"It's the Dosage, stupid": The ECJ clarifies the Border between Medicines and Botanical Food Supplements

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In a long-awaited ruling dated March 5, 2009, the European Court of Justice (ECJ) confirmed that the quantity of active substances is the key criterion to distinguish foods from medicines, thereby confirming the dual legal regime applying to medicinal plants.[1] *This approach was encapsulated in two other recent judgments, Commission v Germany (Garlic Judgment)*[2] *and Hecht-Pharma v Staatliches Gewerbeaufsichtsamt Lüneburg (Hecht-Pharma).*[3]

I. Introduction

In *Commission v Spain*, the ECJ found Spain in breach of Articles 28 and 30 EC for withdrawing from the market botanical food supplements legally marketed and/or manufactured in other Member States following an administrative practice consisting of classifying as medicinal products by function any product based on medicinal herbs not included in a positive list laid down in a Spanish Instruction of 1973.[4]

The action of the European Commission had been prompted by a number of complaints, filed since 2004, from food business operators whose products had been withdrawn from the market by the Spanish Medicines and Sanitary Products Agency (*Agencia Española de Medicamentos y Productos Sanitarios* – AEMPS) on the grounds that they were medicinal products marketed without the authorization required under Spanish Act No 25/1990 on medicinal products.[5]

The complaints referred to products formulated with "*various herbs and herb extracts*", some of which could qualify as "*medicinal herbs*"[6] according to the common denomination, whilst other substances did not enter this definition. During court proceedings, the Commission specified, and this was picked up by the ECJ, that the products at hand were "*products based on medicinal herbs*", described as "*products containing one or more herbs which, because of their properties and their physiological effects, can be used as ingredients in medicinal products or in other types of products, such as food supplements*".

This terminological remark at the outset of the ruling already embedded the dual legal nature of medicinal plants, as ingredients of food or medicinal products.

The jurisprudential innovations of *Commission v Spain* relate, on the one hand, to the consecration of the dosage in active substances as key criterion to distinguish botanical food supplements from medicinal products, and, on the other hand, to the application, by analogy, of the ECJ's settled case-law

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1 ECJ Judgment of 5 March 2009, Commission v Spain, Case C-88/07, not yet published.

2 ECJ Judgment of 15 November 2007, Commission v Germany, Case C-319/05, ECR 2007 Page I-09811.

3 ECJ Judgment of 15 January 2009, Hecht-Pharma GmbH v Staatliches Gewerbeaufsichtsamt Lüneburg, Case C-140/07, not yet published.

4 Instruction on the creation of a special register of medicinal herb-based preparations (Orden Ministerial por la que se establece el Registro Especial Paragraph Preparados a Base de Especies Vegetales Medicinales) of October 3, 1973 (Spanish Official Journal of October 15, 1973, p. 19866).

5 Act No 25/1990 on medicinal products (Ley 25/1990 del Medicamento) of December 20, 1990 (Spanish Official Journal No 306 of December 22, 1990, p. 38228), which is now repealed by Act 29/2006 on the guarantees and rational use of medicines and health products (Ley 29/2006 de Garantías y Uso Racional de los Productos Medicinales y Sanitarios) of July 26, 2006 (Spanish Official Journal No 178 of July 27, 2006, p. 28122).

6 The ECJ uses the expression "medicinal herbs" instead of "medicinal plants". Both terms can be used indistinctly for the purposes of this analysis.

developed in relation to vitamin and mineral preparations to the specific case of botanicals.

In both aspects, this judgment builds on the jurisprudence developed in the *Garlic Judgment* and in *Hecht-Pharma*. This article will attempt to describe the salient points of these recent jurisprudential developments, namely: (i) the principles governing the classification of products containing medicinal plants as medicinal products "*by virtue of their function*"; (ii) the dosage in active substances as the key criterion in this assessment; (iii) the margin of manoeuvre left to Member States when they invoke the "rule of doubt" provided for in Article 2(2) of the Medicinal Products Directive[7]; and (iv) the application of the principle of free movement of goods.

II. Definition of medicinal products "by virtue of their function"

According to Article 1(1) of the Medicinal Products Directive, a product can be considered medicinal either if it is "*presented as having properties for treating or preventing disease in human beings*" (medicinal product "*by its presentation*") or if it "*may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis*" (medicinal product "*by its function*").

