origin; (b) the technical or scientific analyses or laboratory tests already carried out in a State of origin and granted by an inspection or certification body legally established there. The Member State of destination will have the right to require additional tests only under certain circumstances.³¹

On the basis of the information obtained on the product in question, the competent authority of the Member State of destination may examine if and to what extent its national technical rules must apply to the imported product. If these data prove that the level of protection is equivalent to that of the Member State of destination, the marketing of that product shall not be hindered. The technical rules to which the product in question do not conform may only be applied if necessary and proportional to protect legitimate objectives such as consumer protection and public health. Otherwise, national authorities are obliged not to apply these technical rules to a product coming from another Member State. To this regard it is important to remember that, if the Member State of destination decides that the product should be refused access to its market, it shall:³² (a) inform the economic operator in writing of those elements of the national technical rules which, in its opinion, prevent the marketing of the product in

- 34 Judgment of the Court of 20 February 1979 in Case 120/78, Rewe, cit. above.
- 35 Judgment of the Court of 17 March 1983 in Case 94/82, Kikvorsch, Rec. 1983, p. 947.
- 36 Judgment of the Court of 19 February 1981 in Case 130/80, Kelderman, Rec. 1981, p. 527.
- 37 Judgment of the Court of 9 December 1981 in Case 193/80, Commission/Italy, Rec. 1981, p. 3019; see also Judgment of the Court of 15 December 1985 in Case 281/83, Commission/Italy, Rec. 1985, p. 3397.
- 38 Judgment of the Court of 14 July 1988 in Case 407/85, Drei Glocken GmbH, Rec. 1988, p. 4233; see also Judgment of the Court of 14 July 1988 in Case 90/86, Zoni, Rec. 1988, p. 4285.
- 39 Judgment of the Court of 12 March 1987 in Case 178/84, Commission/Germany, Rec. 1987, p. 1227; see also Judgment of the Court of 12 March 1987, Case 176/84, Commission/Greece, Rec. 1987, p. 1193.

question in the Member State of destination; (b) prove the grounds for which the technical rule must be imposed on the product to the economic operator; (c) invite the economic operator to submit any comments and duly take into account these comments in the final decision; (d) notify the decision restricting the marketing of the product to the economic operator stating the methods of appeal; (e) notify or inform the Commission of this decision.

In any case, the decision to refuse the access of a foodstuff (e.g. food supplement or enriched food) legally manufactured and/or marketed in another Member State, must conform to the principle of free movement of goods laid down in Art. 28-30 EC Treaty as interpreted by the European Court of Justice. To this regard, in the following, some examples will be given.

c. National measures destined to protect consumers' interests (misleading)

As far as national measures destined to protect consumers' (economic) interests are concerned, according to the Court of Justice case law, the prevention from being misled may easily be ensured by appropriate information on the label and/or the packaging.³³ Therefore, according to the Court of Justice case law, the following national measures hindering the free movement of foodstuffs may for example not be justified on the grounds of consumer interests: (a) the fixing of a minimum alcohol content for alcoholic beverages intended for human consumption;³⁴ (b) the prohibition of the marketing of any beer the acidity of which exceeds a certain level, unless that beer is produced by processes traditionally used in that part of the community to obtain sour beer;³⁵ (c) national rules which require the quantity of dry matter in bread to fall within specified sets of limits;³⁶ (d) national legislation which prohibits the marketing and importation of vinegars of agricultural origin other than those originating in the acetic fermentation of wine and which restricts the designation "vinegar" to winevinegar;³⁷ (e) the extension to imported products of a prohibition on the sale of "pasta" made from common wheat or from a mixture of common wheat and durum wheat;³⁸ (f) the restriction of the German designation "Bier" (and its equivalents in the languages of the other Member States) to beers manufactured in accordance with the rules in force in Germany;³⁹ (g) national rules prohibiting cocoa

³¹ See point 4.1. of the Commission's interpretative communication on facilitating the access of products to the markets of other Member States: the practical application of mutual recognition, cit. above.

³² See point 4.3. of the Commission's interpretative communication on facilitating the access of products to the markets of other Member States: the practical application of mutual recognition, cit. above.

