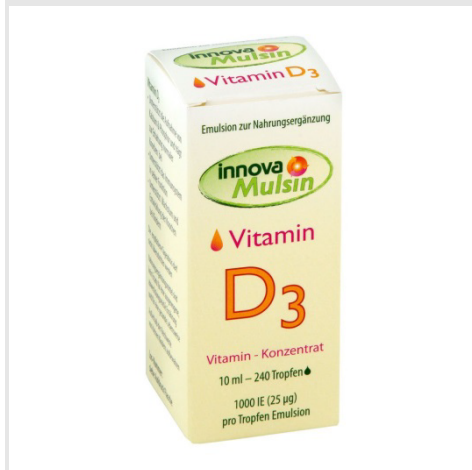


Court of Justice EU, 14 July 2016, Verband Sozialer Wettbewerb v Innova Vital



ADVERTISING LAW

Health claims in food commercials fall within the scope of Regulation 1924/2006, even when the commercial is not aimed at the consumers but at health professionals.

- Food business operators could avoid the obligations of regulation 1924/2006 by addressing the consumer through a health professional.

45. Therefore, those health professionals risk forwarding, in all good faith, incorrect information on foods which are the subject of a commercial communication to final consumers with whom they have a relationship. 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.

46. Furthermore, 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.

Source: curia.europa.eu

Court of Justice EU, 14 July 2016

(L. Bay Larsen, D. Sváby, J. Malenovský, M. Safjan (Rapporteur) and M. Vilaras)

from the Landgericht München

I (Regional Court, Munich I, Germany), made by

decision of 16 December 2014, received at

the Court on 19 January 2015, in the proceedings

Verband Sozialer Wettbewerb eV

v

Innova Vital GmbH,

THE COURT (Third Chamber),

composed of L. Bay Larsen, President of the Chamber, D. Sváby, J. Malenovský, M. Safjan (Rapporteur) and M. Vilaras, Judges,

Advocate General: H. Saugmandsgaard Øe,

Registrar: A. Calot Escobar,

having regard to the written procedure,

after considering the observations submitted on behalf of:

– Innova Vital GmbH, by T. Büttner, Rechtsanwalt,

– the Greek Government, by A. Dimitrakopoulou and K. Karavasili, acting as Agents,

– the French Government, by D. Colas and S. Ghiandoni, acting as Agents,

– the European Commission, by S. Grünheid and K. Herbout-Borczak, acting as Agents,

after hearing [the Opinion of the Advocate General](#) at the sitting on 18 February 2016,

gives the following

Judgment

1 This request for a preliminary ruling concerns the interpretation of 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 (OJ 2006 L 404, p. 9 and corrigendum OJ 2007 L 12, p. 3), as amended by Commission Regulation (EU) No 1047/2012 of 8 November 2012 (OJ 2012 L 310, p. 36) ('Regulation No 1924/2006').

2 The request has been made in proceedings between the Verband Sozialer Wettbewerb eV, a German association safeguarding competition, and Innova Vital GmbH concerning the applicability of Regulation No 1924/2006 to nutrition or health claims made in a written document addressed exclusively to health professionals.

Legal context

EU law

Directives 2000/31/EC and 2006/123/EC

3 Article 2(f) of Directive 2000/31/EC 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 ('Directive on electronic commerce') (OJ 2000 L 178, p. 1), provides that, for the purpose of that directive, the following terms are to bear the following meanings:

"commercial communication": 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. The following do not in themselves constitute commercial communications:

– *information allowing direct access to the activity of the company, organisation or person, in particular a domain name or an electronic-mail address,*

– *communications relating to the goods, services or image of the company, organization or person compiled in an independent manner, particularly when this is without financial consideration.'*

4 Article 4(12) of Directive 2006/123/EC of the European Parliament and of the Council of 12 December 2006 on services in the internal market (OJ 2006 L 376, p. 36), retains a similar definition for the concept of ‘commercial communication’.

Regulation No 1924/2006

5 Under recitals 1, 2, 4, 9, 14, 16 to 18 and 23 of Regulation No 1924/2006:

‘(1) An increasing number of foods labelled and advertised in the Community bear nutrition and health claims. In order to ensure a high level of protection for consumers and to facilitate their choice, products put on the market must be safe and adequately labelled.

(2) Differences between national provisions relating to such claims may impede the free movement of foods and create unequal conditions of competition. They thus have a direct impact on the functioning of the internal market. It is therefore necessary to adopt Community rules on the use of nutrition and health claims on foods.

...

(4) This Regulation should apply to all nutrition and health claims made in commercial communications, including, inter alia, generic advertising of food and promotional campaigns, such as those supported in whole or in part by public authorities. 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. ...

(9) There is a wide range of nutrients and other substances including, but not limited to, vitamins, minerals including trace elements, amino-acids, essential fatty acids, fibre, various plants and herbal extracts with a nutritional or physiological effect that might be present in food and be the subject of a claim. Therefore, general principles applicable to all claims made on foods should be established in order to ensure a high level of consumer protection, give the consumer the necessary information to make choices in full knowledge of the facts, as well as creating equal conditions of competition for the food industry.

...

(14) There is a wide variety of claims currently used in the labelling and advertising of foods in some Member States relating to substances that have not been shown to be beneficial or for which at present there is not sufficient scientific agreement. It is necessary to ensure that the substances for which a claim is made have been shown to have a beneficial nutritional or physiological effect.

...

(16) It is important that claims on foods can be understood by the consumer and it is appropriate to protect all consumers from misleading claims. However, since the enactment of Council Directive 84/450/EEC of 10 September 1984 [relating to the approximation of the laws, regulations and administrative provisions of the Member States concerning misleading advertising (OJ 1984 L 250,

p.17)], the Court of Justice of the European Communities has found it necessary in adjudicating on advertising cases to examine the effect on a notional, typical consumer. In line with the principle of proportionality, and to enable the effective application of the protective measures contained in it, this Regulation takes as a benchmark the average consumer, who is reasonably well informed and reasonably observant and circumspect, taking into account social, cultural and linguistic factors, as interpreted by the Court of Justice, but makes provision to prevent the exploitation of consumers whose characteristics make them particularly vulnerable to misleading claims. Where a claim is specifically aimed at a particular group of consumers, such as children, it is desirable that the impact of the claim be assessed from the perspective of the average member of that group. The average consumer test is not a statistical test. National courts and authorities will have to exercise their own faculty of judgment, having regard to the case-law of the Court of Justice, to determine the typical reaction of the average consumer in a given case.

