December 29, 2016

The European Court of Justice declares that Regulation No 1924/2006 applies to health claims directed at health professionals: the Verband Sozialer Wettbewerb eV judgment (Case C-15/19)

Luis González Vaqué
Silvia Bañares Vilella
Sebastián Romero Melchor

The European Court of Justice declares that Regulation No 1924/2006 applies to health claims directed at health professionals: the Verband Sozialer Wettbewerb eV judgment (Case C-15/19)

Silvia Bañares Vilella, Food Lawyer
Luis González Vaqué, China-EU Food Law Working Party
Sebastián Romero Melchor, Food Compliance International Pte. Ltd.

«The whole problem with the world is that fools are always so certain of themselves, and wiser people so full of doubts».
Bertrand Russell

I. Introduction

In the middle of July 2016 the European Union's Court of Justice (CJ) issued it's much awaited (or feared) Judgment[1] on a request from the *Landgericht München I*[2] for a preliminary ruling under Article 267 TFEU made by decision of 16 December 2014. The request concerned the interpretation of Article 1(2) of Regulation (EC) No 1924/2006 of 20 December 2006 on nutrition and health claims made on foods,[3] and was made as part of a dispute between *Verband*

[1] Case C-19/15 *Verband Sozialer Wettbewerb eV,* judgment of 14 July 2016, ECLI identifier: ECLI:EU:C:2016:563.

[2] Regional Court, Munich I, Germany.

[3] Regulation (EC) of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods (OJ 2006 L 404, p. 9 and corrigendum OJ 2007 L 12, p. 3); it should be noted that the CJ referred to their version amended by Commission Regulation (EU) No 1047/2012 of 8 November 2012 (OJ 2012 L 310, p. 36). On Regulation No 1924/2006 see "Adoptado el Reglamento sobre alegaciones nutricionales y propiedades saludables en los alimentos", *Revista de Derecho Alimentario*, No. 17, 2006, pp. 10-13; "La sentencia *Deutsches Weintor* de 6 de septiembre de 2012: interpretación del Reglamento (CE) No 1924/2006 (alcance de la noción de declaración de propiedades saludables, etc.)", *ReDeco*, No. 28, 2012, pp. 21-33; Amarilla Mateu, N., "Future Liability for Defects in Information provided in Food Health Claims begins with the Right to Information on Food Health", *European Food and Feed Law Review*, No. 4, 2007, pp. 223-229; Bañares Vilella, S., "Los derechos de exclusiva y el Reglamento CE 1924/2006", *Revista de Derecho Alimentario*, No. 54, 2010, pp. 20-28; González Vaqué, L., "La regulación del etiquetado nutricional en la Unión Europea: ¿Un elemento irreversible de deterioro del Mercado único alimentario?", *Revista Aranzadi Unión Europea*, No. 2, 2016, pp. 63-85; Grelier-Lenain, C., "Le Règlement européen concernant les allégations nutritionnelles et de santé", *La Gazette du palais*, Vol. 127, No. 334-335, 2007, pp. 6-10; Masini, S., "Prime note sulla disciplina europea delle indicazioni sulla salute", *Diritto e giurisprudenza agraria, alimentare e dell'ambiente*, No. 2, 2007, pp, 73-80; Meisterernst, A., "A Learning Process? – Three Years of Regulation (EC) No. 1924/2006 on Nutrition and Health Claims Made on Foods", *European Food and Feed Law Review*, No. 2, 2010, pp. 59-72; Segura Roda, I., "Reglamento n° 1924/2006 relativo a las declaraciones nutricionales

Sozialer Wettbewerb eV, a German association safeguarding competition, and *Innova Vital GmbH,* a private company[4], concerning the applicability of the Regulation to such claims when made in a written document addressed exclusively to health professionals.

II. The dispute in the main proceedings

Innova Vital GmbH marketed a nutritional supplement in Germany known as "Innova Mulsin® Vitamin D_3", containing vitamin D_3 and to be administered in the form of drops. In November 2013, its director sent *exclusively* to named doctors a written document (hereafter, the "document at issue") containing the following statements, among others:

> «[...]
>
> You are aware of the situation: 87% of children in Germany have blood vitamin D levels below 30 ng/ml. According to the DGE [(*Deutsche Gesellschaft für Ernährung*, German Food Association)], that level should be approximately 50 to 75 ng/ml
>
> As has already been demonstrated in numerous studies, vitamin D plays an important role in the prevention of several illnesses, such as atopic dermatitis, osteoporosis, diabetes mellitus and MS [multiple sclerosis]. According to those studies, vitamin D deficiency in childhood is partly responsible for the subsequent development of those illnesses.
>
> For that reason, *I have given my son the recommended formula based on vitamin D*[5] and I have found that babies, young children and even school-aged children hardly like the traditional form in tablets. Very often my son spits out the tablets.
>
> As a doctor specialising in immunology, I considered this issue and developed a vitamin D 3 emulsion (*Innova Mulsin® D3*) which can be administered in the form of drops.
>
> [...]
>
> Benefits of *Mulsin®* emulsions:
>
> [...]

y de propiedades saludables en los alimentos: ámbito de aplicación y definiciones", *Revista de Derecho Alimentario*, No. 21, 2007, pp. 21-26; y Tato Plaza, A., "El nuevo régimen jurídico de las declaraciones saludables en la publicidad de los alimentos", *Autocontrol*, No. 134, 2008, pp. 22-30 (see also Haber, B. y Meisterernst, A., *Health & Nutrition Claims*, Lexxion, 2010. 227 pp.).

[4] «The director of which is a doctor», as specified in paragraph 13 of the *Verband Sozialer Wettbewerb eV* judgment.

[5] Emphasis added by the authors.

> Rapid prevention or elimination of nutritional deficiencies (80% of the population is described as being vitamin D 3 -deficient in winter).
>
> [...]
>
> You can find out how to place direct orders and obtain free information material for your surgery by calling [...]».

In addition, the *document at issue* contained an image of the nutritional supplement Innova *Mulsin® Vitamin D 3*, information on its composition, its selling price, and the daily cost of treatment based on the recommended dose of one drop per day.

In response to this advertising, *Verband Sozialer Wettbewerb eV* applied for a prohibitory injunction from *Landgericht München I* against *Innova Vital GmbH* based on Paragraph 8 of the Gesetz gegen den unlauteren Wettbewerb[6], alleging that the *document at issue* included the following two health claims, which are forbidden under Article 10(1) of Regulation No 1924/2006:

> «[…]As has already been demonstrated in numerous studies, vitamin D plays an important role in the prevention of several illnesses, such as atopic dermatitis, osteoporosis, diabetes mellitus and MS [multiple sclerosis]. According to those studies, vitamin D deficiency in childhood is partly responsible for the subsequent development of those illnesses»[7]
>
> and
>
> «Rapid prevention or elimination of nutritional deficiencies (80% of the population is described as being vitamin D 3 -deficient in winter)»[8].

In addition, *Verband Sozialer Wettbewerb eV* claimed in particular that the provisions of Regulation No 1924/2006 applied to advertising that targeted professionals as well as non-professionals.

According to *Innova Vital GmbH* however, Regulation No 1924/2006 does not concern advertising to professionals. Therefore, since the *document at issue* was addressed solely to doctors, the Regulation's provisions do not apply to the health

---

[6] German Law on unfair competition, in the version applicable to the dispute in the main proceedings (see paragraph 12 of the *Verband Sozialer Wettbewerb eV* judgment).

[7] See paragraph 17 of the *Verband Sozialer Wettbewerb* eV judgment.

[8] *Ibidem*.

claims made in the document, which are expressly prohibited by the Regulation at Article 10(1).

It should be pointed out that according to the referring court, the resolution of the dispute in the main proceedings depended on the interpretation of Article 1(2) of Regulation No 1924/2006 concerning the subject matter and scope of said regulation.

III. The question at stake

Given the circumstances, *Landgericht München I* decided to stay the proceedings and refer the following question to the Court of Justice for a preliminary ruling:

> «Must Article 1(2) of Regulation (EC) No 1924/2006 be interpreted as meaning that the provisions of that regulation apply also to nutrition and health claims made in commercial communications in advertisements for foods to be delivered as such to the final consumer if the commercial communication or advertisement is addressed exclusively to the professional sector?»

IV. Opinion of the Advocate General Saugmandsgaard Øe

In his Opinion, delivered on 18 February 2016, the Advocate General Henrik Saugmandsgaard Øe proposed to the Justice Tribunal that it answer the request for a preliminary ruling in the following manner:

> « Article 1(2) of Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods must be interpreted as meaning that the provisions of that regulation apply to nutrition and health claims made in commercial communications on foods to be delivered as such to the final consumer *if those communications are addressed exclusively to the professional sector but are intended to be targeted indirectly at consumers, via the professional sector*[9]»[10].

V. Operative part

In this respect the CJ (Third Chamber) declared that

[9] Emphasis added by the authors.

