High Noon: The Italians try to play solo the Health Claims game

I've got to, that's the whole thing
Gary Cooper (Will)

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I. Introduction

On November 27, 2009, the Italian Government notified a draft regulation on the use of substances other than vitamins and minerals in food supplements before the European Commission, pursuant to the procedure laid down in Article 19 of Directive 2000/13/EC[1] on labelling, presentation and advertising of foodstuffs[2].

It seems timely and appropriate to devote this article to this draft, which, if adopted in its current version, could entail an important breakthrough, as it would make it compulsory to refer to certain health benefits in the labelling of food supplements. The use of such health claims is strictly limited by Regulation (EC) 1924/2006 on nutrition and health claims made on foods[3] and, in particular, its practical implementation by the EU institutions (including the European Food Safety Authority) and the Member States.

From a legal standpoint, the interest of the draft notified by the Italian authorities is twofold. First, it shows the will of a Member State to regulate the use of substances other than vitamins and minerals that can be used in food supplements, after the European Commission has explicitly stated that it has no intention, at least for the time being, to make a legislative proposal in this sense. Moreover, because of the use of so-called mandatory statements (references whose presence in the labelling of foodstuffs is mandatory), it could prove to be useful in order to strike a much-needed balance between the consumer's right to receive truthful and objective information about the food and the industry's obligation not to mislead consumers with health-related claims that are not sufficiently substantiated.

Regulation (EC) 1924/2006 itself acknowledges the special situation of certain categories of foodstuffs, such as food supplements, vis-à-vis the use of claims. Indeed, the rules laid down therein apply *without prejudice* to the provisions of Directive 2002/46/EC[4,5]. This is also the case of foods for particular nutritional uses (hereinafter, "PARNUTS"), which, unlike regular foodstuffs, may in exceptional cases claim properties for the prevention, treatment or cure of human diseases[6], or mineral waters, which are subject to a similar deroga-

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1 Directive of the European Parliament and of the Council of 20 March 2000, on the approximation of the laws of the Member States relating to labelling, presentation and advertising on foodstuffs (OJ 109 No L 109 of 6 May 2000, p. 29). Pursuant to Article 19 thereof, when a Member State deems it necessary to adopt new legislation, it shall notify the Commission and the other Member States of the measures envisaged and give the reasons justifying them. The Commission shall consult the Member States within the Standing Committee on the Food Chain and Animal Health if it considers such consultation to be useful or if a Member State so requests. It further provides that "*Member States may take such envisaged measures only three months after such notification and provided that the Commission's opinion is not negative*".

2 "*Integratori alimentari: disciplina dell'impiego delle sostanze diverse da vitamina e minerali"* in the original text.

3 Regulation (EC) of the European Parliament and of the Council, of 20 December 2006 (OJ L 404 of 30 December 2006 p. 9). See in particular: Corrigendum to Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims on foods (OJ No L 12 of January 18 2007, p. 3.).Regarding the circumstances relating to the (double) publication of these Community legislation, see: "Better Regulation (EC) *fiasco* claims as wrong text is published", EU Food Law, No. 285, 2007, 3–4 (see also "Correct claims published text," *EU Food Law*, No. 286, 2007, p. 14.)

4 Cf. Article 1(5) of Regulation (EC) 1924/2006.

5 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 No L 183 of 12 July 2002, p. 51).

6 Cf. Article 8 of Directive 2009/39/EC of the European Parliament and of the Council of 6 May 2009 on foodstuffs intended for particular nutritional uses (recast) (ON L 124 if May 20, 2009, p. 21).

tion[7]. The express reference to these categories of foodstuffs in Regulation (EC) 1924/2006 may open the door to a different, special regime as regards the use of health claims.

In any case, it is clear that, whilst the first of the objectives of the future Italian legislation (regulating the use of substances other than vitamins and minerals) does not appear to pose major problems from a legal point of view (within the limits established in the Treaty on the Functioning of the European Union (hereinafter "TFEU")), the second one is less peaceful: some scholars have already questioned its legitimacy, on the grounds that it could entail a *deregulation* in the use of health claims allowed in food supplements[8]. These aspects will, ultimately, be the subject of a decision by the European Commission according to the procedure laid down in Article 19 of Directive 2000/13/EC[9].

In this article we advocate for the legality of the Italian draft, and will analyze the practical consequences that its adoption could bring in the European market for food supplements.