(17) Scientific substantiation should be the main aspect to be taken into account for the use of nutrition and health claims and the food business operators using claims should justify them. A claim should be scientifically substantiated by taking into account the totality of the available scientific data, and by weighing the evidence.

(18) A nutrition or health claim should not be made if it is inconsistent with generally accepted nutrition and health principles or if it encourages or condones excessive consumption of any food or disparages good dietary practice.

...

(23) Health claims should only be authorised for use in the Community after a scientific assessment of the highest possible standard. In order to ensure assessment of these claims, the European Food Safety Authority should carry out such assessments. ...’

6 Article 1 of Regulation No 1924/2006, entitled ‘Subject matter and scope’, provides, in paragraphs 1 and 2:

‘1. This Regulation harmonises the provisions laid down by law, regulation or administrative action in Member States which relate to nutrition and health claims in order to ensure the effective functioning of the internal market whilst providing a high level of consumer protection.

2. 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. ...’

7 Article 2 of Regulation No 1924/2006, entitled ‘Definitions’, provides:

‘1. For the purposes of this Regulation:

(a) the definitions of “food”, “food business operator”, “placing on the market”, and “final consumer” set out in Articles 2, 3(3), 3(8) and 3(18) of 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 2002 L 31, p.1)] shall apply;

...

2. The following definitions shall also apply:

1. "claim" means 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;

...

4. "nutrition claim" means any claim which states, suggests or implies that a food has particular beneficial nutritional properties due to:

(a) the energy (calorific value) it

(i) provides;

(ii) provides at a reduced or increased rate; or

(iii) does not provide; and/or

(b) the nutrients or other substances it

(i) contains;

(ii) contains in reduced or increased proportions; or

(iii) does not contain;

5. "health claim" means any claim that states, suggests or implies that a relationship exists between a food category, a food or one of its constituents and health;

...

8 Chapter II of that regulation, relating to general principles, includes Articles 3 to 7 thereof.

Under the heading 'General principles for all claims', Article 3 of Regulation No 1924/2006 provides:

'Nutrition and health claims may be used in the labelling, presentation and advertising of foods placed on the market in the Community only if they comply with the provisions of this Regulation.

Without prejudice to Directives 2000/13/EC and 84/450/EEC, the use of nutrition and health claims shall not:

(a) be false, ambiguous or misleading;

...

9 Article 5 of that regulation, entitled 'General conditions', states, in paragraphs 1 and 2:

'1. The use of nutrition and health claims shall only be permitted if the following conditions are fulfilled:

(a) the presence, absence or reduced content in a food or category of food of a nutrient or other substance in respect of which the claim is made has been shown to have a beneficial nutritional or physiological effect, as established by generally accepted scientific evidence;

...

2. The use of nutrition and health claims shall only be permitted if the average consumer can be expected to understand the beneficial effects as expressed in the claim.'

10 Articles 10 to 19 of that regulation concern health claims.

11 Article 10 of that regulation, entitled 'Specific conditions', provides, in paragraph 1:

'Health claims shall be prohibited unless they comply with the general requirements in Chapter II and the specific requirements in this Chapter and are authorised in accordance with this Regulation and included in the lists of authorised claims provided for in Articles 13 and 14.'

German law

12 The first sentence of Paragraph 8(1) of the Gesetz gegen den unlauteren Wettbewerb (Law on unfair competition), in the version applicable to the dispute in the main proceedings (BGBl. 2010 I, p. 254), provides:

'Where a person engages in an unlawful commercial practice under Paragraphs 3 or 7, an action may be brought against that person to eliminate that practice and, where there is a risk of recurrence, for an injunction requiring him to desist.'

The dispute in the main proceedings and the question referred

13 Innova Vital, the director of which is a doctor, marketed a nutritional supplement in Germany known as 'Innova Mulsin® Vitamin D3' which is administered in the form of drops.

14 In November 2013, the director of Innova Vital sent exclusively to named doctors a written document worded as follows ('the document at issue'):

...

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 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 D3 emulsion (Innova Mulsin® D3) which can be administered in the form of drops.

...

Benefits of Mulsin® emulsions:

...

Rapid prevention or elimination of nutritional deficiencies (80% of the population is described as being vitamin D3-deficient in winter)

...

You can find out how to place direct orders and obtain free information material for your surgery by calling ...'

15 The document at issue contained an image of the nutritional supplement Innova Mulsin® Vitamin D3, information on its composition, its selling price and the daily cost of treatment based on the recommended dose of one drop per day.

16 The Verband Sozialer Wettbewerb brought an action before the Landgericht München I (Regional Court, Munich I, Germany) for a prohibitory injunction against Innova Vital, based on Paragraph 8 of the Law on unfair competition, in the version applicable to the dispute in the main proceedings.

17 That association claimed before the referring court that the document at issue contains health claims which are prohibited by Article 10(1) of Regulation No 1924/2006, that is, the following two claims:

‘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’

and

‘Rapid prevention or elimination of nutritional deficiencies (80% of the population is described as being vitamin D3-deficient in winter)’.

18 In that regard, the Verband Sozialer Wettbewerb claimed in particular that the provisions of Regulation No 1924/2006 apply to advertising to professionals as well as to nonprofessionals.

19 In contrast, Innova Vital argues that Regulation No 1924/2006 does not concern advertising to professionals. Consequently, since the document at issue was addressed solely to doctors, the provisions of that regulation do not apply to the health claims prohibited by Article 10(1) of Regulation No 1924/2006 contained in that document.

20 According to the referring court, the resolution of the dispute in the main proceedings depends on the interpretation of Article 1(2) of Regulation No 1924/2006, which concerns the subject matter and scope of that regulation.

21 In those circumstances, the Landgericht München I (Regional Court, Munich I) decided to stay the proceedings and to 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?’

Consideration of the question referred

22 By its question, the referring court asks, in essence, whether Article 1(2) of Regulation No 1924/2006 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, fall within the scope of that regulation.

23 According to the Court’s settled case-law, for the purpose of interpreting a provision of EU law, it is necessary 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 (see, inter alia, judgments of 17 November 1983 in Merck, 292/82, EU:C:1983:335, paragraph 12; 4 May 2010 in TNT Express Nederland, C-533/08, EU:C:2010:243, paragraph 44; and [17 March 2016 in Liffers, C-99/15, EU:C:2016:173, paragraph 14](#)).