Contrary to the definition of medicinal product "*by virtue of its presentation*", the broad interpretation of which is designed to protect consumers from products which do not have the effectiveness which they are entitled to expect, the definition of a medicinal product "*by virtue of its function*" is intended to cover only those substances which have a genuine medical or therapeutic effect. According to settled case-law by the ECJ, for the purposes of determining whether a product falls within the definition of a medicinal product by function, account should be taken of all the characteristics of the product, in particular its composition, its pharmacological properties – to the extent to which they can be established in the present state of scientific knowledge –, the manner in which it is used, the extent of its distribution, its familiarity to consumers and the risks which its use may entail.[8]

The ECJ case-law relating to the classification of botanical borderline products is fairly recent in comparison with that concerning vitamin and mineral preparations. Although the Court has assessed the status of various products containing medicinal plants for tariff classification purposes prior to the *Garlic Judgment,*[9] these judgments have a limited value in the present analysis, since the definition of pharmaceutical product for the purposes of the Combined Nomenclature has a different scope from that provided under the Medicinal Products Directive.[10]

In the *Garlic Judgment*, the German authorities classified a garlic extract powder capsule as a medicinal product by function without taking into consideration the extent of the therapeutic effects of the product. In their view, "*neither the Medicinal Products Directive nor the case-law of the ECJ indicated a 'material threshold' according to which a specific level of pharmaceutical effects had to be proven*".[11]

However, the Court confirmed that products containing medicinal plants are not medicinal products *per se*. As it is the case with vitamin and mineral preparations, the ECJ stated that products which, irrespective of their composition, do not *significantly* affect the metabolism and do not *strictly* modify the way in which it functions should not be classified as medicinal products by function.[12]

Furthermore, the ECJ reminded that the physiological effect is not specific to medicinal products

7 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 (OJ L311/67, of 28.11.2001, p. 67–128).

8 See, inter alia, ECJ Judgments of 30 November 1983, Criminal proceedings against Leendert van Bennekom, Case C-227/82, ECR 1983 I–03883 (paragraph 29); of 21 March 1991, Criminal proceedings against Monteil and Samanni, Case C-60/89, ECR 1991 I-01547 (paragraph 29); and of 16 April 1991, Upjohn Company and Upjohn NV v Farzoo Inc. and J. Kortmann., Case C-112/89, ECR 1999 I-1703 (paragraph 23).

9 For instance, the ECJ considered a product consisting of hawthorn drops to be medicinal, since its objective characteristics were clearly of a prophylactic nature, with a concentrated effect on precise functions of the human organism, namely the cardiac, circulatory and neuron-vegetative functions (Vid. ECJ Judgment of 14 January 1993, Bioforce v. Oberfinanzdirektion München, Case C-177/91, ECR 1993 I-00045). A similar case can be found with a product consisting of echinacea drops (Vid. ECJ Judgment of 15 May 1997, Bioforce v. Oberfinanzdirektion München, Case C-405/95, ECR 1997 I-02581).

10 ECJ Judgment of 12 March 1998, Laboratoires Sarget v. Fonds d'intervention et de régulation du marché du sucre (FIRS), Case C-270/96, ECR 1998 I-01121, paragraph 23.

11 Vid. Garlic Judgment, paragraphs 24-25.

12 Vid. Garlic Judgment, paragraph 60.

but is also among the criteria used for the definition of food supplements, and restricted the classification of medicinal products to those which "*strictly speaking have the function of treating or preventing disease*"[13] or to those "*whose pharmacological properties have been scientifically observed and which are genuinely designed to make a medical diagnosis or to restore, correct or modify physiological functions*"[14]. Although the application of one criterion or the other may lead to different results (the former is more restrictive than the latter), what emerges from the ruling is that the definition of "*medicinal product by its function*" should be strictly interpreted, especially when considering that food supplements do have "*beneficial effects on health*", and may even "*serve therapeutic purposes*".[15]

II. The dosage in active substances as a key criterion for the assessment of botanical food supplements

In *HLH Warenvertrieb and Orthica*[16] the ECJ had suggested that, among the criteria developed in the case-law for the purposes of determining whether a product falls within the definition of a medicinal product by function, it attaches special importance to the "*pharmacological properties*", defined as "*the factor on the basis of which it must be ascertained, in the light of the potential capacities of the product, whether it may, for the purposes of the second subparagraph of Article 1(2) of Directive 2001/83, be administered to human beings with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions in human beings*".

This definition, almost tautological, demanded a correlative, quantifiable parameter that could serve the purposes of distinguishing between products in the borderline between medicines and food.