II. Objective and scope of the notified draft

The draft object of our analysis lays down provisions for food supplements containing substances other than vitamins or minerals. Among these substances are amino acids, essential fatty acids, fibre and various plant and herbal extracts.[10]

The draft aims to achieve a high level of consumer protection and to help consumers choosing between different products available on the market. It includes positive lists of nutrients and other substances with a nutritional and/or physiological effect to be used in the production of food supplements. Maximum limits are laid down in relation to some specific substances (e.g. betaine, bioflavonoids, carnitine, carnosin or coline).

The draft also contains, and this is where it becomes controversial, mandatory statements to be included in the labelling of food supplements containing certain plant extracts and other substances with nutritional and/or physiological effect.

It should be noted that the draft specifies, for each of the substances listed therein, the physiological effect which can be attributed to them[11]. For example, food supplements that contain oil of *Aloe Vera L.* should include information on its effects on intestinal transit and digestive and liver function. Similarly, the use of the gel of the same plant triggers the obligation to include in the labelling a reference to several health effects in connection to its emollient and soothing properties, digestive system regulation or beneficial properties for the throat. Similarly, the use of the leaf or the fruit of *Cassia Acutifolla Del.*, triggers the obligation to mention its properties for regulating the intestinal transit, the use of the root of the plant *Panax ginseng CA Meyer* should be followed by a reference to its adaptogenic and tonic properties, as well as to its capacity as an antioxidant and its effects in physical and mental fatigue and metabolism of carbohydrates, etc.

The use of mandatory statements which relate to the specific nutritional and/or physiological effect of a substance or a nutrient is not new in EU law. Directive 2008/5/EC[12] provides for the obligation to indicate in the label of foodstuffs to which polyols have been added in a proportion exceeding 10 %, that their consumption may have a *laxative effect*. Another example along these lines can be found in Regulation (EC) 608/2004[13], which includes a mandatory statement in foodstuffs containing plant

7 Cf. Art. 2(1)(b) of Directive 2000/13/EC cited in note 1.

8 See Klaus, "List published by the Italian Ministry of Health regarding the use, in the manufacture of food supplements, of other substances than vitamins and minerals, with a nutritional or physiological effect", *European Food and Feed Law Review*, Vol 4, nº 6, 2009, p. 439–440 and the related article in this issue.

9 See note 1.

10 Cf. Recital 6 of Directive 2002/46/EC, cited in note 5.

11 The draft also provides for safety warnings to be included in the labelling of food supplements containing the following substances: *Cimicifuga racemosa* Nutt, *Citrus aurantium* L., *Ginkgo biloba* L., *Hypericum perforatum* L., mixtures of amino acids, branched chain amino acids, bioflavonoids, creatine, and *Monascus purpureus* (red yeast rice) monacolin.

12 Commission Directive of 30 January 2008, concerning the compulsory indication on the labelling of certain foodstuffs of particulars other than those provided for in Directive 2000/13/EC of the European Parliament and of the Council (OJ No L 27 of 31 January 2008, p. 12).

13 Commission Regulation (EC) of 31 March 2004, concerning the labelling of foods and food ingredients with added phytosterols, phytosterol esters, phytostanols and/or phytostanol esters (OJ No L 97 of 1 April 2004, p. 44).

sterols that the product is intended exclusively for people who want to *lower their blood cholesterol* level[14].

The best example, however, is to be found in the PARNUTS legislation and concerns the obligation imposed by Directive 2009/39/EC[15] to include "*an indication of* [the product's] *particular nutritional characteristics*"[16]. In many cases, that mandatory statement will fall under the definition of health or nutrition claims within the meaning of Regulation (EC) 1924/2006, but will be exempted from the application of those rules precisely because of their mandatory character.

The Italian draft decree contains a clause of mutual recognition (cf. Article 5) which allows products lawfully produced and/or marketed in other Member States to be lawfully marketed in Italy without having to modify their labelling as per the requirements established therein.

III. Application of the principle of mutual recognition to products lawfully marketed under the proposed rules

1. General considerations

As it will be developed herein below, articles 34 TFEU (ex Article 28) and 36 TFEU (ex Article 30) apply to food supplements produced in Italy in accordance with the notified draft decree. Therefore, their marketing in other Member States will benefit from the principle of mutual recognition. Indeed, these products would be "*products legally produced and/or marketed in Italy*", for as long as they comply with the said rules.

