Health Claims on Botanical Food Supplements: and if Italy had been showing “the Way to go” for the entire Community?

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The peculiar situation created by the co-existence of the Italian legislation on food supplements and the Community legislation on nutrition and health claims, when applied in Italy to food supplements characterised by the presence of plants or plants extracts, is continuing to provoke controversy between the Community institutions. In this article we join those scholars who have already advocated the legality of the Italian draft legislation1.

Going, however, one step further, we contend that, pending the resolution of the scientific and methodological difficulties that currently prevent the completion of harmonisation at Community level, the approach selected by Italy might be the way to go for regulating the so-called Article 13(1) health claims when they are made on botanical food supplements throughout the Community. This, we will advocate, would allow achieving for such products a proper balance between the interests of consumers and those of economic operators, in full compliance with the applicable legal principles, including subsidiarity and proportionality.

I. Setting the Scene


The national rules applicable to the placing on the market of food supplements have been only partially harmonized by Directive 2002/46/EC2, as amended (the Directive). The scope of the Directive extends to all food supplements3, irrespective of whether they contain nutrients (vitamins and minerals) or other substances with a nutritional or physiological effect (including botanicals, amino acids, essential fatty acids, fibre) but the degree of the harmonisation actually achieved is uneven. Although labelling requirements are fully harmonised4 and while a positive list of the vitamins and minerals (and their forms5) that may be used for their manufacture has been established, the setting of maximum amounts of vitamins and minerals called for by the Directive6 has not been achieved yet.

Similarly, recalling that the Directive had provided7 that not later than 12 July 2007 the Commission was due to submit to the European Parliament and the Council a “report on the advisability of establishing specific rules, including, where appropriate, positive lists, on categories of nutrients or of substances with a nutritional or physiological effect other than (…) vitamins and minerals listed in Annex I, in the forms listed in Annex II (…) accompanied by any proposals for amendment to this Directive which the Commission deems necessary”, it is noted that the Commission eventually published such a report in December 20088 concluding that

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3 Cf. Article 2(a) of Directive 2002/46/EC.
4 Cf. Article 6 of Directive 2002/46/EC.
5 Cf. Article 4 and Annexes I and II of Directive 2002/46/EC.
6 Cf. Article 5 of Directive 2002/46/EC.
7 Cf. Article 4(8) of Directive 2002/46/EC.
“laying down specific rules applicable to substances other than vitamins and minerals for use in food supplements is not justified”.

2. The Italian Response to Directive 2002/46/EC

In Italy, the rules applicable to the placing on the Italian market of food supplements have been set by the Framework Decree of 21 May 2004, n° 169 governing food supplements, transposing Directive 2002/46/EC into Italian law.

Its Article 6(4)(f) requires that the labelling of food supplements must indicate, in addition to the information required in Directive 2002/46/EC, “the nutritional or physiological effect attributed to the product based on its ingredients in ideal fashion in order to correctly direct consumers’ choices”.

It is against this background that, recognising that the use of substances other than vitamins and minerals will for the foreseeable future remain regulated by national laws subject to the application of the principle of mutual recognition, a draft decree had been prepared by Italy, reflecting the manner by which it intends to apply its 2004 Decree to the specific case of the use and the labelling of such substances in food supplements to be marketed in Italy.

3. The Scope of the Harmonisation achieved for the Use of Nutrition and Health Claims

The Nutrition and Health Claims Regulation, Regulation (EC) 1924/2006, as amended, laying down the conditions for the use of nutrition and health claims on food products, including food supplements, (the NHCR) defines a ‘claim’ (Article 2(2)(1) as “any message or representation, which is not mandatory under Community or national legislation, including pictorial, graphic or symbolic representation, in any form, which states, suggests or implies that a food has particular characteristics”. (Underline added). With respect to health claims, the NHCR establishes a prior authorisation system involving evaluation by EFSA of the scientific evidence supporting the claimed health effect.

Since that definition of claim provides that the Regulation applies only to the use of messages or representations which, although they state, suggest or imply that a food has particular characteristics, are not made to comply with mandatory labelling indications required by other Community or national provisions, any message, statement or representation that will provide consumers in Italy the information required by Article 6(4)(f) of the 2004 Decree – national legislation – is not a claim as defined in the NHCR and is therefore not governed by its provisions.

II. The Legality of the 2004 Decree and the Draft Decree

The draft decree was initially notified on 11 September 2009 to the Commission, pursuant to the procedure established by the Directive 98/34/EC. As part of the process following that notification, the Commission and Spain issued comments following which the draft had to be notified a second time, this time under Directive 2000/13/EC.

Following that notification by Italy, it has been questioned whether Member States would still be allowed to introduce national measures imposing mandatory statements for substances with nutritional and/or physiological effects as this would circumvent the rules laid down in the NHCR.

