



Reports of Cases

JUDGMENT OF THE COURT (Third Chamber)

14 July 2016*

(Reference for a preliminary ruling — Consumer protection — Regulation (EC) No 1924/2006 — Nutrition and health claims made on foods — Article 1(2) — Scope — Foods to be delivered as such to the final consumer — Claims made in a commercial communication addressed exclusively to health professionals)

In Case C-19/15,

REQUEST for a preliminary ruling under Article 267 TFEU 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. Šváby, 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-Borcza, acting as Agents,

after hearing the Opinion of the Advocate General at the sitting on 18 February 2016,

gives the following

* Language of the case: German.

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, organisation 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 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.

...

- (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 harmonised scientific 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 non-professionals.
- 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]