³³ See for example Judgment of the Court of 23 February 1988 in Case 216/84, Commission/France, Rec. 1988, p. 793; Judgment of the Court of 14 July 1988 in Case 407/85, Drei Glocken GmbH, Rec. 1988, p. 4233.

and chocolate products which comply with the requirements as to the minimum content laid down in Council Directive 73/241/EEC of 24 July 1973 from being marketed in Italy under the name used in the Member State of production, and by requiring that those products may only be marketed under the name chocolate substitute;⁴⁰ (h) prohibition of any statement alluding to sugar in the labelling of artificial sweeteners;⁴¹ (i) general prohibition of references to health or slimming;⁴² (j) legislation prohibiting the marketing of margarine or edible fats where each block or its external packaging does not have a particular shape (e.g. the shape of a cube).⁴³

d. National measures destined to protect consumer health

As is known, non-harmonised national measures designed to protect consumer health still exist. It is important to emphasise that in the absence of harmonisation, Member States have the right to decide on the level of protection of human health and life they wish to guarantee.⁴⁴ However, in these cases, the Member States may apply their safety requirements to imported products which are legally manufactured and/or marketed in another Member State only when specific criteria are fulfilled. First of all such national measures have to be necessary and appropriate to protect human health. Therefore, national authorities, which invoke the need of

41 Judgment of the Court of 12 December 1990 in Case C-241/89, SARPP, Rec. 1990, p. I-4695. such a safety measure, shall demonstrate, on the basis of scientific data available and the most recent results of international research, that a certain foodstuff or food ingredient pose a real risk to consumer health and that state intervention is therefore necessary to avert these risks.⁴⁵ Furthermore, it must be shown that human health may not be protected equally effectively by less restrictive intra-Community trade measures. In this context, it is necessary to assess the protection provided by alternative measures. The necessary risk assessment shall be carried out on the common criteria set out by Art. 14 of Regulation (EC) No. 178/2002.

With regard to correct risk management, it is important to emphasise that the criterion of nutritional need of the population of a Member State requiring or not the addition of nutrients to the foodstuffs concerned, may only play a role where this addition may pose a real risk to public health. On the other hand, the judgment of the Member States relating to the protection of public health is particularly autonomous where it is shown that there is still uncertainty in the current state of scientific research, such as certain nutrients (e.g. vitamins), which are not generally harmful in themselves.⁴⁶ However there may be risks in cases of excessive consumption (precautionary principle).

As far as national measures regulating the use of nutrients or of substances with a nutritional or physiological effect in food supplements and in foodstuffs for common use are concerned, partially

- 45 See for example Judgment of the Court of 23 September 2003 in Case C-192/01, Commission/Denmark, cit. above; Judgment of the Court of 5 February 2004 in Case C- 24/00, Commission/ France, cit. above; Judgment of the Court of 2 December 2004 in Case C-41/02, Commission/Netherlands, cit. above.
- 46 See for example Judgment of the Court of 23 September 2003 in Case C-192/01, Commission/Denmark, cit. above; Judgment of the Court of 5 February 2004 in Case C- 24/00, Commission/ France, cit. above; Judgment of the Court of 2 December 2004 in Case C-41/02, Commission/Netherlands, cit. above.

⁴⁰ Judgment of the Court of 16 February 2003 in Case C-14/00, Commission/Italy, Rec. 2003, p. I-513; see also Judgment of the Court of 16 February 2003 in Case C-12/00, Commission/Spain, Rec. 2003, p.I-459; see to this regard Klaus, Wann dürfen Schokoladeerzeugnisse auch tatsächlich unter dem Namen "Schokolade" vermarktet werden? – Beitrag zum Urteil des EuGH, 16. Januar 2003, C-14/00, DLR 2003, p. 365.

⁴² See Judgment of the Court of 23 January 2003 in Case C-221/00, Commission/Austria, Rec. 2003, p. I-1007; Judgment of the Court of 23 January 2003 in Joined Cases C-421/00, C-426/00 and C-16/01, Sterbenz, Haug, e.a., Rec. 2003, p. I-1065; Judgment of the Court of 15 July 2004 in Case C-239/02, Douwe Egberts, cit. above.