1. The 2004 Decree pre-existed the NHCR

We must stress that all the draft decree is intended to do is to apply to the specific case of food supplements containing botanicals or other substances, the labelling requirements already established by the 2004 Decree for the entire category of food supplements.
We must stress as well that it would be difficult to sustain that the 2004 decree itself should be declared illegal on grounds that setting mandatory labelling requirements would be in contradiction with the "core principle" of a Regulation, adopted by the EU in 2006 that claims are made on a voluntary basis. When excluding in 2006 from the scope of the NHCR those statements that are mandatory under Community or national legislation, the Community legislator cannot have ignored that the 2004 Decree which had transposed Directive 2002/46/EC into Italy15, already required that the labelling of food supplements must indicate in addition to the information required in Directive 2002/46/EC, "the nutritional or physiological effect attributed to the product based on its ingredients in ideal fashion in order to correctly direct consumers' choices".

It is also submitted that the mandatory labelling requirement in 6(4)(f) must not be looked at "in isolation", but as only one component of the package of legislative measures enacted by Italy16, consistent with its duties to ensure the protection and information of consumers, in an area where harmonisation was in 2004 – and still is today – a "work in progress".


The debate on the Italian legislation highlights a fundamental inconsistency between the legislative approaches chosen by the EU for regulating two otherwise neighbouring categories: food supplements and foods for special nutritional purposes, respectively.

The two categories have in common to be applicable to foods that are not part of the normal diet: foods in the PARNUTS category are "suitable for a particular nutritional use"18; food supplements are "a concentrated source of nutrients or other substances with a nutritional or physiological effect" whose purpose is "to supplement the normal diet"19.

Despite this, however, the Community has not followed a similar approach for their labelling: in the case of PARNUTS, in Directive 2009/39/EC it has elected to set up "... the indication of suitability for a particular nutritional use..." as a mandatory labelling requirement, which it has elected not to do in Directive 2002/46/EC, in the case of food supplements.

One way to look at the approach selected by Italy back in 2004, is to consider that it has then decided to apply to food supplements marketed in Italy the very same requirements as had been used by the EU for the arguably comparable situation of the PARNUTS, i.e. to require that the consumer be informed about the effects attributed to the product. Indeed, pursuant to the EU legislation on food supplements, the consumer of a food supplement will be informed that the product is a concentrated source of nutrients or substances with a nutritional or physiological effect20; he/she will know the identity of the nutrients or substances in question21; but – unlike the case of PARNUTS – he/she will only know about the nutritional or physiological effect attributed to the product via the voluntary information provided by the producer!

It might accordingly be contended that if the joint between the different pieces of Community legislation and the Italian legislation causes quite serious difficulties (and breaches legal principles such as legal certainty and legitimate expectation, equality and non discrimination and sound administration), it may be difficult to sustain that the source of the problem lies on the Italian side: Italy had simply, back in 2004, decided to apply a very high level of consumer protection and safety, notably by making it an obligation when marketing a food supplement in Italy, to declare the nutritional and physiological effect attributed to the product, a requirement that the EU itself had instituted for PARNUTS but not for food supplements.

15 And had been notified as such to the European Commission, allowing the Commission to close the infringement procedure it had initiated against Italy for non transposition in time of the Directive 2002/46/EC.
16 Such measures include a compulsory notification, the authorisation of manufacturing plants, a negative list of plants not allowed, a positive list of plants allowed, a system of pharmacovigilance, and the mandatory declaration of the nutritional or physiological effect attributed to the product based on its ingredients.
17 One might as well raise the inconsistencies existing between the food legislation and the neighbouring legislation on traditional herbal medicines.
18 Article 1(2)(a) Directive 89/398/EC.
19 Article 2(a) Directive 2002/46/EC.
20 Because marketed as a food supplement, as such term is defined by Directive 2002/46/EC.
21 Article 6(3) of Directive 2002/46/EC.
In our opinion, the argument that the 2004 Decree ought to be declared null and void because the mandatory labelling requirement it contains would be contrary to a Regulation that has been subsequently adopted to deal with voluntary claims would be quite difficult to sustain, recognising that it is precisely to avoid such conflicts happening that the NHCR itself – adopted at a time when the 2004 Decree was fully known – had clearly provided that it would not be applicable to such mandatory (Community or) national labelling requirements.

III. The Approach selected by Italy in 2004 might now be “the way to go” for the entire Community

The objectives pursued by the Community legislator when adopting the NHCR were (1) to achieve a high level of consumer protection (2) to improve the free movement of goods within the internal market (3) to increase legal security for economic operators and (4) to ensure fair competition in the area of foods, thereby reflecting a good balance between consumers’ interests and those of economic operators.

One must accordingly put in the proper perspective the objective of achieving a high level of consumer protection and recall that, contrary to what is generally believed or contended, the European consumer did not have to wait for the adoption of the NHCR in 2006 to be protected against misleading claims on food products. Such protection had been in place since 1979, as a result of Article 2(1)[a][ii] of Council Directive 79/112/EEC of 18 December 1978 on the labelling of foodstuffs. 22. It is since that date, more than 30 years ago, that it has been prohibited, throughout the EU, to mislead the consumer to a material degree by attributing to the foodstuffs effects or properties which it does not possess.

It is therefore particularly appropriate when assessing the implementing measures of the NHCR regarding the use of health claims on food supplements characterised by the presence of plants or plant extracts, not to neglect the objectives of free movement, legal certainty and fair trade.