In the *Garlic Judgment* and, especially, *Commission v Spain*, the ECJ identified this parameter.

The dosage in active substances had already been taken into account in the case-law of the ECJ with regard to vitamin and mineral based preparations. In *Van Bennekom*, the ECJ held that, *"[i]nasmuch as vitamins are defined as substances which, in minute quantities, form an essential part of the daily diet and are indispensable for the proper functioning of the body, they may not, as a general rule, be regarded as medicinal products when they are consumed in small quantities*".[17] The same reasoning was applied with vitamin and mineral based supplements in *Commission v Austria*[18] and *Commission v Germany*[19].

In the *Garlic Judgment*, the ECJ extended this case-law to botanical foods. The Court held that a garlic extract powder capsule could not be classified as a medicinal product by function precisely because its physiological effects were "*no more than the effects of a foodstuff consumed in a reasonable quantity*"; the physiological effects alleged by the German authorities, essentially with respect to the prevention of arteriosclerosis, could also

13 Ibid. paragraph 64. According to the Court, "That statement is even more relevant in the case of products which, in addition to being food supplements, are recognised as having beneficial effects on health. As the Advocate General observed, in point 60 of her Opinion, there are many products generally recognised as foodstuffs which may also serve therapeutic purposes. That fact is not sufficient however to confer on them the status of medicinal product within the meaning of Directive 2001/83".

14 Ibid. paragraph 61.

15 Vid. supra note 13. Of course, a different issue is whether these products may claim these therapeutic purposes in the labelling or advertisement, which, as Community law stands, is reserved exclusively to medicinal products. Thus, the fact that foodstuffs can actually have the property of preventing a human disease has been recently acknowledged by the European Food Safety Authority in its Opinion on Xylitol chewing gum/pastilles and reduce the risk of tooth decay (The EFSA Journal (2008) 852, 1-15), where it expressly stated that "xylitol chewing gum reduces the risk of caries in children". However, as this claim would constitute a "preventive" claim, reserved to medicinal products (and not a 'reduction of disease risk claim' in the sense of Article 2(2)(6) of Regulation 1924/2006), the Commission requested EFSA to identify a risk factor of the disease of caries. Following this request, EFSA identified dental plaque as a risk factor in the development of caries from the data contained in the dossier submitted by the applicant (cf. Standing Committee on the Food Chain and Animal Health – Section on General Food Law, Summary Record of Meeting of 27 April 2009).

16 Vid. ECJ Judgment of 9 June 2005, HLH Warenvertrieb and Orthica, Joint Cases C-211/03, C-299/03 and 316/03 to C-318/03, ECR 2005 I-5141, paragraph 52.

17 The Court follows on to say "[s]imilarly, it is a fact that vitamin or multi-vitamin preparations are sometimes used, generally in large dosages, for therapeutic purposes in combating certain diseases other than those of which the morbid cause is a vitamin deficiency. In such cases, it is beyond dispute that the vitamin preparations constitute medicinal products". Vid. Criminal proceedings against Leendert van Bennekom cited supra in note 8, paragraph 26-27.

18 ECJ Judgment of 29 April 2004, Commission v Austria, Case C-150/00, ECR 2004, I-03887, paragraph 63.

19 ECJ Judgment of 29 April 2004, Commission v Germany, Case C-387/99, ECR 2004 I-607, paragraph 69.

be obtained by ingesting 7,4 g of garlic as foodstuff.[20]

Whilst this reasoning might have been motivated because garlic is commonly used as a foodstuff in its natural state, thereby limiting the legal implications of the ruling, the ECJ later confirmed that this understanding could be virtually extended to *all* medicinal plants.

Thus, in *Hecht-Pharma*, the German authorities considered that a product composed of fermented red rice had to abide by the legislation on medicinal products since it contained significant levels of monacolin k, a substance which could also be found in a number of prescription medicinal products[21]. In reply to the question referred by the German authorities, the Court confirmed that the content in active substances should be taken into account as part of the overall composition of the product to determine whether it enters the definition of medicinal product by function.[22]

Even though the ruling was not as explicit as the Advocate General Trstenjak's Conclusions[23] in this regard, the ECJ introduced for the first time the product's dosage in active substances as a characteristic of the composition which should be taken into account for the purposes of the classification. In Trstenjak's opinion, it was "*absolutely mandatory*" to take the intended dosage criterion as the basis for the product's classification.