[10] See González Vaqué, L., "Is Regulation (EC) No 1924/2006 on nutrition and health claims applied to commercial communications addressed exclusively to the professional sector (B2B)?", *eFood Lab*, No. 2, 2016, available on the following Internet page consulted on 19 July 2016: https://www.researchgate.net/publication/304344312_Is_Regulation_EC_No_19242006_on_nutrition_and_health_claims_applied_to_commercial_communications_addressed_exclusively_to_the_professional_sector_B2B.

> « Article 1(2) of Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods, as amended by Commission Regulation (EU) No 1047/2012 of 8 November 2012, must be interpreted as meaning that nutrition or health claims made in a commercial communication on a food which is intended to be delivered as such to the final consumer, if that communication is addressed not to the final consumer, but exclusively to health professionals, falls within the scope of that regulation».

VI Comments

1. The interpretation of EU law used to make a preliminary ruling

In principle, the legal issue seemed to centre on the forwarding court's question as to whether article 1.2 of Regulation No 1924/2006 meant that the nutritional and health claims made in a commercial communication relating to a food to be supplied as such to the final consumer came within said Regulation's scope of application *even if* the communication was aimed, not at the consumer in question, but *exclusively* to health professionals.

As Paragraph 23 of the *Verband Sozialer Wettbewerb eV* judgment states, in keeping with settled case law it is necessary when interpreting a provision of European Union law to «consider not only its wording but also the context in which it occurs and the objectives pursued by the rules of which it is part[11]».

2. Scope of Regulation No 1924/2006: article 1.2

Article 1.2 establishes that[12]

> « This Regulation shall apply to nutrition and health claims made in commercial communications, whether in the labelling, presentation or advertising of foods to be delivered as such to the final consumer.
>
> In the case of non-prepackaged foodstuffs (including fresh products such as fruit, vegetables or bread) put up for sale to the final consumer or to mass caterers and foodstuffs packed at the point of sale at the request of the purchaser or pre-packaged with a view to immediate sale, Article 7 and Article 10(2)(a) and (b) shall not apply. National provisions may apply until

[11] See in particular the following paragraphs: para 12 of Case 292/82, *Merck* judgment of 17 November 1983 (EU:C:1983:335); para 44 of Case C-533/08, *TNT Express Nederland,* judgment of 4 May 2010 (EU:C:2010:243 – commented on in Magrone, M. E., "Trasporto merci: Convenzione *ad hoc* applicabile solo se prevedibile e in grado di limitare liti parallele", para 21, *Guida al Diritto*, 2010, pp. 96-98); and para 14 of Case C-99/15, *Liffers* judgment of 17 March 2016, (EU:C:2016:173).

[12] According to the latest consolidated version (available at: http://eur-lex.europa.eu/legal-content/ES/TXT/?uri=CELEX:02006R1924-20141213).

the eventual adoption of Community measures designed to amend non-essential elements of this Regulation, inter alia, by supplementing it, in accordance with the regulatory procedure with scrutiny referred to in Article 25(3).

This Regulation shall also apply in respect of foods intended for supply to restaurants, hospitals, schools, canteens and similar mass caterers.»

Therefore it should be noted that, pursuant to this regulation, this Rule is applicable to nutritional and health claims when:

- such declarations are made in a commercial communication that is in the form of a labelling of foods, a presentation of them, or in advertising regarding them

and

- the foods in question are destined to be supplied as such to the final consumer.

3. The concept of *commercial communication*

As the Court of Justice notes in paragraph 25 of its judgment, Regulation No 1924/2006 «does not contain a definition of the concept of a *commercial communication*». However in other areas of EU law the concept is defined in the provisions of secondary legislation. In the present case, these provisions should be used as a guide in order to ensure that community law is consistent. It notes in this respect that

- «under Article 2(f) of Directive 2000/31[13], *commercial communication* means any form of communication designed to promote, directly or indirectly, the goods, services or image of a company, organisation or person pursuing a commercial, industrial or craft activity or exercising a regulated profession»[14];

[13] Directive [on electronic commerce'] of the European Parliament and of the Council of 8 June 2000 on certain legal aspects of information society services, in particular electronic commerce, in the Internal Market (OJ L 178, 17.7.2000, p. 1).

[14] See paragraph 26 of the *Verband Sozialer Wettbewerb eV* judgment.