24 As regards, in the first place, the wording of Article 1(2) of Regulation No 1924/2006, it should be noted that, under that provision, that regulation applies to nutrition and health claims if, first, those claims are made in commercial communications, whether they appear in the form of labelling foods, presentation or advertising of foods, and that, second, the foods in question are to be delivered as such to the final consumer.

25 That regulation does not contain a definition of the concept of a ‘commercial communication’. However, that concept is defined, in other areas of EU law, by provisions of secondary legislation, which should, in the present case, be used as a guide in order to ensure consistency of EU law.

26 Accordingly, under Article 2(f) of Directive 2000/31, ‘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.

27 Article 4(12) of Directive 2006/123 contains a similar definition of the concept of ‘commercial communication’. 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 (see judgment of 5 April 2011 in Société fiduciaire nationale d’expertise comptable, C-119/09, EU:C:2011:208, paragraph 33).

28 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’.

29 In those circumstances, the concept of a ‘commercial communication’ within the meaning of Article 1(2) of Regulation No 1924/2006, must be understood as covering, inter alia, a communication made in the form of advertising foods, designed to promote, directly or indirectly, those foods.

30 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.

31 Furthermore, it should be noted that Article 1(2) of Regulation No 1924/2006 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. It follows that, as the Advocate General stated in point 39 of his Opinion, it is the product itself, and not the communication of which it is the subject matter, which must necessarily be aimed at consumers.

32 In those circumstances, it must be stated that it follows from the wording of that provision, read in the light of Article 2(f) of Directive 2000/31 and of Article 4(12) of Directive 2006/123, that Regulation No 1924/2006 applies to nutrition or health claims made in a commercial communication addressed exclusively to health professionals.

33 It should be noted, in the second place, that such an interpretation is not invalidated by the analysis of the context of Article 1(2) of Regulation No 1924/2006.

34 Admittedly, as Innova Vital claims, certain recitals and provisions of Regulation No 1924/2006, in particular recitals 1, 9, 16, 29 and 36, and Article 5(2) of that regulation, specifically cover ‘consumers’, without referring to ‘professionals’.

35 However, 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. In such a situation, that communication between the food business operators 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.

36 It should be added that it does not follow from any provision of Regulation No 1924/2006 that it does not apply to commercial communications addressed to health professionals.

37 In the last place, the objectives pursued by that regulation confirm the interpretation that that regulation applies to commercial communications addressed exclusively to health professionals.

38 Indeed, under Article 1(1) of Regulation No 1924/2006, the aim of the regulation is to ensure the effective functioning of the internal market whilst providing a high level of consumer protection.

39 In that regard, as is apparent from recitals 1 and 18 of Regulation No 1924/2006, health protection is among the principal aims of that regulation (judgment of 6 September 2012 in *Deutsches Weintor, C-544/10, EU:C:2012:526, paragraph 45*). Accordingly, it is necessary, in particular, to give the consumer the necessary information to make choices in full knowledge of the facts (judgments of 10 April 2014 in *Ehrmann, C-609/12, EU:C:2014:252, paragraph 40*, and 17 December 2015 in *Neptune Distribution, C-157/14, EU:C:2015:823, paragraph 49*).

40 In support of this, Article 5(1)(a) of Regulation No 1924/2006 provides that the use of nutrition and health claims is to be allowed only if the presence, absence or reduced content in a food or category of food of a nutrient or other substance in respect of which the claim is made has been shown to have a beneficial nutritional or physiological effect, as established by generally accepted scientific evidence. Recital 14 of that regulation also contains a statement to that effect.

41 As stated in recital 17 of that regulation, the scientific substantiation is to be the main aspect to be taken into account for the use of nutrition and health claims. Moreover, recital 23 of the regulation provides that the health claims are 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 is to carry out such assessments.

42 Regulation No 1924/2006 provides for a procedure to determine whether a claim, within the meaning of that regulation, is scientifically substantiated.

43 Admittedly, health professionals may be considered to have scientific knowledge superior to that of a final consumer, understood as an average consumer, who is reasonably well informed and reasonably observant and circumspect, as stated in recital 16 of that regulation. However, those professionals cannot be regarded as being in a position to permanently 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.

44 As stated by the Advocate General in point 49 of his Opinion, 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.

45 Therefore, those health professionals risk forwarding, in all good faith, incorrect information on foods which are the subject of a commercial communication to final consumers with whom they have a relationship. 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.

46 Furthermore, 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.

47 Consequently, 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.

48 The arguments put forward by Innova Vital are not such as to invalidate the interpretation that that regulation applies to nutrition or health claims made in a commercial communication, including if the latter is addressed exclusively to health professionals.

49 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.

50 However, 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.

51 In fact, 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. 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.

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.

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, in the situation where the communication is of a non-commercial nature.

54 Having regard to the foregoing, the answer to the question referred is that Article 1(2) of Regulation No 1924/2006 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.

Costs

55 Since these proceedings are, for the parties to the main proceedings, a step in the action pending before the national court, the decision on costs is a matter for that court. Costs incurred in submitting observations to the Court, other than the costs of those parties, are not recoverable. On those grounds, the Court (Third Chamber) hereby rules:

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.

[Signatures]

* Language of the case: German.

OPINION OF ADVOCATE GENERAL SAUGMANDSGAARD ØE

delivered on 18 February 2016 [1]

Case C-19/15

Verband Sozialer Wettbewerb e.V.

v

Innova Vital GmbH

(Request for a preliminary ruling from the Landgericht München I (Munich Regional Court I, Germany))

(Reference for a preliminary ruling — Consumer protection — Regulation (EC)

No 1924/2006 — Article 1(2) — Scope of application — Nutrition and health claims made on foods to be delivered as such to the final consumer — Claims made in commercial

communications addressed exclusively to the professional sector)

I – Introduction

1. The request for a preliminary ruling from the Landgericht München I (Munich Regional Court I) concerns the interpretation of 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. [2]

2. That request stems from a dispute between an association protecting the commercial interests of its members and an undertaking selling a nutritional supplement, and concerns some statements made in advertising mail sent by the latter exclusively to doctors. The Court is called upon, for the first time, to determine whether the requirements under that regulation are applicable where nutrition and health claims on foods to be delivered as such to consumers are made in commercial communications addressed not directly to consumers but exclusively to professionals.

