The Nutrition and Health Claims Regulation Applies to Commercial Communications Addressed to Health Professionals

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Case C-19/15 Verband Sozialer Wettbewerb eV v Innova Vital GmbH (ECJ, 14 July 2016)

*On 14 July 2016, the Court of Justice delivered its judgment on a request for a preliminary ruling concerning the interpretation of Article 1(2) of Regulation (EC) No 1924/2006 on nutrition and health claims made on foods. The Court ruled for the first time that the Regulation applies to nutrition and health claims made in commercial communications exclusively addressed to health professionals. This represents a major breakthrough as – in a climate of uncertainty – the established industry practice was to interpret Article 1(2) in the sense that the Regulation only applied to commercial communications addressed to final consumers. From now on, food business operators will need to take further precautionary steps to ensure that any information they communicate to health professionals either qualifies as non-commercial or complies with the Regulation. The following case note analyses the content of the judgment and its main implications (authors' summary).****

I. Legal Context

Regulation (EC) No 1924/2006 on nutrition and health claims made on foods (NHCR)[1] establishes the legal framework for food business operators wishing to emphasise beneficial nutritional or health properties of their food products. In particular, the NHCR regulates the use of voluntary messages that state, suggest or imply that (i) a food has particular beneficial nutritional properties (nutrition claims – such as "source of fibre") or that (ii) a relationship exists between a food category, a food or one of its constituents and health (health claims – such as "iron contributes to the reduction of tiredness and fatigue") when such claims are made in commercial communications.

The NHCR sets specific conditions for the use of nutrition and health claims in relation to food products. The main requirement is that those claims be substantiated by scientific evidence in order to protect consumers from misleading or false information and to ensure fair competition. Moreover, claims must be worded in such a way that consumers can understand the beneficial effects of the food covered by the claims. Further to an authorisation by the European Commission, which is based *inter alia* on a scientific opinion by the European Food Safety Authority (EFSA), approved claims are listed in a public EU Register. As a general rule, food business operators may only make nutrition or health claims on food where the claims (i) comply with the requirements set in the NHCR, and (ii) are included in the EU Register.

Article 1(2) NHCR, defining the scope of the Regulation, states that the Regulation applies 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. [...]*"

II. Facts

1. Underlying National Dispute

The underlying proceedings stem from a dispute between Verband Sozialer Wettbewerb eV, an industry

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*** 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 L 404, 30.12.2006, p. 9-25, and corrigendum OJ L 12, 18.1.2007, p. 3-18), last amended by Commission Regulation (EU) No 1047/2012 of 8 November 2012 (OJ L 310, 9.11.2012, p. 36-37).

1 Supra note ***.

association (the Association), and Innova Vital GmbH, a manufacturer of food supplements (Innova), before the Landgericht München I in Germany (Regional Court). Innova markets a food supplement containing Vitamin D (Innova Mulsin® Vitamin D3), which is administered in the form of drops.

The dispute concerns the applicability of the NHCR to certain statements made in written communication that Innova sent exclusively to doctors (Document). The Document contained general disease awareness information associated with Vitamin D deficiency in children, as well as information on the alleged beneficial properties of Innova's product. The statements were not included in the EU Register as approved claims. Such statements included the following:

– "*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
– *"Benefits of Muslin® emulsions: ... Rapid prevention or elimination of nutritional deficiencies (80% of the population is described as being vitamin D_3-deficient in winter)".* [2]

The Document also contained an image of the food supplement, as well as information on its composition, selling price and estimated daily cost of treatment.

The Association brought an action before the Regional Court for a "prohibitory injunction" against Innova pursuant to the German Law on unfair competition. The action was based on the allegation that the Document included unpermitted health claims under the NHCR. In defence, Innova argued that the NHCR does not concern advertising directed at professionals and thus did not apply to the health claims that were included in the Document. The Association claimed that the NHCR applies to both advertising to consumers and advertising to professionals. Therefore, claims addressed to professionals must be authorised under the NHCR. Whether the statements actually represented (unpermitted) health claims was not subject to dispute.