- «Article 4(12) of Directive 2006/123[15] contains a similar definition of the concept of *commercial communication*»[16] (in that regard, the Court has stated that, for the purposes of that provision, «a commercial communication covers not only traditional advertising but also other forms of advertising and communications of information intended to obtain new clients»[17]; and

- «it is also clear from recital 4 of Regulation No 1924/2006 that the concept of a 'commercial communication' includes a communication which pursues the objective of *promotion*»[18].

In view of the above, the CJEU considered that, in keeping within the meaning of article 1.2 of Regulation No 1924/2006, the concept of a «commercial communication» should be understood as including «a communication made in the form of advertising foods, designed to promote, directly or indirectly, those foods»[19]. It further specified that such a «communication may also take the form of an advertising document which food business operators address to health professionals, *containing nutritional or health claims within the meaning of that regulation, in order that those professionals recommend, if appropriate, that their patients purchase and/or consume that food*[20]»[21].

4. Consumers and health professionals: Two public/end users with identical characteristics and knowledge?

The CJEU refers to point 39 of the aforementioned Opinion of the Advocate General Saugmandsgaard Øe, which states

[15] Directive of the European Parliament and of the Council of 12 December 2006 on services in the internal market (OJ L 376, 27.12.2006, p. 36).

[16] See paragraph 27 of the *Verband Sozialer Wettbewerb eV* judgment.

[17] *Ibidem* [CJEU mentioned in particular paragraph 33 of the judgment "Société fiduciaire nationale d'expertise comptable" of 5 April 2011 (case C-119/09, EU:C:2011:208 – commented in: Barbièri, J.F., "Professions réglementées: hors la loi, la prohibition générale du démarchage!", *Petites affiches*, No. 124, 2011, pp. 12-15)].

[18] See paragraph 28 of the *Verband Sozialer Wettbewerb eV* judgment.

[19] *Ibidem*, paragraph 29.

[20] Emphasis added by the authors.

[21] See paragraph 30 of the *Verband Sozialer Wettbewerb eV* judgment.

> «[that] the legislature has made no distinction based on the capacity of the addressee of communications containing the nutrition and health claims covered by [Regulation No 1924/2006]. The only requirements laid down in the regulation concern the purpose and nature of those communications. First, they must relate to foods to be delivered to a final consumer[22] and, secondly, they must be of a commercial nature, whether they take the form of the labelling or presentation of such foods, or — as in the dispute in the main proceedings — the advertising of those foods[23]. It is therefore the product itself, and not the communication of which it is the subject matter, which must necessarily be aimed at consumers[24].»

It then reiterated that article 1.2 of Regulation No 1924/2004 «does not include any details on the addressee of the commercial communication and *makes no distinction according to whether that addressee is a final consumer or a health professional*[25]»[26]. In this respect the CJEU's reasoning is similar to that of the Advocate General at point 39 of his conclusions in the sense that it is the product itself and not the communication relating to it that must be aimed at the final consumer. Therefore the CJ, having confirmed that under said rule [article 2(f) of Directive 2000/31 and article 4.12 of Directive 2006/123] Regulation No 1924/2006 *applies to nutrition or health claims made in a commercial communication addressed exclusively to health professionals*, states that «such an interpretation is not invalidated by the analysis of the context of Article 1(2) of Regulation No 1924/2006»[27].

The CJEU recognises that although health professionals possess a *scientific knowledge superior* to that of a final consumer, understood in recital 16 of Regulation 1924/2006 as an average consumer who is reasonably well informed and reasonably observant and circumspect, nevertheless «… those

---

[22] Those foods are «delivered as such» either directly to the final consumer (see recital 3 and the first subparagraph of Article 1(2) of Regulation No 1924/2006) or indirectly in the context of 'supply to restaurants, hospitals, schools, canteens and similar mass caterers' (see the third subparagraph of Article 1(2) of that regulation).

[23] See the fourth recital and first paragraph of article 1.2 of Regulation No 1924/2006. The Advocate General Saugmandsgaard Øe indicated that this requirement did not exist in the Proposal COM(2003) 424 final.

[24] See Dehove, R. *et al.*, *Lamy Dehove*, Volume 1, Part 2, Study 285, Wolters Kluwer France, Paris, 2014, paragraph 285-126: «the provisions [of Regulation No 1924/2006] concern, therefore, both advertisements aimed at the final consumer and those aimed at professionals (including health professionals) in so far as they concern all commercial communications or advertising relating to a product which is itself aimed at the final consumer» (note transcribed from the Opinion of the Advocate General Saugmandsgaard Øe).

[25] Emphasis added by the authors.

[26] See paragraph 31 of the *Verband Sozialer Wettbewerb eV* judgment.