According to this principle, products lawfully marketed in a Member State may be freely marketed in other Member States provided that (i) they comply with the general safety requirements laid down in Regulation (EC) No 178/2002[17]; (ii) they do not possess medicinal properties in the sense of Directive 2001/83[18]; and (iii) they are not novel foods in the sense of Regulation (EC) No 258/97[19].

Aside from these three hypothetical cases, the authorities of the importing Member State may not hamper the placing in the market of a food supplement legally marketed in Italy.

It should be reminded at this stage that mutual recognition applies only in the absence of Community legislation, since harmonized areas of law are subject to the specific Community rules relating thereto, and not Articles 34 to 36 TFEU. In the case of the mandatory statements object of our study, Articles 34 to 36 TFEU still apply even if, *prima facie* it would seem that this area has been fully harmonized (first by Directive 2000/13/EC, then by Directive 2002/46/EC and, finally, by Regulation (EC) 1924/2006).

2. Application of the principle of mutual recognition to the *composition* of food supplements from Italy

Directive 2002/46/EC on food supplements chose to harmonise only the legislation applicable to vitamins and minerals that may be used in food supplements, leaving for a later stage the regulation of other substances such as amino acids, essential fatty acids, fibres and various plants and herbal extracts.

Hence, Directive 2002/46/EC (and the national implementing laws) will apply to food supplements based on vitamins and minerals. On the other hand, food supplements incorporating other substances that are not included within the scope of the said Directive continue to be governed, inasmuch as

14 It also requires mentioning that patients on cholesterol lowering medication should only consume the product under medical supervision; there shall be an easily visible and legible statement that the product may not be nutritionally appropriate for pregnant and breastfeeding women and children under the age of five years; advice shall be included that the product is to be used as part of a balanced and varied diet, including regular consumption of fruit and vegetables to help maintain carotenoid levels, in the same field of vision as the particular required above, there shall be a statement that the consumption of more than 3 g/day of added plant sterols/plant stanols should be avoided.

15 See note 6.

16 See article 9.3(a) of Directive 2009/39/EC, cited in note 6.

17 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 of 1.2.2002).

18 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 L 311, 28.11.2001, p. 67–128).

19 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. 1–6).

their composition is concerned, by national laws and the terms of the TFEU (in particular, Articles 34 to 36)[20] until a specific EU-wide regulation is adopted.

Indeed, Directive 2002/46/EC "*... partially* harmonises"[21] the rules applicable to the placing of food supplements on the market[22].

As it is explained in the eighth Recital of the said directive, "*without prejudice to the provisions of the Treaty, national rules concerning nutrients or other substances with nutritional and/or physiological effect used as ingredients of food supplements*" will apply until Community specific rules have been adopted.

In sum, it seems beyond doubt, that the principle of mutual recognition applies to the *composition* of food supplements marketed and/or produced in Italy in accordance with its regulations.

3. Application of the principle of mutual recognition to the *labelling* of food supplements from Italy

More controversial is, however, the application of the principle of mutual recognition not only to the products themselves (their *composition*) but also to their *labelling*.

There are specific Community rules that harmonize the labelling of food products in general (Directive 2000/13/EC) and food supplements in particular (Article 6 of Directive 2002/46/EC provides that, without prejudice to Directive 2000/13/EC, their labelling must include, *inter alia*, the names of the categories of nutrients or substances that characterise the product or an indication of the nature of those nutrients or substances and the portion of the product recommended for daily consumption).

However, even though it might seem *a priori* that we are dealing with a harmonized area, where coexistence of national laws- and consequently, the application of the principle of mutual recognition- is not possible, a further analysis proves otherwise.

a. Scope of the harmonisation achieved by Directive 2000/13/EC

First, the *full* harmonization carried out by Directive 2000/13/EC is *exhaustive* only in relation to those aspects covered, and to the extent and terms expressly provided therein. Regarding these *terms*, it should be highlighted that Articles 4.2, 6.7, 8.1, 8.2 (b) and 11.2 thereof provide Member States with a possibility to adopt non-harmonized rules under the procedure established in Article 19.