II – Legal context

3. According to recitals 1, 4, 9, 23 and 29 of Regulation No 1924/2006:

‘(1) An increasing number of foods labelled and advertised in the Community bear nutrition and health claims. In order to ensure a high level of protection for consumers and to facilitate their choice, products put on the market, including imported products, should be safe and adequately labelled. ...

(4) This Regulation should apply to all nutrition and health claims made in commercial communications, including, inter alia, generic advertising of food and promotional campaigns, such as those supported in whole or in part by public authorities. 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 noncommercial communications and information in the press and in scientific publications. ...

*...
(9) There is a wide range of nutrients and other substances ... with a nutritional or physiological effect that might be present in a food and be the subject of a claim. Therefore, general principles applicable to all claims made on foods should be established in order to ensure a high level of consumer protection, give the consumer the necessary information to make choices in full knowledge of the facts, as well as creating equal conditions of competition for the food industry.*

*...
(16) It is important that claims on foods can be understood by the consumer and it is appropriate to protect all consumers from misleading claims. ...*

*...
(23) Health claims should only be authorised for use in the Community after a scientific assessment of the highest possible standard. In order to ensure harmonised scientific assessment of these claims, the European Food Safety Authority should carry out such assessments. ...*

*...
(29) In order to ensure that health claims are truthful, clear, reliable and useful to the consumer in choosing a healthy diet, the wording and the presentation of health claims should be taken into account in the opinion of the European Food Safety Authority and in subsequent procedures.'*

4. Article 1(1) and (2) of that regulation provides:

'1. This Regulation harmonises the provisions laid down by law, regulation or administrative action in Member States which relate to nutrition and health claims in order to ensure the effective functioning of the internal market whilst providing a high level of consumer protection.

2. 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. ...'

5. Article 2(1)(a) of Regulation No 1924/2006 refers, for the purposes of the application of that regulation, to the definitions of the concepts of 'food' and 'final consumer' set out in Article 2 and Article 3(18) of Regulation (EC) No 178/2002. (3) Article 2(2), subparagraphs 1, 4 and 5, of Regulation No 1924/2006 defines what is meant by 'claim', 'nutrition claim' and 'health claim' within the meaning of Regulation No 1924/2006.

6. Chapter II, which contains Articles 3 to 7 of Regulation No 1924/2006, lays down the general principles for the use of nutrition and health claims.

7. Article 3, entitled 'General principles for all claims', provides that 'nutrition and health claims may be used in the labelling, presentation and advertising of foods placed on the market in the Community only if they comply with the provisions of this Regulation'. It also

provides that 'without prejudice to Directives 2000/13/EC [(4)] and 84/450/EEC, [(5)] the use of nutrition and health claims shall not [in particular] be false, ambiguous or misleading'.

8. According to Article 5(1) and (2), entitled 'General conditions', the use of nutrition and health claims is to be permitted only if the conditions laid down in that article are fulfilled and 'if the average consumer can be expected to understand the beneficial effects as expressed in the claim'.

9. Chapter III of Regulation No 1924/2006, which contains Articles 8 and 9, sets out the conditions for the use of nutrition claims.

10. Chapter IV of that regulation, which contains Articles 10 to 19, contains specific provisions applicable to health claims.

11. Under Article 10(1) and (2), entitled 'Specific conditions':

'1. Health claims shall be prohibited unless they comply with the general requirements in Chapter II and the specific requirements in this Chapter and are authorised in accordance with this Regulation and included in the lists of authorised claims provided for in Articles 13 and 14.

2. Health claims shall only be permitted if the ... information [set out in this paragraph] is included in the labelling, or ... if no such labelling exists, in the presentation and advertising.'

12. Under Article 13, the health claims identified therein may be used 'without undergoing the [authorisation] procedures laid down in Articles 15 to 19' if they are indicated 'in the list provided for in paragraph 3' of that article, if they 'based on generally accepted scientific evidence' and if they are 'well understood by the average consumer'.

13. Under Article 14, 'reduction of disease risk claims' and 'claims referring to children's development and health' may be used 'where they have been authorised in accordance with the procedure laid down in Articles 15, 16, 17 and 19' of that regulation.

III – The dispute in the main proceedings, the question referred for a preliminary ruling and the procedure before the Court

14. Verband Sozialer Wettbewerb e.V. ('Verband Sozialer Wettbewerb') is a registered association, one of the statutory duties of which is to protect the commercial interests of its members, and in particular to ensure compliance with the rules of fair competition.

15. Innova Vital GmbH ('Innova Vital'), a German undertaking the director of which is a doctor, markets an emulsion containing vitamin D which is administered in the form of drops and is called 'Innova Multin® Vitamin D3'.

16. In November 2013, the director of Innova Vital sent a written communication exclusively to named doctors stating that that nutritional supplement helped to prevent diseases caused by vitamin D deficiency. It was worded as follows:

'You are aware of the situation: 87% of children in Germany have blood vitamin D levels below 30 ng/ml. According to the German Food Association (Deutsche

Gesellschaft für Ernährung, DGE), 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.

[...]

As a doctor specialising in immunology, I considered this issue and developed a vitamin D3 emulsion (Innova Mulsin® D3) which can be administered in the form of drops.

[...]

Benefits of Mulsin® emulsions:

[...]

– Rapid prevention or elimination of nutritional deficiencies (80% of the population is described as being vitamin D3-deficient in winter)

[...]

You can find out how to place direct orders and obtain free information material for your surgery by calling ...' (6)

17. That written communication also contained images of the product in question, information on its composition, its selling price and the daily cost of treatment based on the recommended dose of one drop per day or as advised by a doctor. It stated that *'with a selling price of EUR 26.75, your patients are investing EUR 0.11 per day for balanced vitamin D3 supplement'*.

18. Verband Sozialer Wettbewerb brought before the referring court an action for a prohibitory injunction against Innova Vital pursuant to the German Law on Unfair Competition (Gesetz gegen den unlauteren Wettbewerb). (7) That action was based on an infringement of Regulation No 1924/2006, with particular emphasis on two of the abovementioned statements. (8)

19. In support of its action, Verband Sozialer Wettbewerb submits that the provisions of Regulation No 1924/2006 are applicable both to advertising addressed to professionals and advertising addressed to non-professionals. Principally, it argues that health claims are prohibited under Article 10(1) of that regulation unless they have been authorised in accordance with the regulation and are included in the list of authorised claims provided for in Article 13 thereof, which is not the case as regards the claims at issue. It adds that, given the composition and efficacy of the nutritional supplement in question, it does not fulfil the general conditions provided for in Article 5(1) of that regulation. In the alternative, it alleges an infringement of Article 10(2) of that regulation on the ground that the advertisement at issue does not include the information which is mandatory under that provision.