 Suffice it to look at the situation of an operator active in Italy 23 facing the following dilemma: on the one hand, the mandatory labelling requirements set up by the 2004 Decree make it an obligation to declare the benefits attributed to the plants or plant extracts, while, on the other hand, because notably of the arguably disproportionate approach taken by the Community Institutions and their bodies when conducting the evaluation and authorisation process for health claims based on botanical ingredients, it is very unlikely that the relevant mandatory statements will be ultimately included in the Community list.

1. Too far, too soon?

The decision by the Community legislator to apply the NHCR to all claims made on botanical food supplements – without taking into account the very same difficulties it had recognised in Directive 2002/46/EC when it wisely organised a phased and conditional completion of the harmonisation process for their compositional aspects – was arguably overly ambitious, and is certainly proving to be inadequate.

Recalling that the Commission has now recognised that the harmonisation process is neither necessary nor feasible in the immediate future for the compositional aspects of such products 24, one has to note the sharp contrast between, on the one hand, that very sound assessment by the Commission of the (doubtful) feasibility and the (absence of) necessity to lay down at this stage specific rules applicable to substances other than vitamins and minerals used in food supplements, and, on the other hand, the quasi “dogmatic” approach taken by the Community institutions and bodies when it turns to implementing the NHCR to food supple-

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22 Now Directive 2000/13/EC.
23 Including importers.
24 The Commission’s conclusions were based, in essence, on the following considerations: “Unlike vitamins and minerals, the use of which is fairly similar throughout the Member States, the other substances correspond to very varied consumption habit”. Moreover, given the available scientific information, which is essentially limited to substances that may be added for specific nutritional purposes to foods for particular nutritional uses, the Commission believes that a proposal for harmonisation in this area could only be limited to some substances, thus restricting its usefulness”. “Taking account, also, of the scientific and methodological difficulties which would have to be overcome, the Commission believes that the prospect of extending Directive 2002/46/EC to substances other than vitamins and minerals could only be envisaged in the light of the experience gained when the rules on the use of vitamins and minerals were being laid down, bearing in mind that these rules still need to be supplemented by laying down maximum quantities in accordance with Article 5 of the Directive”. 24
ments characterised by the presence of plants or herbal extracts referred to in paragraph 1 of Article 13 of the NHCR.

2. A Way forward?

As just one example of a pragmatic and lawful option it might be suggested to order an immediate hold on the evaluation by EFSA of the health claims on botanical products submitted to it pursuant to Article 13 paragraph 3 of the NHCR, and to launch simultaneously the legislative process leading to an amendment of Directive 2002/46: the aim of that amendment would be to institute additional labelling requirements in the Directive for food supplements characterised by the presence of plants or herbal extracts.

Specifically, in addition to the existing requirement that the labelling shall bear the names of the categories of nutrients or substances that characterise the product or an indication of the nature of those nutrients or substances, the additional mandatory labelling particular would be set up to require that: "in the case of food supplements characterised by the presence of plants or herbal extracts, an indication of the role of such plants or herbal extracts in growth, development and the functions of the body, or psychological and behavioural functions, or slimming or weight control or a reduction in the sense of hunger or an increase in the sense of satiety or to the reduction of the available energy from the diet; such indication shall be sufficient to inform adequately the purchaser when trying to make healthy choices in the context of a varied diet.

This would be tantamount to extending the Italian approach to the entire Community. It would result in excluding the health claims referred to in Article 13(1) NHCR when attributed to plants or herbal extracts (not to those relating to other substances) contained in food supplements, from the requirement to be included in the Community list called for by Article 13(3) NHCR.

The use of such health claims would become instead governed by the additional labelling requirements under Directive 2002/46, the provisions of which would accordingly be binding upon the Member States when enforcing such additional new labelling requirements, under the control of the Courts.

Pending the resolution of the scientific and methodological difficulties that prevent the full completion of harmonisation at this stage, and with due respect to the principle of subsidiarity and proportionality, this would allow (1) to achieve a high level of consumer protection under the responsibility of the Member States (2) to ensure the free movement of goods within the internal market, by application of the principle of mutual recognition (3) to restore the legal security for economic operators and (4) to ensure fair competition in the area of foods, thereby reflecting the sought after balance between consumers’ interests and those of economic operators and the full compliance with all applicable legal principles.

IV. Conclusion

It is not unreasonable to conclude that “something must be done” by the Community institutions. It may not be unreasonable either for the institutions to “think twice” before deciding that the proper response to the situation could simply be to challenge the legality of the Italian legislation: we fear that this might be like “disposing of the baby with the water of the tub”.

Going one step further, indeed, one might suggest that the time has come for the Community legislator to take measures to reflect, with respect to the use of health claims referred to in Article 13(1) NHCR made on botanical food supplements, the very same factual issues and scientific and methodological difficulties that have led it to suspend its harmonisation efforts for the compositional aspects of such products.

26 As had been the case since 1978.
27 See in particular González Vaqué and Romero Melchor, cited in footnote 1.