2. Reference to the Court of Justice

The Regional Court stayed proceedings and referred a question to the Court of Justice (CJ) for a preliminary ruling on the interpretation of Article 1(2) NHCR. The Regional Court asked the CJ whether Article 1(2) must "*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.*"

Advocate General H. Saugmandsgaard Øe (AG) pointed out that, while the scope of the question referred to professionals in general – as opposed to final consumers,[3] who qualify as non-professionals –, the professionals concerned by this case were health professionals.[4]

Accordingly, the CJ narrowed the question of the Regional Court and assessed whether the NHCR applies to nutrition and health claims made in commercial communications addressed exclusively to *health professionals*.[5]

III. Proceedings before the Court of Justice

1. Main Arguments of the Parties

Innova, the French and Greek governments and the European Commission submitted observations during the proceedings. The AG delivered its Opinion on the matter on 18 February 2016.[6]

Innova defended its position that the NHCR does not apply to advertising to professionals. Innova al-

2 Case C-19/15 *Verband Sozialer Wettbewerb eV v Innova Vital GmbH* (14 July 2016), para. 14.

3 Art. 2(1)(a) NHCR refers to the definition of 'final consumer' set out in Regulation (EC) No 178/2002 on food law. Art. 3(18) of Regulation 178/2002, as amended, defines 'final consumer' as "*the ultimate consumer of a foodstuff who will not use the food as part of any food business operation or activity.*"

4 Case C-19/15 *Verband Sozialer Wettbewerb eV v Innova Vital GmbH*, Opinion of AG Saugmandsgaard Øe (18 February 2016), para. 32.

5 *Verband Sozialer Wettbewerb eV v Innova Vital GmbH*, supra note 2, para. 22.

6 Opinion of AG Saugmandsgaard Øe, supra note 4.

so argued that, if the NHCR applied to advertising to professionals, the use of technical or scientific terminology in nutrition or health claims would be prohibited, as the NHCR requires that claims be understandable by the average consumer.

To the contrary, the AG considered that a literal, contextual and teleological interpretation of Article 1(2) NHCR called for the CJ to interpret it as meaning that the Regulation applies to nutrition and health claims made in commercial communications addressed exclusively to the professional sector but intended to be targeted indirectly at consumers, via the professional sector.

The French and Greek governments and the European Commission shared the view that commercial communications sent exclusively to professionals fall under the scope of the NHCR.

On 14 July 2016, the CJ delivered its judgment C-19/15 in line with the Opinion of the AG.

2. Findings of the Court of Justice

a. Scope of the NHCR

The CJ reminded that, for the purposes of interpreting a provision of EU law, the Court must consider (i) its literal wording, (ii) its context, and (iii) its objectives.

i. Literal Interpretation

According to the wording of Article 1(2) NHCR, the Regulation applies to nutrition and health claims if two conditions are met: (i) those claims are made in commercial communications – whether they appear in the form of labelling, presentation or advertising of foods; and (ii) the foods in question are to be delivered as such to the final consumer.

Regarding the first criterion, the CJ observed that, while it is clear from Recital 4 NHCR that the concept of 'commercial communication' refers to communications that pursue the objective of promotion ("*including inter alia generic advertising of food and promotional campaigns*"), the concept is not defined in the NHCR. Therefore, 'commercial communication' should be interpreted by reference to other provisions of secondary legislation, in order to ensure consistency of EU law. The CJ found such interpretative guidance in Directive 2000/31/EC on electronic commerce[7] and Directive 2006/123/EC on services in the internal market.[8] According to such provisions, 'commercial communication' may be interpreted as covering any form of communication designed to promote, directly or indirectly, any goods or services, or otherwise intended to obtain new customers. Consequently, the concept of 'commercial communication' within the meaning of Article 1(2) NHCR must be understood as covering, *inter alia*, communication made in the form of advertising of foods designed to promote, directly or indirectly, such foods.[9] The CJ took the position that "*[s]uch 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*".[10] In the AG's views, the aim of commercial communications is indeed to influence the decision of potential buyers – in this case, patients – via such promotion.[11]