[27] *Ibidem*, paragraph 33.

professionals cannot be regarded as being in a position to *permanently*[28] have all specialised and up-to-date scientific knowledge necessary to evaluate each food and the nutrition or health claims used in the labelling, the presentation or advertising of those foods»[29]. This latter statement can probably be interpreted as referring to scientific communications between pharmaceutical companies and health professionals (in which the information in question usually uses technical terms and expressions that cannot be understood by patients).

The Court of Justice's judgment is clearly ambiguous: referring to point 39 of the Advocate General's conclusions it adds that «… it cannot be ruled out that the health professionals themselves may be misled by nutrition or health claims which are false, deceptive, or even mendacious»[30]. It then inexplicably concludes that those health professionals risk forwarding, *in all good faith*[31], incorrect information on foods which are the subject of a commercial communication to final consumers with whom they have a relationship and that «that risk is all the more remarkable as such professionals are likely, because of the relationship of trust which generally exists between them and their patients, to exercise *significant influence* over the latter»[32]. This is disconcerting to read because the EJC would appear to be unaware of the scope of the principle of truthfulness (which must be taken into consideration both in commercial and scientific communications), as well as the fact that doctor-patient relations go beyond a «significant influence» and include, as they should, recommending, prescribing, guiding the patient, etc.

Elsewhere the CJ bases its reasoning on the following generic arguments:

- Although (as argued by *Innova Vital GmbH)* some recitals and provisions of Regulation No 1924/2006 - in particular recitals 1, 9, 16, 29 and 36 and article 5.2 - refer expressly to the «consumers» without mentioning the «professionals», nonetheless «the absence of any reference to *professionals*' in those recitals and provisions does not mean that that regulation does not apply to the situation where a commercial communication is addressed exclusively to health professionals»[33] («in such a situation that communication between the food business operators

[28] Emphasis added by the authors.

[29] See paragraph 43 of the *Verband Sozialer Wettbewerb eV* judgment.

[30] *Ibidem*, paragraph 44.

[31] *Sic* in paragraph 45 of the *Verband Sozialer Wettbewerb eV* judgment.

[32] Ibid.

[33] *Ibidem*, paragraph 35.

and the health professionals *covers principally the final consumer, in order that that consumer acquires the food which is the subject of that communication, following the recommendations given by those professionals*[34]»[35]);

- « … it does not follow from any provision of Regulation No 1924/2006 that it does not apply to commercial communications addressed to health professionals»[36];

and

- the objectives of the community standard in question «… confirm the interpretation that that regulation applies *to commercial communications addressed exclusively to health professionals*[37]»[38] (given that under paragraph 38 of the judgment and pursuant to article 1.1 of Regulation No 1924/2006, the objective of the latter is to ensure the efficiency of the internal market whilst providing a high level of consumer protection)[39].

5. Aims and objectives of Regulation No 1924/2006

In responding to the *Landgericht München I*'s request for a ruling, the CJ has essentially based itself on a teleological interpretation of Regulation No 1924/2006. So it is worth examining the scope and contents of that interpretation in some detail:

Firstly, it is true that article 5.1(a) of said Regulation provides for authorisation of the use of nutritional and health claims if it has been demonstrated that the presence, absence, or reduced content in a food or category of foods of a nutrient

[34] Emphasis added by the authors.

[35] See also paragraph 35 of the *Verband Sozialer Wettbewerb eV* judgment.

[36] See paragraph 36 of the *Verband Sozialer Wettbewerb eV* judgment.

[37] Emphasis added by the authors.

[38] See paragraph 37 of the *Verband Sozialer Wettbewerb eV* judgment.

[39] See paragraph 39 of the *Verband Sozialer Wettbewerb eV* judgment: «as is apparent from recitals 1 and 18 of Regulation No 1924/2006, health protection is among the principal aims of that regulation » [see paragraph 45 of case C-544/10, *Deutsches Weintor* judgment of 6 September 2012 (EU:C:2012:526 – discussed in "El CJEU interpreta el Reglamento No 1924/2006 relativo a las declaraciones de propiedades saludables en los alimentos: la sentencia *Deutsches Weintor*", *Rivista di diritto alimentare*, No. 2, 2012, pp. 44-54, available on the following internet page consulted on 19 July 2016: http://www.rivistadirittoalimentare.it/rivista/2012-03/VAQUE.pdf)].

or other substance with respect to a claim possesses *a beneficial nutritional or physiological effect, as established by generally accepted scientific evidence* [40];

On the other hand, as specified by recital 17 of said Regulation, the main aspect to consider in relation to the use of nutritional and health claims should be their scientific basis. This is confirmed by recital 23, which provides that «health claims only be authorised for use in the European Union after a scientific assessment of the highest possible standard and that, in order to ensure harmonised scientific assessment of these claims, the European Food Safety Authority [EFSA] is to carry out such assessments».