As Directive 2000/13/EC is of general scope and applies horizontally, it allows Member States to maintain or even adopt regulations *in addition* to the provisions laid down therein. It is precisely in the case of adoption of *new* legislation that Member States must notify the draft legislation to the Commission, under the procedure established Article 19[23].

The limits of the powers retained by the Member States in adopting new rules are set by the directive itself in so far as it lists exhaustively, in Article 18.2, the grounds on which the application of non-harmonised national provisions prohibiting trade in foodstuffs may be justified (namely, protection of public health, prevention of fraud, protection of industrial and commercial property rights, statements of provenance, designations of origin and prevention of unfair competition).

Furthermore, the CJEU has stated in *Douwe Egberts*[24] that, in general terms, Directive 2000/13/EC exhaustively harmonizes the aspects relating to mandatory elements in the labelling (which is not

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20 Cf. Recital nº 8, and second paragraph of Article 11 of Directive 2002/46/EC. This dichotomy regarding the application of either legislation has been specifically acknowledged by the Court of Justice of the European Union (hereinafter the "CJEU") in its Judgment of 12 July 2005 in Joined Cases C-154/04 and Case C-155/04, *Alliance for Natural Health and Nutri-Link*, Rec. p. I-06451 (paras. 59 and 60).

21 Our emphasis.

22 Cf. Report of the Commission to the Council and the European Parliament "on the use of substances other than vitamins and minerals in food supplements". Document COM(2008) 824 final of 5 December 2008 (Introduction), (hereinafter, the "2008 Report")], which is available at the following internet address: http://ec.europa.eu/food/food/labellingnutrition/supplements/documents/COMM_PDF_COM_2008_0824_F_EN_RAPPORT.pdf [last visited 28 March 2010].

23 There are several precedents, not very encouraging in this area. For example, Greece submitted a draft decree on the presentation of information in all types of dairy products, according to which it would be compulsory to indicate the country of origin of raw material (milk) used in the manufacture and sale of such products to the final consumer, imposing obligations on retailers regarding how to provide dairy products in retail outlets, etc. Finally, the legislation could not be adopted after a negative decision by the Commission (OJ No L 58 of 9 March 2010, p. 20). Today, another Italian draft is discussed on a similar topic. Furthermore, a draft regulation regarding the Dutch pre-packaged smoked eel, required the compulsory indication of the date of packaging in the labelling, but was eventually withdrawn by the Dutch authorities after several communications with the Commission (OJ No L 58 of the 9 March 2010, p. 20).

24 CJEU Judgment of 15 July 2004 in Case C-239/02 *Douwe Egberts* ECR p. I-7007.

the case for advertising). However, the CJEU referred, as a limit of such *exhaustiveness*, to the possibility that Member States have, in exceptional cases, "*to apply non-harmonised national provisions prohibiting trade in directive-compliant foodstuffs where they are justified under Article 18.2*", without it being necessary to appraise them in the light of Articles 34 and 36 TFEU. Obviously, national regulations that overcome the procedure laid down in Article 19 are another exception to the complete/exhaustive harmonisation at hand.

In other words, the mandatory statements required by non-harmonized national provisions which comply with the provisions of Directive 2000/13/EC must be accepted in other Member States. This is the case, for example, of the mandatory statements imposed by Belgian law, which establishes the obligations to include, *inter alia*, the statement "*not to be consumed by pregnant women*" if the product contains the plant *Alchemilla alpina L.* or "*Seek advice from your doctor in case of simultaneously intake of anticoagulants*" if the product contains the plant *Ginkgo biloba L.*[25].

b. Scope of the harmonisation achieved by Regulation (EC) 1924/2006

Regulation (EC) 1924/2006 harmonises the national provisions which relate to nutrition and health claims[26]. However, by defining "claim" as "*... any message or representation which is not mandatory under Community or national legislation*[27]*, including any form of pictorial, graphic or symbolic, which states, suggests or implies that a food has particular characteristics*", it expressly excludes *mandatory* statements such as those envisaged in the Italian draft from its scope of application[28].

The Italian draft decree object of our study makes it mandatory to include a statement on the nutritional and/or physiological effect of plants, plant extracts and other substances used in food supplements. Although these statements might fall under the definition of nutrition or health claim as per Articles 2.4 and 2.5 of Regulation (EC) 1924/2006, they escape the scope of application of the Regulation because of their *mandatory* character, as is it the case with the statements about the laxative effect of polyols, the effects of cholesterol-lowering plant sterols or the statements on the nutritional use of PARNUTS.