On the second criterion, the CJ clarified, in line with the AG, that Article 1(2) NHCR makes no distinction with respect to whether the addressee of a commercial communication is a final consumer or a health professional. In fact, "*it is the product itself, and not the communication of which it is the subject matter, which must necessarily be aimed at consumers*".[12]

Likewise, the AG maintained that the commercial nature of a communication does not necessarily depend on whether it is addressed directly to final consumers, provided that consumers "*are in fact the persons at whom that commercial communication is in-*

7 Directive 2000/31/EC on information society services and electronic commerce (OJ L 178, 17.07.2000, p. 1-16).

8 Directive 2006/123/EC on services in the internal market (OJ L 376, 27.12.2006, p. 36-68).

9 *Verband Sozialer Wettbewerb eV v Innova Vital GmbH*, supra note 2, para. 29.

10 Ibid., para. 30. The CJ focused on the scenario where health professionals receive the commercial communication in their professional capacity and not as final consumers. The AG noted that there can indeed be little doubt as to the applicability of the NHCR in the latter case – where the professional is the final consumer of the product –, as in such case the communication is directly received by the final consumer (Opinion of AG Saugmandsgaard Øe, supra note 4, footnote 31).

11 Opinion of AG Saugmandsgaard Øe, supra note 4, para. 41.

12 *Verband Sozialer Wettbewerb eV v Innova Vital GmbH*, supra note 2, para. 31.

directly 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. 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".[13]

The CJ concluded that, according to a literal interpretation of Article 1(2) NHCR read in light of Directive 2000/31/EC and Directive 2006/123/EC, the NHCR "*applies to nutrition or health claims made in a commercial communication addressed exclusively to health professionals*".[14]

ii. Contextual Interpretation

The CJ found that such interpretation is not invalidated by the context of Article 1(2) NHCR. In particular, albeit the fact that certain recitals and provisions refer to "consumers" and make no reference to "professionals," the CJ nonetheless concluded that "*this does not mean that that regulation does not apply to the situation where a commercial communication is addressed exclusively to health professionals*," arguing that "*communication between the food business operators and 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*".[15]

iii. Teleological Interpretation

Finally, the CJ found that also the objectives pursued by the NHCR support this interpretation of Article 1(2). In this respect, the CJ took the position that the application of the NHCR to nutrition or health claims made in commercial communications addressed to health professionals contributes to the objective of ensuring a high level of consumer protection in the context of the internal market – in particular, by enabling consumers to make informed choices on food upon objective information based on claims that are scientifically substantiated. The CJ noted, in line with the AG, that although health professionals may have scientific knowledge superior to that of final consumers, they may be misled by claims which are false, deceptive or even mendacious, since they do not possess all the specialised and up-to-date scientific knowledge that is necessary to evaluate each food and related claims. This may result in health professionals forwarding to their patients incorrect information on foods which are the subject of a commercial communication. According to the Court, "*[t]hat 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*".[16] This may lead to potential circumventions of the requirements set by the NHCR: if the latter did not apply to commercial communications to health professionals, food business operators could use claims that are not scientifically substantiated by "*addressing the final consumer through health professionals, in order that those professionals recommend their foods to that consumer*".[17]

Importantly, the AG acknowledged that, where there is a relationship of trust between consumers and professionals, there could paradoxically be more harmful implications for consumers than if the commercial communications were addressed directly to them. This would be because consumers "*may even act with a lesser degree of reflection and hesitation than they would when they, as laypersons, have to make their own assessment*." Consequently, "*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*".[18]

b. Article 5(2) NHCR

As an additional element of the CJ's (contextual) analysis of Article 1(2) NHCR, the CJ considered that its reasoning is not contradicted by the fact that Article 5(2) NHCR allows the use of nutrition and health

13 Opinion of AG Saugmandsgaard Øe, supra note 4, para. 42.

14 *Verband Sozialer Wettbewerb eV v Innova Vital GmbH*, supra note 2, para. 32.