Moreover, «Regulation No 1924/2006 provides for a procedure to determine whether a claim is scientifically substantiated»[41] within the meaning of that regulation.

VII Final comments

1. Contradictory logic?

At paragraph 46 of its judgment the CJEU states categorically that

> «(…) if the nutritional or health claims addressed to health professionals were not within the scope of Regulation No 1924/2006, with the result that such claims could be used without necessarily being based on scientific evidence, there would be a risk that the food business operators would circumvent the obligations laid down by that regulation, addressing the final consumer through health professionals, in order that those professionals recommend their foods to that consumer».

Such a statement will certainly not be passively accepted by either the interested parties or by legal doctrine. The following arguments will also undoubtedly be the subject of much debate:

> «(…) the application of that regulation to the nutrition or health claims made in a commercial communication addressed to professionals contributes to a high level of consumer protection, in the context of the internal market, whose effective functioning Regulation No 1924/2006 seeks to ensure» (paragraph 47);
>
> and

[40] See recital 15, which also includes the following statement: «in order to ensure that the claims made are truthful, it is necessary that the substance that is the subject of the claim is present in the final product in quantities that are sufficient, or that the substance is absent or present in suitably reduced quantities, to produce the nutritional or physiological effect claimed [and] the substance should also be available to be used by the body. In addition, and where appropriate, a significant amount of the substance producing the claimed nutritional or physiological effect should be provided by a quantity of the food that can reasonably be expected to be consumed».

[41] See paragraph 42 of the *Verband Sozialer Wettbewerb eV* judgment.

> «admittedly, it follows from Article 5(2) of Regulation No 1924/2006 that the use of nutrition and health claims is to be permitted only if the average consumer can be expected to understand the beneficial effects as expressed in the claim» (paragraph 49).

It is not easy in this context to evaluate the scope and possible interpretation(s) of paragraph 50, in which the CJ specifically admits that «… it cannot be inferred from that that any objective information from food business operators addressed to health professionals about new scientific developments involving the use of technical or scientific terminology, as, in the present case, the use of the words *atopic dermatitis* is prohibited».

In equally ambiguous (or mistaken) and, it would seem, contradictory fashion, the CJEU then goes on to argue that article 5.2 of Regulation No 1924/2006 «must be understood in the sense that it applies if the nutrition and health claims are communicated directly to the final consumer, to enable him to make choices in full knowledge of the facts»,[42] submitting that «… as noted by the Advocate General in point 54 of his Opinion, in a case such as that in the main proceedings, the document containing those allegations is not to be submitted as such to the final consumer, but is sent to health professionals who are implicitly invited to recommend the food covered by the claims to that consumer»[43].

2. Case law of limited scope and not applicable to *scientific communications*

Finally we include the following two paragraphs which, very straightforward in their meaning, should help clarify what can be done and by whom in the field of health claims:

> «52. Moreover, recital 4 of Regulation No 1924/2006 states that *it should not apply to claims which are made in non-commercial communications, such as dietary guidelines or advice issued by public health authorities and bodies, or non-commercial communications and information in the press and in scientific publications*[44].
>
> 53. Consequently, that regulation does not preclude the objective information for health professionals about new scientific developments, involving the *use of a technical or scientific terminology*[45], in the situation where the communication is of a non-commercial nature.»

[42] *Ibidem*, paragraph 51.

[43] *Ibidem*.

[44] Emphasis added by the authors.

[45] Emphasis added by the authors.

In our opinion it ought to be acknowledged that the origin of the litigation was a rather unusual communication containing a series of very limited and anecdotal comments And the parties focussed on this content. But neither they, the *Landgericht München I* nor the Advocate General himself paid particular attention to the broader legal implications - unlike the French Government and the European Commission, whose observations are briefly mentioned in the Advocate General's Opinion.

It would be a mistake to apply the ECJ's logic in a generalised way as it would create legal uncertainty and eventually have unintended consequences which would be inconsistent with the very purpose of Regulation No 1924/2006. Furthermore the Court's reasoning runs counter to the administrative practices of many EU countries, some of which have published directives expressly excluding communications directed at health professionals from the scope of application of the Regulation[46]. Such reasoning also contradicts prevailing opinion in the literature[47].