20. Innova Vital claims, on the contrary, that Articles 5 and 10 of Regulation No 1924/2006 are not applicable to the statements made in the communication at issue,

since it was addressed exclusively to doctors, and that that regulation cannot be applied to advertisements directed at professionals.

21. In that context, by decision of 16 December 2014, lodged at the Court on 19 January 2015, the Landgericht München I (Munich Regional Court I) decided to stay the proceedings and to refer the following question to the Court for a preliminary ruling:

'Must Article 1(2) of Regulation 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?'

22. Written observations were submitted by Innova Vital, the Greek and French Governments and the European Commission. No hearing has been held.

IV – Analysis

A – Preliminary considerations

23. In view of the written observations submitted to the Court, it seems that a number of questions in relation to the material scope of Regulation No 1924/2006, should be examined first of all, that is to say, before the question referred for a preliminary ruling can be answered.

24. I note from the outset that, according to the referring court, it has been established that, under the conditions for application set out in Article 1(2) of that regulation, first, the product referred to in the written communication at issue in the main proceedings constitutes a food to be delivered as such to the final consumer and, secondly, the communication from Innova Vital was intended as advertising for that food.

1. The assessment of the disputed statements in the light of Regulation No 1924/2006

25. It is clear from the order for reference that the applicant in the main proceedings claimed that the written communication forming the subject matter of its action contained 'health claims' prohibited under Regulation No 1924/2006. The Landgericht München I (Munich Regional Court I) does not challenge that assessment, although the question it has referred for a preliminary ruling relates, without distinction, both to the 'nutrition' claims and to the 'health' claims covered by that regulation.

26. The French Government is unsure whether that assumption is correct. It takes the view that the disputed statements do not constitute nutrition claims or health claims as defined in Article 2(2) of Regulation No 1924/2006 and, therefore, do not fall within the scope of application of that regulation. Instead, those statements fall within the category of food information which attributes to those foods properties of preventing, treating or curing a human disease, the use of which is, in principle, prohibited under Article 7 of Regulation No 1169/2011/EU. (9) However, it considers that the Court is required to answer the question raised (10) on the ground that Regulation No 1924/2006 in this case is not manifestly

inapplicable as its inapplicability is conditional on the legal characterisation of the disputed statements.

27. It is settled case-law that it is for the national court alone to assess and characterize the facts giving rise to the dispute in the main proceedings and to apply the relevant provisions of EU law as interpreted by the Court.⁽¹¹⁾ That rule has already been

implemented by the Court in relation, in particular, to the provisions of Regulation No 1924/2006. ⁽¹²⁾ I would nevertheless point out that, like the Commission, I take the view that the present question referred for a preliminary ruling is not a hypothetical one since, in the light of the abovementioned facts in the proceedings, the disputed statements do seem to be covered by the concept of ‘health claims’ within the meaning of that regulation, as interpreted in the Court judgments concerning that concept. ⁽¹³⁾

2. The relationship between Regulation No 1924/2006 and Directive 2000/13

28. The Commission considers that the question should be raised whether, in a situation such as that in the main proceedings, the use of the disputed statements is already prohibited by Article 2(1)(b) read in conjunction with Article 2(3) of Directive 2000/13, which lays down the general principle that food information, particularly in advertisements, must not attribute to food the property of preventing a human disease. ⁽¹⁴⁾

29. The same line is taken, in essence, by the French Government, which submits that statements of that nature are covered by the provisions of Article 7(3) and (4) of Regulation No 1169/2011, which are equivalent to the abovementioned provisions of Directive 2000/13. Given that that regulation repealed Directive 2000/13 with effect from 13 December 2014, ⁽¹⁵⁾ therefore after the facts giving rise to the dispute in the main proceedings, ⁽¹⁶⁾ it is, however, not applicable *ratione temporis* to the present case.

30. It should be noted that Directive 2000/13, which relates in particular to food advertising, applies in parallel with, rather than to the detriment of, Regulation No 1924/2006. According to recital 3 of that regulation, its aim is to complement the general principles in Directive 2000/13 ⁽¹⁷⁾ and lay down specific provisions concerning the use of nutrition and health claims concerning food to be delivered as such to the consumer. The second paragraph of Article 3 of Regulation No 1924/2006 maintains the application of Directive 2000/13 as a general rule, subject to the exceptions provided for in that regulation. In particular, Article 14(1) of Regulation No 1924/2006 expressly allows derogation from Article 2(1)(b) of that directive for the use of two specific types of health claims, namely, those relating to reduction of disease risk and those referring to children’s development and health, provided that those claims have been authorised in accordance with the strict conditions set out by that regulation.

31. As the Commission itself observes, the fact that Directive 2000/13 may cover a dispute such as that in the main proceedings is by no means incompatible with

the examination of the present request for a preliminary ruling, as Regulation No 1924/2006 accordingly operates as a supplement rather than an alternative to that directive. Moreover, the implementation of the provisions of that regulation in the dispute in the main proceedings is clearly contemplated by the referring court, which alone is in a position to assess whether the question it is raising is appropriate and necessary for the purpose of determining the case before it. ^[18]

B – The applicability of Regulation No 1924/2006 in respect of commercial

communications sent exclusively to professionals

32. The question raised in the present case concerns whether or not Regulation No 1924/2006 applies to nutrition and health claims made in commercial communications on foods for sale to final consumers if such communications are addressed not to those consumers but exclusively to professionals, who are, in this case, health professionals.

The Court has never before received a request for interpretation of this nature, but the practical implications are nonetheless considerable. ⁽²⁰⁾

33. The parties in the main proceedings have adopted opposing views as regards the applicability of that regulation in such circumstances. The referring court states that the question raised is also answered in different ways in German-language legal literature, setting out in detail the terms of that academic debate.

34. According to the observations submitted to the Court, only Innova Vital claims that commercial communications sent exclusively to professionals are not governed by the provisions of Regulation No 1924/2006. By contrast, both the Greek and French Governments and the Commission submit that the scope of that regulation does cover such a case. I share that view.