⁴³ See Judgment of the Court of 10 November 1982 in Case 261/81, Rau/De Smedt, cit. above; see also Judgment of the Court of 13 March 1984 in Case 16/83, Prantl, Rec. 1984, p. 1299; Judgment of the Court of 4 December 1986, in Case 179/85, Commission/Germany, ECR 1986, p. 3879.

⁴⁴ See for example Judgment of the Court of 5 February 1981 in Case 53/80, Eyssen, Rec. 1984, p. 409; Judgment of the Court of 14 July 1983 in Case 174/82, Sandoz, Rec. 1983, p. 2445; Judgment of the Court of 6 June 1984 in Case 97/83, Melkuni,

Rec. 1984, p. 2367; Judgment of the Court of 10 December 1985 in Case 247/84, Motte, Rec. 1985, p. I-3887; Judgment of the Court of 8 April 1992 in Case C-95/89, Commission/Italy, Rec. 1992, p. I-4545; Judgment of the Court of 16 July 1992 in Case C-344/90, Commission/France, Rec. 1992, p. I-4719; Judgment of the Court of 24 October 2002 in Case C-121/00, Hahn, Rec. 2002, p. I-9193; Judgment of the Court of 23 September 2003 in Case C-192/01, Commission/Denmark, Rec. 2003, p. I-9693; Judgment of the Court of 5 February 2004 in Case C-24/00, Commission/France, Rec. 2004, p. I-1277; Judgment of the Court of 5 February 2004 in Case C-95/01, Greenham e Abel, Rec. 2004, p. I-1333; Judgment of the Court of 5 February 2004 in Case C- 24/00, Commission/France, cit. above; Judgment of the Court of 2 December 2004 in Case C-41/02, Commission/Netherlands, Rec. 2004, p. I-11375.

they still differ considerably. In particular, some Member States require prior authorisation for the marketing of foodstuffs enriched with such substances. It is important to emphasise that, for food supplements, the requirement of authorisation would not be lawful anymore because Directive 2002/46/EC, which has harmonised the general requirements of the manufacturing and marketing of food supplements, only allows the prior notification (see Art. 10 of Directive 2002/46/EC). With regard to the enrichment of foodstuffs for common use (e.g. with nutrients such as vitamins and minerals), where uniform Community rules at the moment do exist, according to the Court of Justice case law the requirement of prior authorisation for foodstuffs, that are legally manufactured and/or marketed in another Member State, is justified only under very strict conditions:⁴⁷ (a) the prior authorisation procedure must be readily accessible and capable of being completed within a reasonable time; (b) that procedure shall be expressly provided for in a measure of general application which is binding on the national authorities; (c) if the procedure leads to a refusal, that decision must be open to challenge before the courts; (d) a prohibition of marketing the foodstuff is only justified where the existence of the risk to public health can be shown.

For example, the Court of Justice has declared the following national measures regulating the use of certain substances do not conform to EU Law due to not establishing that such foodstuffs entail a real risk to consumer health and/or failing to fulfill the

- 49 Judgment of the Court of 19 June 2003 in Case C-420/01, Commission/Italy, Rec. 2003 p. I-6445.
- 50 Judgment of the Court of 23 September 2003 in Case C-192/01, Commission/Denmark, cit. above.
- 51 Judgment of the Court of 5 February 2004 in Case C-24/00, Commission/France, cit. above.
- 52 Judgment of the Court of 5 February 2004 in Case C-270/02, Commission/Italy, Rec. 2004, p. I-1559.
- 53 Judgment of the Court of 2 December 2004 in Case C-41/02, Commission/Netherlands, cit. above.
- 54 Judgment of the Court of 29 April 2004, in Case C-150/00, Commission/Austria, cit. above.
- 55 Judgment of the Court of 29 April 2004, in Case C-387/99, Commission/Germany, cit. above.