As we have seen, article 1.2 of Regulation No 1924/2006 effectively establishes that it applies to nutritional and health claims made in commercial communications, be they in the labelling, presentation or advertising of foods supplied as such to the final consumer, with the latter concept defined in Regulation (EC) No 178/2002[48] as «…the ultimate consumer of a foodstuff who will not use the food as part of any food business operation or activity».

It would appear that to justify applying its logic to communications to health professionals, the CJ essentially relies on a strictly literal interpretation of article 1.2. This explains why it states that the phrase «to be delivered as such to the final consumer» refers to food products themselves and not communications related thereto. Having established this premise, it then attempts to argue, perhaps with more willing than certainty, that its reasoning is compatible with the objectives of said Regulation. But if such a position is accepted then it will make no difference whether advertising is targeted at the final consumer or health

---

[46] See, *inter alia*, the guide produced by the UK's *Food Standards Agency*: "*Guidance to compliance with Regulation (EC) 1924/2006 on nutrition and health claims made on foods*", November 2011: «*While the Regulation applies to claims made in commercial communications about foods it is our opinion that it will not control claims made in communications within trade (business to business), to doctors or other health professionals, or to their organisations, whether the claim is in the labelling, advertising or other presentation of the food. This is provided that the recipients are acting within the scope of their professional activities and that they are not being addressed as final consumers of the foods. It therefore follows that if the information were, at any time, conveyed to final consumers within a commercial context, any claims made would need to comply with the requirements of the Regulation*».

[47] See for example Romero Melchor, S. and Timmermans. E., "But what is it, Doc?" – Health Care Professionals under Regulation 1924/2006", *European Food and Feed Law Review*, No. 5, 2010, pp. 270-280.

[48] Regulation of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31, 1.2.2002, p. 1).

professionals, as long as the products involved are supplied to the final consumer[49].

The question has also been raised as to whether Regulation No 1924/2006 would not apply to *food ingredients*. But ingredients as such are not supplied to the final consumer,[50] but rather to other food companies for processing, *including those directed to final consumers.* It is therefore a question which falls outside the main scope of this paper and so, *brevitatis causae*, we will have to wait for another occasion to look at it in more detail.

A general interpretation of the case law enshrined in this judgment would suggest that Regulation No 1924/2006 applies to commercial communications aimed at any kind of professional ('business to business' or B2B communications), and not just health professionals. In our view, however, it would be a mistake to apply such a broad interpretation, because the results would run contrary to the spirit and objectives of said Regulation.

The concept of the final consumer referred to in article 1.2 should be understood as excluding from its scope of application professionals acting in the sphere of their professional activities (e.g. operators of food companies, distributors, manufacturers of ingredients or final products, etc.). The very basis of consumer rights in the European Union[51] rests on this distinction between consumers and professionals, as expressly recognised by legal doctrine[52]. The same principle applies to other areas regulated by the EU, such as prescribed medications and tobacco products. But although promotion to the public (in the form of advertising) is generally forbidden, it is allowed if directed at professionals. This criteria allowing advertising directed at health professionals has been applied in recent

[49] See paragraph 31 of the Verband Sozialer Wettbewerb eV judgment (and Romero Melchor, S., "El CJEU declara que el Reglamento No 1924/2006 se aplica a las declaraciones de propiedades saludables cuando estas van dirigidas a profesionales de la salud", article pending publication).

[50] See: Romero Melchor, S., *op.cit*.

[51] See for example article 1(2)(a) of the Council Directive 85/577/EEC of 20 December 1985 to protect the consumer in respect of contracts negotiated away from business premises (OJ L 372, 31.12.1985, p. 31); el article 2(4) of the Council Directive 90/314/EEC of 13 June 1990 on package travel, package holidays and package tours (OJ L 158, 23.6.1990, p. 59); article 2(b) of the Council Directive 93/13/EEC of 5 April 1993 on unfair terms in consumer contracts (OJ L 95, 21.4.1993, p. 29); and many other community standards expressing the consumer/professional dichotomy [an almost complete list can be found in Romero Melchor, S., *op.cit*.]