This approach was finally confirmed in *Commission v Spain*. The Spanish authorities classified as medicinal products by function products containing species such as guarana, ginseng, soy isoflavones, alfalfa, spiruline, passiflora, etc. lawfully marketed as food supplements in other Member States.

According to the ECJ, the mere fact that a product contains medicinal herbs is not sufficient to classify it as a medicinal product, not even as a "traditional herbal medicinal product", since it is possible that, "*having regard, in particular, to the small amount of the active substances contained in it and/or the manner in which it is used, a product based on medicinal herbs will have no effect on physiological functions or that its effects will not suffice for it to be a medicinal product by function*".[24]

In so doing, the Court confirmed the dual legal regime applying to medicinal plants, which had been implicitly recognized in the *Garlic Judgment* and *Hecht-Pharma*. The mere presence of one or various medicinal herbs in the composition of a product remains insufficient to classify it as medicinal product by function, as account must be taken of the nature and, especially, the extent of the physiological effect exerted by the product as a whole, which is linked to the dosage in active substances contained therein.

Consequently, a *medicinal plant* (or any other substance for this purpose) is not *per se* a medicine or a foodstuff. It is the *product* containing it that may or may not be classified as a medicinal product, depending on the criteria developed by the ECJ case-law, and in particular, the amount of active substances.[25]

Interestingly, the recognition of the dosage on active substances as the key criterion in the assessment of borderline products containing medicinal herbs reflects the recently published '*Homeostasis* model' developed under the *aegis* of the Council of Europe.[26] In this model, the dosage in active substances is identified as the main quantifiable parameter to determine the nature of the induced effect of a given product which differentiates foods from medicines.

The '*Homeostasis* model' has been successfully used in Belgian law since 1997 through Royal Decree of August 29, 1997 on the manufacture and marketing of foods composed of or containing plants or plant preparations.[27] Annex 3 thereof establishes a positive list of plants that may be used

20 Vid. Garlic Judgment, paragraphs 66-68. In this regard, the ruling is in line with the position of the Commission who stated that "where a product which is claimed to be a medicinal product does nothing more than a conventional foodstuff, it is clear that its pharmacological properties are insufficient for it to be accepted as a medicinal product (…) a product which has no more effect on the body than a foodstuff has not reached the threshold above which it must be regarded as medicinal product by function".

21 Vid. Hecht-Pharma, paragraph 13.

22 Ibid., paragraph 42.

23 Opinion of Advocate General Trstenjak delivered on 19 June 2008 in Case C-140/07, Hecht-Pharma.

24 Vid. Commission v Spain, paragraph 75.

25 Vid., along the same lines, Coppens Patrick, The Use of Botanicals in Food Supplements and Medicinal Products: The Co-existence of two Legal Frameworks, European Food and Feed Law Review, Volume 3, Number 2, 2008, p. 97.

26 Council of Europe, Homeostasis, a model to distinguish between foods (including food supplements) and medicinal products, Partial Agreement in the Social and Public Health Field, of 07/02/2008.

27 Arrêté Royal du 29 août 1997 relatif à la fabrication et au commerce de denrées alimentaires composées ou contenant des plantes ou préparations de plantes (Mon. 21.XI.1997).

in food supplements and fortified foods and applies specific limits on active substances. When these limits are exceeded, the product is considered a medicinal product by the Belgian authorities. For instance, food supplements containing *Glycine max* (L.) Merr. may not provide more than 40 mg isoflavones per day on the basis of the dosage recommended in the labeling or advertising. Likewise, products formulated with *Harpagophytum procumbens* (Burch.) DC. may not provide more than 40 mg iridoids daily, etc.

This pioneering model has prompted companies established in countries with a stricter approach towards botanical food supplements (such as Spain or France) to resort to the mutual recognition principle in order to legally market their products in their home countries.

IV. The "rule of doubt": the burden of proof lies with the national authorities who invoke it

Both in *Hecht-Pharma* and in *Commission v Spain*, the national authorities relied on the "*rule of doubt*" provided under Article 2(2) of the Medicinal Products Directive to justify the applicability of the legislation on medicinal products to the products at hand. According to the latter provision, when a product may fall both within the definition of a medicinal product and within the definition of a product covered by other Community legislation, the classification as medicinal product must prevail.