35. Various considerations, arising not only from a literal interpretation but also a teleological and contextual interpretation, support my recommendation that the question referred for a preliminary ruling be answered in the affirmative.

1. The wording of the relevant provisions of Regulation No 1924/2006

36. Innova Vital relies on recitals 1, 8 to 10, 15 and 28 and Article 5(2) of Regulation No 1924/2006 in support of its claim that that instrument does not apply to advertisements addressed to a professional public, since those provisions focus on consumers and make no reference whatsoever to professionals.

37. It is true that that regulation contains numerous references to consumers, and, in particular, the perception of nutrition and health claims which the ‘average consumer’ is likely to have is used as a point of reference several times in that regulation. ⁽²¹⁾

38. Nevertheless, in view of the wording of Article 1(2) and of all the other provisions of Regulation No 1924/2006, it cannot, in my view, be ruled out that that regulation may govern both commercial communications addressed directly to consumers and communications which, although addressed exclusively to professionals, are in fact intended to be targeted

indirectly at the consumers who may purchase the food concerned.

39. The legislature has made no distinction based on the capacity of the addressee of communications containing the nutrition and health claims covered by that regulation. 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)

40. The criterion that communications must be of a commercial nature is, in my view and that of the Greek Government and the Commission, a major factor in answering the question raised in the present case. (25) In that regard, recital 4 of that regulation makes a clear distinction between commercial communications, to which that instrument is applicable, and non-commercial communications, which it does not cover, stating that the former serve ‘advertising’ or ‘promotional’ purposes. (26)

41. Although that criterion is not expressly defined in Regulation No 1924/2006, it is clear from other acts of EU law, as stated by the Commission, that commercial communication generally refers to a communication which has the aim of ensuring the economic promotion of products and services, either ‘directly’ (27) or ‘indirectly’, (28) and thereby influencing the decisions of potential buyers. I note that a similar approach was taken, at international level, in the ‘Guidelines for use of nutrition and health claims’, adopted by the Codex Alimentarius, (29) to which recital 7 of that regulation expressly refers. (30)

42. According to the wording of Regulation No 1924/2006, its scope of application is not limited to communications addressed directly to final consumers, since the commercial nature of such communications does not necessarily depend on that being the case. In circumstances such as those under consideration by the referring court, even if the consumers themselves do not receive the communication containing claims covered by that regulation, they are in fact the persons at whom that commercial communication is indirectly aimed, given that the food which is the subject of that communication is theoretically intended to be sold to those consumers, and not to the professionals who have received the advertising mail. (31) In such a case, the latter are mere intermediaries who are contacted by a food business precisely because they are capable of promoting the product that it is selling by passing on the commercial information concerning that product to potential buyers, and even recommending that they purchase the product.

43. Professionals are generally in a position to significantly influence the consumers who go to them, and this is particularly so in the case of health

professionals, who command a high degree of trust and confidence among patients. The very purpose of advertising mail such as that at issue in the main proceedings is for the doctors who have received it to advise their patients to consume the product concerned. However, it is not guaranteed that, before potentially taking on that promotional role, all the professionals contacted will be fully in a position to test the claims made in that commercial communication and will know how to distance themselves from them if necessary. (32)

44. In my opinion, for the purposes of applying Regulation No 1924/2006, it is irrelevant whether professionals pass the document they have received onto consumers as it is or they pass on only the substance of that document, the main point being, in my view, that the nutrition and health claims made in that document, which fall within the scope of that regulation, may be communicated to the final consumers, even indirectly, as in the present case. (33)

2. The objectives of Regulation No 1924/2006

45. The interpretation of the wording of the relevant provisions of Regulation No 1924/2006 which I propose the Court should adopt is supported by the objectives of that regulation.

46. It is established that that regulation has the dual objective of ‘ensur[ing] the effective functioning of the internal market’, by, inter alia, ‘creating equal conditions of competition’ for product promotion and providing ‘a high level of consumer protection’, (34) primarily by enabling consumers to make informed dietary choices thanks to objective information and based on evidence. (35)

47. To that end, it permits the use of nutrition and health claims in commercial communications, as that information can be useful to consumers provided that it is clear and truthful, (36) but it places strict limits on that use. As regards, in particular, health claims, their use is subject to specific restrictions and that regulation allows the use of those claims only after an independent and harmonised scientific assessment carried out by the European Food Safety Authority (EFSA), and after the Commission has granted a Community authorisation. (37)

48. Such objectives and principles require an interpretation of the scope of application of Regulation No 1924/2006 broad enough to ensure that the fulfilment of those objectives and observance of those principles are not compromised, in accordance with the approach that the Court has taken to date in respect of food industry operators attempting to limit the material scope of that regulation. (38) In the present case, unless the consumers are expressly designated as the only potential addressees, that regulation should, in my view, be considered as also being applicable to a commercial communication, such as that at issue in the main proceedings, addressed exclusively to professionals, which satisfies the other conditions set out in that instrument.

49. It is true that professionals are, in principle, (39) more circumspect and better informed than the average

consumer. However, in practice, both the filtering of information they may carry out and the safeguard they may thus create for consumers have limitations, since it cannot be ruled out that they themselves may be misled by claims which are false, deceptive, or even mendacious. As the Greek Government states, it is, in practical terms, impossible for them to have at their disposal at all times all the up-to-date expertise necessary to evaluate all foods and any kind of claim made in relation thereto.

50. Like the French Government, I consider that, if it were accepted that nutrition and health claims are not covered by the provisions of Regulation No 1924/2006 if they appear in commercial communications addressed to professionals, this could, paradoxically, have even more serious and harmful implications for consumers than if advertisements were addressed directly to consumers. Consumers will generally trust the opinion of professionals who recommend the product in question to them in good faith, and they may even act with a lesser degree of reflection and hesitation than they would when they, as laypersons, have to make their own assessment. In the circumstances described in the question referred for a preliminary ruling, the need to protect consumers from false claims is equal to, if not even greater than, when consumers receive the advertisement themselves and make their dietary choices alone.

51. Moreover, excluding that type of communication from the scope of application of the regulation would deprive it of part of its practical effect, particularly in so far as the absence of a prior assessment by the EFSA would enable the use of health claims which are not based on scientific evidence. In practice, for food businesses, the possibility of circulating their claims among consumers through professionals could constitute an easy means of circumventing the strict requirements of Regulation No 1924/2006. In any event, as a consequence of such an interpretation, the proper functioning of the internal market may be impaired and the level of consumer protection may be reduced, despite the fact that these are objectives pursued by that regulation.