As some scholars have pointed out[29], it would be desirable to leave the Community legislator moving forward in an area as controversial as health claims included in food supplements. It remains nevertheless that, from a strictly legal perspective, nothing prevents the Italian authorities from adopting the draft decree, particularly when Regulation (EC) 1924/2006 itself opens the door for a particular regime for this category of foods and the European Commission has explicitly favoured mutual recognition as the best strategy for the effective functioning of the internal market of food supplements.[30]

The 2008 Report expressly acknowledges that mutual recognition remains an important tool to ensure the free movement of food supplements within the Community market as it states that "*[m]utual recognition is not free from the risk that technical obstacles to the free movement of the products concerned can be maintained or created. However, these risks should be put into perspective, in that the Court of Justice, as part of its judicial supervision, has set precise limits within which the Member States may validly exempt themselves from mutual recognition by availing themselves of Article [36 TFEU], including in the area of foodstuffs.*"

As mentioned above, Member States are entitled to invoke the need to protect the interests referred to in Article 36 TFUE, in particular the protection of human health, only under the conditions defined by the CJEU as indicated above and to the extent that there is no *harmonized* legislation that can protect the same interests.

In this context, it should be noted that since May 13, 2009, denials to the application of mutual recognition by national authorities are subject to the conditions laid down in Regulation (EC) 764/2008[31].

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

26 Cf. Article 1 of Regulation (EC) 1924/2006.

27 Our emphasis.

28 Cf. Article 2.2.1 of Regulation (EC) 1924/2006.

29 See Klaus, cited in note 8.

30 At least, regarding the use of substances other than vitamins and minerals.

31 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 (CE) of the European Parliament and of the Council 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 No L 218 of 13 August 2008, p. 21).

Products meeting the requirements (including those related to mandatory statements) laid down in the Italian draft rules – if finally adopted – shall be regarded as legally produced and marketed in a Member State for the purposes of implementing the principle of mutual recognition. In addition, they shall be presumed to be *safe*, as per Article 14.9 of Regulation (EC) 178/2002[32], which provides that "*where there are no specific Community provisions, food shall be deemed to be safe when it conforms to the specific provisions of national food law of the Member State in whose territory the food is marketed, such provisions being drawn up and applied without prejudice to the Treaty, in particular Articles [34 and 36] thereof*"[33].

IV. Consequences of the adoption of the Italian draft decree

It is not adventuresome to state that, if the Italian legislation object of our analysis is to be adopted in its current version, the consequences would extend, in a short period of time, not only to the domestic production but to the entire European food supplements market.

On the short term, food supplements producers in other Member States could benefit from the Italian rules and have their products registered there prior to their commercialization in their domestic markets, via mutual recognition. This is currently the case with Belgium, and, to a lesser extent, Italy or Portugal.

Indeed, the *Belgian formula*, successfully adopted in 1997,[34] provides for a model which establishes a positive list of plants that can be used in food supplements and fortified foods as well as specific limits that apply to certain active substances. When these limits are exceeded, the product is classified by the authorities as a medicinal product [e.g. food supplements containing *Glycine Max* L. Merrill can be sold as food supplements below a daily dose of 40 mg of isoflavones; food supplements containing *Harpagophytum procumbens* (Burch.) DC. can be marketed as such provided they do not contain more than 40 mg of iridoid per day, etc.].

This model of *homeostasis* has indirectly been consecrated by the CJEU, who has referred to the dose of active substances of a plant as the criterion differentiating food supplements from medicinal products[35]. The recognition of this criterion reflects the *Homeostasis model* developed under the auspices of the Council of Europe[36].

The Belgian system, pioneer in the adoption of this model, has had the effect that companies established in Member States with a more restrictive approach regarding botanical food supplements (e.g. Spain or France) rely on the principle of mutual recognition in order to legally sell their products in their countries of origin.