In *Hecht-Pharma*, the German authorities considered that, since the plaintiff failed to prove the absence of pharmacological action of the red rice capsule containing specially fermented grain of rice, the legislation on medicinal products prevailed, without it being required to establish that the product entered the definition of medicinal product.[28]

This reasoning could not be held in the light of the Court's interpretation of Article 2(2) of the Medicinal Products Directive. Bearing in mind the definition of medicinal product by function, the Court ruled that Article 2(2) must be interpreted as meaning that the Medicinal Products Directive "*does not apply to a product in respect of which it has not been scientifically established that it is a medicinal product by function, even if that possibility cannot be ruled out*"[29].

In other words, botanical food supplements are presumed to fall out of the scope of the Medicinal Products Directive unless the national authorities, having regard to the entirety of the products' characteristics, prove the contrary.

This principle closes the door to those Member States who rely on the application of the precautionary principle in order to justify the aprioristic classification of "suspicious" (i.e. borderline) products as medicinal products.

V. The principle of free movement of goods

In *Commission v Spain*, the Spanish authorities contended that, as opposed to vitamins – which are not, as a general rule, harmful in themselves – products based on medicinal herbs are almost always products the safety of which has not been thoroughly examined, and therefore, the ECJ case law on vitamins and minerals developed in *Commission v Germany*[30] and *Commission v Austria*[31] was not applicable to the case at hand.[32]

The ECJ rejected this reasoning based on the alleged "general principle of innocuousness" of vitamins and minerals and expressly stated that the case-law developed with regard to foodstuffs enriched with vitamins and minerals was also applicable to products based on medicinal herbs intended for human consumption.[33]

In this sense, it is also worth mentioning that in *Hecht-Pharma* the ECJ rejected the argument that preparations marketed as food supplements are as a rule taken unsupervised and in greater quantities than the recommended dosage, and therefore, even if the daily recommended intake results in small amounts of active substances, they could pose a risk to human health.[34] Along the same lines, in the recent *BIOS Naturprodukte ruling*, the ECJ has confirmed that the risk to health is an autonomous

28 Vid. Hecht-Pharma, paragraphs 15-17.

29 Ibid., paragraph 29. Vid. supra note 22.

30 Vid. Commission v Germany, cited supra in note 19.

31 Vid. Commission v Austria, cited supra in note 18.

32 Vid. Commission v Spain, paragraphs 48-51.

33 Ibid., paragraph 90.

34 Vid. Hecht-Pharma, paragraphs 15-17.

factor which cannot convert a food supplement into a medicine: "[t]*he risk to health, although it must be taken into consideration in the classification of a product as a medicinal product by function, is none the less an autonomous factor.*[35]

Whilst the Court had already confirmed the application of the principle of free movement of goods to botanical food supplements in the *Garlic Judgment*, that case related to the ill-classification of a single product and not to an administrative practice of consistent and general nature.[36]

On several occasions, the Court had condemned national administrative practices resulting in classifying products as medicinal without performing a case-by-case analysis. In *Commission v Austria*, the Court found Austria in breach of Articles 28 and 30 EC for systematically classifying as medicinal products vitamin preparations with levels of vitamins exceeding the recommended daily amount of these substances, and any preparation containing vitamins A, D or K or minerals other than those in the chromate group. Similarly, in *Commission v Germany*[37] the Court condemned an administrative practice consisting in automatically classifying as medicinal products vitamin preparations containing three times more vitamins, other than vitamins A and D, than the daily amount recommended by the German Food Association. Another example can be found in *Commission v Denmark*[38], where the Danish authorities were found in breach of Community law for prohibiting the addition of nutrients to foods unless it could be shown that such enrichment met a nutritional need in the Danish population. Similar scenarios were addressed in *Commission v The Netherlands*[39] for fortified foods and in *Commission v Italy*[40], for food products for sportspersons.

Along these lines, in *Commission v Spain*, the Court ruled against an administrative practice consisting in automatically and systematically classifying as medicinal product by function any product containing a medicinal herb not listed in the annex to the 1973 Instruction.

Although Community law does not, in principle, preclude a Member State from tying the marketing of food supplements containing substances other than those authorized under Directive 2002/46/EC[41] to a system of prior authorization, the principle of proportionality must be complied with. In practice, this means that the national authorities of that Member State have to show "*that the marketing of the products in question poses a real risk to public health*".[42]

To this end, Spain should have analyzed each product withdrawn from the market on a case-by-case basis, taking into account all the characteristics of the products described above. As explained previously, the dosage of active substances remains the key classification criterion, since it provides a benchmark for anticipating the significance of the physiological effects attached to the product.