52. The teleological interpretation which I recommend cannot, in my opinion, legitimately be called into question by Innova Vital's arguments against that approach which, according to the statements made in its observations and in the order for reference, are based on the views of some German legal writers.

53. First, Innova Vital argues that the binding scheme provided for in Regulation No 1924/2006 is ill-suited to the knowledge possessed by professionals, who are experts. It states, in essence, that if commercial communications addressed to professionals fell within the scope of application of that regulation, the use of technical or scientific terminology in nutrition or health claims would be prohibited under Article 5(2), (40) since such terms would be unlikely to be understood by the 'average consumer', whereas they would be known to the specialists to whom the advertisement was addressed.

54. However, that argument is ineffective in my view since, in circumstances such as those forming the subject matter of the dispute in the main proceedings, advertising mail is intended not to be submitted as such to the consumer, but to be sent to professionals who are implicitly invited to explain to the consumer in what respects the product in question is beneficial to him. (41) The sound understanding of claims made in commercial communications, as required under Article 5(2), is achieved in this case through professionals, who are responsible for transmitting the information, having rephrased it if necessary, to non-professionals.

55. Secondly, according to Innova Vital, the rules provided for in Regulation No 1924/2006 have a negative impact on communications between professionals, given that professionals' expectations are different to those of consumers, particularly as regards objective information on new scientific developments. (42)

56. It is indeed the case that, if the Court were to accept that the provisions of Regulation No 1924/2006 apply in circumstances such as those of the dispute in the main proceedings, communications between professionals may be affected or even restricted. However, in order for the system which places restrictions on the use of nutrition and health claims, provided for in that regulation, to be applicable, the purpose of the communications in question must, in principle, be not to provide purely technical information, but to circulate 'commercial' information, in accordance with the first subparagraph of Article 1(2). I would recall that recital 4 of that regulation also explicitly precludes the application of the regulation to '*non-commercial ... information ... in scientific publications*'. In the context of commercial canvassing, and therefore of non-neutral information, it seems natural that the legitimate aim of protecting consumers from false claims should outweigh the desire to allow the transmission of information between professionals.

57. Therefore, I am of the opinion that Article 1(2) of Regulation No 1924/2006 must be interpreted as meaning that that regulation is applicable where nutrition or health claims are made in commercial communications which, although addressed exclusively to professionals are in practice aimed indirectly at final consumers to whom the foods in relation to which those claims are made will, theoretically, be delivered as such.

V – Conclusion

58. In view of the foregoing considerations, I propose that the Court answer the question referred for a preliminary ruling by the Landgericht München I (Munich Regional Court I) as follows:

'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.'

1 – Original language: French.

2 – OJ 2006 L 404, p. 9. That regulation has been the subject of a corrigendum (OJ 2007 L 12, p. 3) and was last amended by Commission Regulation (EU) No 1047/2012 of 8 November 2012 with regard to the list of nutrition claims (OJ 2012 L 310, p. 36).

3 – 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 2002 L 31, p. 1).

4 – 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 the labelling, presentation and advertising of foodstuffs (OJ 2000 L 109, p. 29)

5 – Council Directive of 10 September 1984 relating to the approximation of the laws, regulations and administrative provisions of the Member States concerning misleading advertising (OJ 1984 L 250, p. 17).

6 – The words in bold typeface also appeared in bold in the original written communication.

7 – In accordance with the first sentence of Article 8(1) of that law, in the version applicable to the dispute in the main proceedings, an action for a prohibitory injunction may be brought against any person who engages in an unlawful commercial practice under Articles 3 and 7 of that law.

8 – Namely, first: *'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'*; and secondly:

'rapid prevention or elimination of nutritional deficiencies (80% of the population is described as being vitamin D3-deficient in winter)'.

9 – Regulation of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, amending Regulations No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004 (OJ 2011 L 304, p. 18).

10 – To that effect, the French Government cites, inter alia, judgments in *Woningstichting Sint Servatius* (C-567/07, EU:C:2009:593, paragraph 43) and *Dresser-Rand* (C-606/12 and C-607/12, EU:C:2014:125, paragraph 34).

11 – See, inter alia, judgments in *Jestel* (C-454/10, EU:C:2011:752, paragraph 21); *Asociația Accept* (C-81/12, EU:C:2013:275, paragraph 41 et seq.); and *Grupo Itevelesa and Others* (C-168/14, EU:C:2015:685, paragraph 77).

12 – See judgment in *Ehrmann* (C-609/12, EU:C:2014:252, paragraph 36).

13 – See judgments in *Deutsches Weintor* (C-544/10, EU:C:2012:526, paragraph 34 et seq.) and *Green — Swan Pharmaceuticals CR* (C-299/12, EU:C:2013:501, paragraph 22 et seq.), although, in the latter case, the claims at issue in the main proceedings were made, as in this case, in relation to a nutritional supplement containing vitamin D3.

14 – In that regard, the Commission refers to the judgment of the General Court in *Hagenmeyer and Hahn v Commission* (T-17/12, EU:T:2014:234, paragraph 76).

15 – See Article 53(1) of Regulation No 1169/2011.

16 – I note that the written communication in dispute was sent in November 2013.

17 – Recital 3 states that Directive 2000/13 'generally prohibits the use of information that would mislead the purchaser or attribute medicinal properties to food'.

18 – See, inter alia, judgments in *Syndesmos Melon tis Eleftheras Evangelikis Ekklesias and Others* (C-381/89, EU:C:1992:142, paragraphs 18 and 19) and *Križan and Others* (C-416/10, EU:C:2013:8, paragraph 66).

19 – In the light of the general wording of the question and the grounds for raising it, I note that the scope of the question referred by the national court is not limited to health professionals alone, but seems to cover all professionals as opposed to final consumers, who fall into the category of non-professionals.

20 – There is strong pressure from food business operators with regard to the use of nutrition and health claims without constraint, since such claims constitute a very lucrative marketing tool (see Lucas-Puget, A.-S., 'Les allégations sur les produits alimentaires de consommation courante: quelques questions d'actualité', *Petites affiches*, No 103, 24 May 2006, p. 4 et seq.).