In sum, it is not unreasonable to predict that, should it overcome the procedure laid down in Arti-

32 Regulation (EC) (CE) 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 security (OJ No L 31 of 1 February 2001, p. 1). See, on this regulation: "New food law principles apply from farm to fork", *Consumer Voice*, n° 3, 2002, 1–2; Alemanno, "Trade In Food – Regulatory and Judicial Approaches to Food Risks in the EC and the WTO", Cameron May, London, 2006, 73-160; Aubry-Caillaud, "Sécurité alimentaire en Europe: la mise en place du nouveau cadre juridique", *Journal des tribunaux – Droit européen*, Vol. 12, n° 114, 2004, 289–295; Broberg, "Transforming the European Community's Regulation (EC) of Food Safety", SIEPS, Stockholm, 2008, 65–69; González Vaqué, "Objetivo: la seguridad alimentaria en la Unión Europea (el Reglamento (CE) n° 178/2002)", *Gaceta Jurídica de la UE*, n° 223, 2003, 59–71; Hagenmeyer, "Modern food safety requirements: according to EC Regulation (EC) no. 178/2002", *Zeitschrift für das gesamte Lebensmittelrecht*, Vol. 29, n° 4, 2002, 443–459; Jeannin, "1er janvier 2005: naissance du droit alimentaire européen", *Recueil Dalloz*, n° 42, 2004, 3057–3059; Mahieu y Verdure, "La régulation européenne des risques alimentaires: un palimpseste moderne?" en Mahieu y Nihoul, "La sécurité alimentaire et la réglementation des OGM", Larcier, Bruselas, 2005, 63–86; Pardo Leal, "El Reglamento n° 178/2002: Orientaciones y directrices que *dirigen* pero desorientan", *Boletín del Centro Europeo para el Derecho del Consumo*, n° 106, 2005, 3–6; Petit, "Les règles de sécurité alimentaire: de l'influence de la réglementation sanitaire sur les productions alimentaires et animales", *Revue de droit rural*, n° 349, 2007, 37–39; van der Meulen y van der Velde, "Food Safety Law in the European Union: An introduction", Wageningen Academic publishers, Wageningen, 2004, 147–161; y Vitolo, "La circolazione dei prodotti e il diritto alimentare", *Il diritto dell'agricoltura*, n° 2, 2003, 264–272.

33 Cf. paragraph 2.1.2 of the 2008 Report.

34 *Arreté Royal du 29 Aout 1997 relatif à la fabrication et au commerce de denrées alimentaires composées ou contenant des plantes ou préparations de plantes*, cited in note 26.

35 Cf. CJEU Judgment of March 5, 2009 in Case C-88/07, *Commission vs Spain*, not yet published (para. 75). See Romero Melchor and Timmermans, "*It's the Dosage, stupid*: The CJEU clarifies the Border between Medicines and Botanical Food Supplements", *European Food and Feed Law Review*, nº 3, 2009, 185–191.

36 "*Homeostasis, a model to distinguish between foods (including food supplements) and medicinal products*", Council of Europe, February 7, 2008.

cle 19 of Directive 2000/13/EC, the "*Italian model*" will bear consequences on the EU policy on information to consumers of food supplements.

V. Conclusion

As per the exchanges between the European Commission and the Member States within the framework of the proceedings under Article 19 of Directive 2000/13/EC, the objections raised to the Italian draft can be summarized as follows: through the use of mandatory statements for substances with nutritional and/or physiological effects subject of the draft decree, the Italian legislation would be *circumventing* the implementation of Regulation (EC) 1924/2006[37].

Whilst such an effect would be an inevitable consequence of the application of the proposed decree, the fact remains that, from a strict legal perspective, its adoption is not incompatible with Community law, and hence should be accepted.

As outlined in Section 1 of the 2008 Report, unlike the market of food supplements containing vitamins and minerals (relatively homogeneous), the market of food supplements containing other substances is characterized by its heterogeneity. Indeed, the EU market for these products is highly diversified, both regarding the substances used and the situation from one Member State to another.

In this context, the adoption and implementation of the Italian draft will provide legal certainty not only for the products marketed in the Italian market, but also in other Member States, especially those in which "*... there is a strong tradition of use of certain substances*"[38].

Moreover, the approach taken by the Italian legislator is *better* than the underlying Regulation (EC) 1924/2006 (which is proving so difficult and complex in its application), at least as regards legal certainty and immediacy of application.

The answer, or at least the result of the first round, is expected on April 23, 2010, when the European Commission will deliver its decision on the possible adoption of the draft decree.

37 Cf. summary of the February 22, 2010 meeting of the *Standing Committee on the Food Chain and Animal Health – Section on General Food Law*.

38 Cf. Section 1 of the 2008 Report.