15 Ibid., para. 35.

16 *Verband Sozialer Wettbewerb eV v Innova Vital GmbH*, supra note 2, paras. 43-45.

17 Ibid., para. 46. For the AG, this would result in depriving the NHCR 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*" (Opinion of AG Saugmandsgaard Øe, supra note 4, para. 51).

18 Opinion of AG Saugmandsgaard Øe, supra note 4, para. 50.

claims only if the average consumer can be expected to understand the beneficial effects of a food as expressed in the claims. This on the basis that Article 5(2) NHCR "*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 facts.*" In the case at hand, the communication was not sent as such to the final consumer but it was sent to health professionals who were, as per the CJ, "*implicitly invited to recommend the food covered by the claims to that consumer*".[19]

On this point, the AG also maintained that consumers would adequately understand a claim made in commercial communications exclusively addressed to professionals, for said professionals, who are responsible for transmitting the information and explaining the benefits of the food product to patients, would have "*rephrased it if necessary, to non-professionals*".[20]

c. Commercial vs. Non-commercial Communications

In addition to the above, the CJ confirmed that the NHCR does not prevent food business operators from providing health professionals with objective information about scientific developments, involving the use of technical or scientific terminology (such as "atopic dermatitis"), in situations where the communication is of a non-commercial nature. This is in line with Recital 4 NHCR, stating that the Regulation 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*".[21]

d. Conclusion

In view of the foregoing, the CJ ruled that Article 1(2) NHCR "*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*".[22] For the AG, those communications are addressed exclusively to the professional sector "*but are intended to be targeted indirectly at consumers, via the professional sector*".[23]

3. Additional Arguments Raised by the Parties

The CJ did not address the argument submitted by the French Government that the disputed statements did not constitute nutrition or health claims but rather medicinal claims.[24] Based on such argument, France considered that the statements did not fall under the scope of the NHCR and were prohibited under Regulation (EU) No 1169/2011 on the provision of food information to consumers (FIC Regulation),[25] which prohibits the use of statements that attribute to a food the property of preventing, treating or curing a human disease or refer to such properties.[26] The European Commission also raised this possibility yet with regard to Directive 2000/13/EC,[27] the precursor of the FIC Regulation, which included a similar prohibition (as the facts giving rise to the dispute in the main proceedings took place before the FIC Regulation entered into force).

On this point, the AG responded in the sense that Directive 2000/13/EC, applicable *ratione temporis* to the case, applied in parallel, and not as an alternative to the NHCR, which complemented the general prin-

19 *Verband Sozialer Wettbewerb eV v Innova Vital GmbH*, supra note 2, para. 51.

20 Opinion of AG Saugmandsgaard Øe, supra note 4, para. 54.

21 *Verband Sozialer Wettbewerb eV v Innova Vital GmbH*, supra note 2, paras. 52-53.

22 Ibid., para. 54.

23 Opinion of AG Saugmandsgaard Øe, supra note 4, para. 58.

24 As the AG reminded in his Opinion, it is for the national court alone to assess and characterise the facts giving rise to the dispute in the main proceedings and to apply the relevant provisions of EU law as interpreted by the CJ to national situations (e.g. Case C-81/12 *Asociația ACCEPT v Consiliul Național pentru Combaterea Discriminării* (25 April 2013), paras. 41-43; and Case C-609/12 *Ehrmann AG v Zentrale zur Bekämpfung unlauteren Wettbewerbs eV* (10 April 2014), para. 36) (Opinion of AG Saugmandsgaard Øe, supra note 4, para. 27).

25 Regulation (EU) No 1169/2011 on the provision of food information to consumers (OJ L 304, 22.11.2011, p. 18-63, and corrigendum OJ L 247, 13.9.2012, p. 17), as amended.