However, the criterion used by the Spanish authorities for requiring marketing authorization (presence of medicinal herbs not listed in the annex to the 1973 Instruction) did not allow, on the basis of the most recent scientific data, to take into account the actual risk to public health presented by the said products.[43] Therefore, the challenged administrative practice did not meet the requirements of Community law, and in particular, the fact that there should be "*a detailed assessment, on a case-by-case basis, of the risk to public health which the marketing of a product based on medicinal herbs might entail*".[44]

Moreover, Spain could have envisaged less restrictive measures to protect consumers such as appropriate labeling requirements informing consumers of the nature, ingredients and characteristics of the products based on medicinal herbs. Failing this, the Court stated that the Spanish authorities could have explained why such measures would not have adequately protected public health.[45]

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35 ECJ Judgment of 15 January 2009, BIOS Naturprodukte GmbH v Saarland, Case C-27/08, not yet published.

36 The Court held in particular that the arguments put forward by the German authorities were insufficient to prove the existence of an actual risk to public health posed by the product at hand, since they mainly related to the effect of garlic consumed as a foodstuff – not to the product itself – and to risks arising in very specific circumstances. Vid. Garlic Judgment, paragraph 93.

37 Vid. Commission v Germany, cited supra in note 19.

38 ECJ Judgment of 23 September 2003, Commission v Denmark, Case C-192/01, ECR 2003 I-12447.

39 ECJ Judgment of 2 December 2004, Commission v The Netherlands, Case C-41/02, ECR 2004 I-11375.

40 ECJ Judgment of 5 February 2004, Commission v Italy, Case C-270/02, ECR 2004 I-1559.

41 Vid. Commission v Spain, paragraph 90.

42 Ibid., paragraph 89.

43 Ibid., paragraph 94.

44 Ibid., paragraph 95.

45 Ibid., paragraph 98.

VI. Conclusion

In the course of the last two years, the ECJ has considerably sharpened the borderline between medicinal products and botanical food supplements, thereby limiting the margin of manoeuvre of Member States to hamper intra-community trade of foodstuffs containing botanicals.

In this respect, the content in active substances clearly emerges as the key criterion to measure the physiological effect of borderline products and assess whether these products fall under the scope of the Medicinal Products Directive.

The Court also discarded the misuse of the "rule of doubt" of Article 2 of the said Directive and ruled out the preventive approach taken by some Member States consisting in the *a priori* classification of borderline products as medicines owing to the alleged risks to public health they may entail.

Notwithstanding these longed-for clarifications, it is still regrettable that, as Community law stands, and even with harmonized definitions of "foodstuffs", "food supplements" and "medicinal products", Member States may still reach different conclusions for the classification of the same products.[46]

One of the solutions which could remedy this fragmentation of the internal market is the establishment of a Community procedure requiring Member States to notify the Commission each time they apply the medicinal products legislation to a product freely marketed as a foodstuff or a food supplement in another Member State.[47] Although the monitoring scheme established by Decision 3052/95[48] setting a procedure for the exchange of information derogating from the principle of the free movement of goods within the Community has proved largely unsuccessful,[49] it is reasonable to expect that the momentum raised by its successor, the newly applicable Regulation 764/2008[50] on mutual recognition encourages Member States to cooperate in this area.

46 In HLH Warenvertriebs Gmbh, Orthica BV v Bundesrepublik Deutschland, the Court expressly stated that the fact that a product is classified as a foodstuff in another Member State could not prevent it from being classified as a medicinal product in the Member State of importation, if it displays the characteristics of such a product (cf. HLH Warenvertrieb and Orthica, paragraph 56).

47 Vid., in this respect, A. BOURGES Leticia, Las definiciones de medicamento y complemento alimenticio: criterios diferenciales y primacía del Derecho farmacéutico, Reseña de Jurisprudencia del TJCE, Revista de Derecho Alimentario, nº 45, May 2009, page 28.

48 Decision No 3052/95/EC of the European Parliament and of the Council of 13 December 1995 establishing a procedure for the exchange of information on national measures derogating from the principle of the free movement of goods within the Community (OJ L 321, 30.12.1995, p. 1–5).

49 In fact, in Commission v Spain, the ECJ also condemned Spain for failing to communicate the withdrawals of the products to the European Commission under Articles 1 and 4 of Decision No 3052/95.

50 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. 21–29).