requirements of a simplified procedure; they therefore may not be applied to foodstuffs legally manufactured and/or marketed in another Member State: (a) the prohibition in Belgium and Italy to market foodstuffs containing a certain level of gelatine;⁴⁸ (b) the prohibition on the marketing of energy drinks in Italy containing caffeine in excess of a certain limit;⁴⁹ (c) the prohibition on marketing of foodstuffs to which vitamins and minerals have been added in Denmark;⁵⁰ (d) the prohibition in France of marketing certain foodstuffs, such as food supplements and dietary products containing the substances L-tartrate and L-carnitine, and confectionery and drinks to which certain nutrients have been added;⁵¹ (e) the requirement of prior authorisation in Italy for marketing food products for sportsmen and women without having shown that it is necessary and proportionate;⁵² (f) the Dutch administrative practice under which foodstuffs for everyday consumption fortified with certain vitamins may be marketed only when they are neither substitution products nor reconstituted foodstuffs and only if that enrichment meets a nutritional need in the population (in addition, without ascertaining whether those fortified foodstuffs might be a substitute for foodstuffs already marketed for which the addition of those nutrients); 5^{3} (g) the German and Austrian administrative practice under which certain vitamin and mineral nutrient preparations, which have been lawfully produced and/or placed on the market as food supplements in other Member States are classified as medicinal products where they exceed the daily dose⁵⁴ or (Germany) where the daily dose of such vitamins and minerals is more than three times that recommended by the German Gesellschaft für Ernährung.⁵⁵

IV. Measures when the principle of free movement of goods is not respected

There are several measures that can be taken when Member States do not respect the principle of free movement of goods.

1. Member State liability for damage

Member States are obliged to make good loss or damage caused to individuals by breaches of Community Law for which they can be held responsi-

⁴⁷ See Judgment of the Court of 5 February 2004 in Case C-95/01, Greenham e Abel, cit. above; Judgment of the Court of 5 February 2004 in Case C-24/00, Commission/France, cit. above.

⁴⁸ Judgment of the Court of 11 May 1989 in Case 52/88, Commission/Belgium, Rec. 1989, p. I-1137; Judgment of the Court of 11 July 1984 in Case 51/83, Commission/Italy, Rec. 1984, p. 2793.

ble.⁵⁶ Under certain conditions, economic operators, who suffer damage from hindering their product, legally manufactured and/or marketed in one Member State, to be marketed in another Member State, may ask for the payment of compensation.

2. Requests for a preliminary ruling (Art. 234 of EC Treaty)

The authorities and courts in each Member State are responsible for ensuring that Community Law is properly applied in that country. If a national court is in any doubt about the interpretation or validity of a Community Law it may, and sometimes must, ask the Court of Justice for advice. This advice is given in the form of a preliminary ruling. It has to be emphasised, that in the context of requests for preliminary rulings, the Court of Justice has no jurisdiction either to apply the EC Treaty to a specific case or to decide upon the validity of a provision of domestic law in relation to the Community Law.⁵⁷ Nevertheless, the Court has the power to extract from a question imperfectly formulated by the national court those questions which alone pertain to the interpretation of Community Law and may give an abstract answer that then has to be observed by the national court in its decision relating to the concrete case.

State still do not apply Community Law principles, economic operators may involve the European Commission to get that Member State to fulfil its obligations arising from European Law. Indeed, when a Member State has failed to fulfil such an obligation, the Commission or another Member State can bring the matter before the Court of Justice (Art. 227-228 EC Treaty). If the Court of Justice should declare that a Member State has failed to fulfil its obligations arising from Community Law, this Member State must set things right at once. If the Member State concerned fails to take the necessary measures to comply with the judgment the Commission may bring the case again before the Court of Justice and ask for a lump sum or penalty payment to be paid by that Member State. However, in case of missing fulfilment of Community obligations, also the economic operators have possibilities to act. For example, they can make a written complaint about this Member State to the Commission describing the facts of non-fulfilment and asking the Commission for intervention. In fact, those complaints and the cooperation between the economic operators and the Commission have already led on several occasions to cases being heard by the Court of Justice, which often ended with a judgment stating the non-conformity of certain national measures with Community Law.

3. Proceedings for failure to fulfil an obligation (Art. 226-228 of EC Treaty)

Otherwise, when case law regarding a specific topic is quite clear, but authorities of one Member

⁵⁶ See Judgment of the Court of 9 November 1995 in Case C-479/93, Francovich, Rec.1995, p.I-3843; Judgment of the Court of 5 March 1996 in Case C-46/93, Brasserie du pêcheur, Rec.1996, p.I-1029.

⁵⁷ Judgment of the Court of 15 July 1964 in Case 6/64, Costa/E.N.E.L, Rec. 1964, p.1141.