[52] According to the literature, the various definitions of consumer included in the references in the preceding footnote (and the list in Romero Melchor, S., *op.cit,*) share similar characteristics. These characteristics can be summarised as any physical person who, acting outside their professional duties, receives goods or services for their use or final consumption for the purpose of satisfying personal or family needs. See in this respect González Vaqué, L., "La noción de consumidor normalmente informado en la jurisprudencia del Tribunal de Justicia de las Comunidades Europeas: la Sentencia *Gut Springenhedie*", *Derecho de los Negocios*, No. 103, 1999, pp. 1-15; Palao Moreno, G., "La protección de los consumidores en el ámbito comunitario europeo" in *Derecho de Consumo*, Tirant lo Blanch, 2002, pp. 39-40; and Tenreiro, M., "Un Code de la consommation ou un Code autour du consommateur? Quelques réflexions critiques sur la codification et la notion du consommateur" en *Law and diffuse Interests in the European Legal Order - Liber amicorum Norbert Reich*, Nomos, 1997, p. 348.

Food Law regulations (see also Regulation (EU) No 609/2013[53] and Regulation (EU) No 2016/127[54]).

A fortiori, advertising health properties when it comes to food products is not forbidden but is strictly limited by Regulation No 1924/2006. However, as noted earlier, the most controversial aspect of the judgment is its claim to satisfy the objectives of said Regulation by not precluding the possibility that health professionals might themselves be misled by false, ambiguous or misleading nutritional and health claims**[55]**. The ruling goes on to conclude that health professionals run the risk of transmitting *in good faith* (!) false information about foods which are the subject of a commercial communication to final consumers with whom they have a relationship, and that the risk is even greater considering that health professionals can exercise a significant influence on patients thanks to the relationship of trust that usually exists between them**[56]**.

Suffice to say that on this point that health professionals have an ethical and professional duty to verify the information they transmit to consumers. Regulation No 1924/2006 was not designed to encroach on the territory, so to speak, of health professionals' standards and ethical obligations.

VIII Conclusions

1. Is it possible to *communicate* scientific information without falling foul of Regulation No 1924/2006?

Although the judgment in question allows economic operators to communicate *objective information* about new scientific advances to health professionals if such communications are of a *non-commercial nature*[57] (expressly including references to illnesses), it does not offer any criteria for use in defining the meaning of "*objective information*", or in which cases industry communications to health professionals are of a "*commercial nature*"[58].

In practice this means that, as regards the concept of *objective information,* it is very important, essential even, that it be:

---

[53] Regulation of the European Parliament and of the Council of 12 June 2013 on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control and repealing Council Directive 92/52/EEC, Commission Directives 96/8/EC, 1999/21/EC, 2006/125/EC and 2006/141/EC, Directive 2009/39/EC of the European Parliament and of the Council and Commission Regulations (EC) No 41/2009 and (EC) No 953/2009 Text with EEA relevance (OJ L 181, 29.6.2013, p. 35).

[54] Commission Delegated Regulation of 25 September 2015 supplementing Regulation (EU) No 609/2013 of the European Parliament and of the Council as regards the specific compositional and information requirements for infant formula and follow-on formula and as regards requirements on information relating to infant and young child feeding (OJ L 25, 2.2.2016, p. 1).

[55] See paragraph 44 of the *Verband Sozialer Wettbewerb eV* judgment.

[56] *Ibidem*, paragraph 45.

[57] *Ibidem*, paragraphs 50-53.

[58] Beyond the strictly limited assumptions mentioned by Regulation No. 1924/2006 (recital 4), i.e. *orientations or the diet advices facilitated by the authorities or organisations of public health, irrelevant* for practical purposes, or *communications and information that is not commercial in the press and scientific publications.*

(i) exclusively directed to health professionals;

(ii) strictly related to professional interests, i.e. provision of health services; and

(iii) of a purely scientific and objective nature (including, for example, terms, expressions or concepts that the average consumer would not understand[59]).

It would therefore be advisable to follow the recommendations made by the directives for publishing in medical journals, as they provide the highest standards.

2. Influence of the content of communications on the consumer

Secondly, and this demand is harder to comply with, communications must not be of a *commercial nature*. Regulation No 1924/2006 appears to be particularly restrictive as regards non-commercial communications. It refers to "directives on diet or instructions issued by public authorities and organisations", or "non commercial communications and information in the press and scientific publications," although this should not be considered as an exhaustive list. It appears to exclude other communications such as those transmitted by internet or specialised publications.

We would also make a point of highlighting that the main criteria used in distinguishing communications which are commercial from those which are not is whether they have a promotional purpose (directly or indirectly). An excessively liberal definition of indirect effects on the consumer will end up considering any form of communication by a food business operator as having the ultimate intention of promoting its products (in this case indirectly by improving its credibility and reputation among health professionals). This further confirms the limited applicability of the case law enshrined in this ruling in terms of any broader application of Regulation No 1924/2006.

[59] Which does not mean the use of professional jargon expressly, but rather the language appropriate to scientific communications.