21 – See recital 16 and Article 5(2) and Article 13(1) in fine of Regulation No 1924/2006. See, also, paragraph 17 of the explanatory memorandum and recital 10 and Article 2(8), Article 5(2), Article 9(1) and Article 12(1) of Proposal COM(2003) 424 final. The Court has established various assessment criteria relating to the 'average consumer', inter alia, in the judgment in *Green — Swan Pharmaceuticals CR* (C-299/12, EU:C:2013:501, paragraph 24 et seq.).

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 recital 4 and the first subparagraph of Article 1(2) of Regulation No 1924/2006. I note that that

requirement was not set out in Proposal COM(2003) 424 final. See amendments 2 and 16 proposed in the Report of the European Parliament on that proposal dated 12 May 2005 (A6- 0128/2005, p. 6 and 13) and recital 4 and Article 1(2) of the Common Position adopted by the Council of 8 December 2005 (OJ 2006 C 80E, p. 43).

24 – See, also, 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’.

25 – The Commission even considers that ‘by its question, the referring court is requesting, in essence, an interpretation of the concept of “commercial communication”, which is not defined in the regulation, ... as regards the potential addressees of that communication’.

26 – Recital 4 sets out a non-exhaustive list of commercial communications which includes ‘generic advertising of food and promotional campaigns, such as those supported in whole or in part by public authorities’ (my emphasis) and of non-commercial communications which includes ‘dietary guidelines or advice issued by public health authorities and bodies, or non-commercial communications and information in the press and in scientific publications’.

27 – In that regard, the Commission refers to the definition of ‘commercial practices’ in Article 2(d) of Directive 2005/29/EC the European Parliament and of the Council of 11 May 2005 concerning unfair business-to-consumer commercial practices in the internal market (OJ 2005 L 149, p. 22).

28 – The Commission refers, here, to the concept of ‘commercial communication’ as defined in Article 2(f) of Directive 2000/31/EC 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 2000 L 178, p. 1) and Article 4(12) of Directive 2006/123/EC of the European Parliament and of the Council of 12 December 2006 on services in the internal market (OJ 2006 L 376, p. 36). As regards the wording of the latter provision, see the judgment in *Société fiduciaire nationale d’expertise comptable* (C-119/09, EU:C:2011:208, paragraph 29 et seq.).

29 – In the Guidelines adopted by the Codex Alimentarius — a joint body of the Food and Agriculture Organisation of the United Nations (FAO) and the World Health Organisation (WHO) — in 1997, as revised in 2004 and most recently amended in 2008 (CAC/GL 23-1997), it is stated that those directives relate to the use of those claims in ‘advertising’, defined as ‘any commercial communication to the public, by any means other than labelling, in order to promote directly or indirectly, the sale or intake of a food through the use of nutrition and health claims in

relation to the food and its ingredients’ (see paragraph 1.1 and footnote 1).

30 – See, also, paragraphs 10, 11 and 22 of the explanatory memorandum of Proposal COM (2003) 424 final.

31 – Admittedly, a professional to whom the advertisement is addressed may conceivably decide to consume the food in question himself, but that is not the issue raised in the present proceedings, since, in those circumstances, the commercial communication happens to have been received directly by the final consumer, and there can be little doubt regarding the applicability of Regulation No 1924/2006. Moreover, according to the assessment made by the referring court, in the dispute in the main proceedings, the written communication was sent exclusively to doctors in their capacity as professionals, and not as potential consumers.

32 – As rightly stated by some German legal writers, whose view is summarised as follows in the order for reference, ‘in short, if companies target professionals — namely, inter alia, doctors, pharmacists or nutritionists — it is because of the anticipated multiplier effect and therefore, ultimately, the expected significant increase in sales. The professionals in question are generally information intermediaries who, on the basis of their specialist knowledge — which is undoubtedly also subject to the influence of advertising — recommend certain products’ (my emphasis).

33 – For its part, the Commission proposes that the question be answered to the effect that a communication may be considered to be of a commercial nature for the purpose of Regulation No 1924/2006, even if it is addressed exclusively to professionals, ‘if [it] is aimed at and capable of having an external effect, not just on those professionals but on third parties, that could influence the decision of the final consumer in his choice of foods[, which] the national court must determine’. According to the Commission, such an external effect may be identified based on whether, inter alia, the doctor to whom the communication is addressed is used ‘as a multiplier for advertising measures, for example, by enclosing with the communication information to distribute among patients, copies of the communication addressed to the doctor or pamphlets’.

34 – See recitals 1, 2, 9 and 36 and Article 1(1) of Regulation No 1924/2006. See, also, paragraphs 2, 6, 12 and 33 of the explanatory memorandum of Proposal COM(2003) 424 final.

35 – See recitals 1, 9, 10, 11 and 29 of Regulation No 1924/2006; paragraphs 8, 28 and 33 of the explanatory memorandum of Proposal COM(2003) 424 final and points 1.2 and 1.3 of the Opinion of the European Economic and Social Committee on that proposal (OJ 2004 C 110, p. 18). See, also, judgment in *Neptune Distribution* (C-157/14, EU:C:2015:823, paragraphs 49 and 72).

36 – See paragraphs 6, 8, 9 and 16 of the explanatory memorandum of Proposal COM(2003) 424 final.

37 – See recitals 23, 26 and 29 and Article 10 et seq. of Regulation No 1924/2006. See, also, paragraphs 1 and 29 of the explanatory memorandum of Proposal COM(2003) 424 final.

38 – To that effect, see, inter alia, the case-law cited in footnote 13 of the present Opinion, and Nihoul, P., and Van Nieuwenhuyze, E., ‘Allégations nutritionnelles et de santé: quelques stratégies juridiques utilisées par les entreprises pour échapper à la réglementation’, European Journal of Consumer Law, No 1, Larcier, 2014, pp. 65 to 80.

39 – Even though they form part of a diverse group, within which there are varying levels of expertise.

40 – The legal literature which Innova Vital cites in its observations also makes reference, to that effect, to Article 13(1)(ii) of Regulation No 1924/2006, although that article concerns only ‘health claims other than those referring to the reduction of disease risk and to children's development and health’ (my emphasis).

41 – It can be observed that, in this case, the written communication sent by Innova Vital provides doctors with a proposition they can put to their patients, emphasising that, according to Innova Vital, the nutritional supplement it is marketing offers health benefits and is not costly.

42 – The order for reference states that some German legal writers also argue that ‘*[the] growing importance of health-related aspects of nutrition has led to an increased demand for information and exchange on the part of the professional sector*’.