26 Subject to derogations provided within the EU framework applicable to natural mineral waters and foods for particular nutritional uses (currently known as foods for specific groups). See Article 7(3) Regulation (EU) No 1169/2011, supra note 25.

27 Directive 2000/13/EC on the labelling, presentation and advertising of foodstuffs (OJ L 109, 6.5.2000, p. 29–42, and corrigendum OJ L 124, 25.5.2000, p. 66), as amended. See in particular Art. 2(1)(b).

ciples set out in the Directive. Therefore, the AG considered that it was appropriate for the CJ to examine the request for a preliminary ruling on the interpretation of the NHCR.[28]

IV. Comment

1. How Have the Member States Interpreted Article 1(2) NHCR so far?

This was not the first time that the question as to whether the NHCR applies to commercial communications addressed to health professionals was raised. Due to the ambiguity of the wording of Article 1(2) NHCR, several Member States (MS) issued guidance excluding communications to health professionals from the scope of the NHCR, so long as such communications are not shared with final consumers within a commercial context or made easily accessible to them.[29]

As the question remained uncertain, the MS and the European Commission debated on this issue at the Commission Working Group meeting on nutrition and health claims of 23 January 2012.[30] The discussion during the meeting, as summarised in the minutes made available by the UK Government, reflected the absence of a clear position in the interpretation of the wording of Article 1(2) NHCR as to "*whether it was [the commercial communication] or the food that was to be delivered to the final consumer*".[31] The minutes confirmed that "*in some language versions of the NHCR, it is clear that 'to be delivered as such to the final consumer' applies to foods*".[32] This suggests, conversely, that other language versions of the NHCR allow one to interpret Article 1(2) NHCR in the sense that "*to be delivered as such to the final consumer*" applies to "*commercial communications*," in which case the NHCR would not apply to communications to health professionals.[33] As a result, several MS regarded communications to health professionals as within the scope of the NHCR while others, albeit without stating that such communications escape *per se* from the application of the NHCR, took the position that this should be decided on a case-by-case basis. It can be inferred from the minutes of the meeting that the nature and content of the information, as well as the way in which it is presented, including whether it is easily accessible to and understandable by consumers, constitute important criteria for the purposes of this case-by-case determination.

In this respect, the CJ ruling represents a significant step forward in the development of EU food law, to the extent that it adds clarity to the meaning of Article 1(2) NHCR.[34]

28 Opinion of AG Saugmandsgaard Øe, supra note 4, in particular paras. 30-31.

29 For example, the Department of Health of the United Kingdom considered that "*[w]hile the Regulation applies to claims made in commercial communications about foods it is our opinion that it will not control claims made in communications within trade (business to business), to doctors or other health professionals, or to their organisations, whether the claim is in the labelling, advertising or other presentation of the food. This is provided that the recipients are acting within the scope of their professional activities and that they are not being addressed as final consumers of the foods. It therefore follows that if the information were, at any time, conveyed to final consumers within a commercial context, any claims made would need to comply with the requirements of the Regulation*" (Guidance to compliance with Regulation (EC) 1924/2006 on nutrition and health claims made on foods, November 2011 version, para. 35). The Belgian healthcare authorities published a letter acknowledging that, while the article did not state it explicitly – thereby, acknowledging the ambiguity in its wording – the national position was such that the NHCR did not apply to communications either addressed to health professionals or between businesses so long as such communications are not transferred to the final consumer within a commercial context, or are easily accessible to him (e.g. via a website with free access) (Federal Public Service, Health, Food Chain Safety and Environment, letter from Director General Dr. P. Mortier, 'Règlement 1924/2006 – Clarification du champ d'application', 27 September 2013).

30 Department of Health of the United Kingdom, Nutrition and Health Claims Interested Parties Letter of 27 January 2012, Update from the European Commission's Working Group meeting on nutrition and health claims, 23 January 2012. See in particular answer to question 2.

31 Ibid., see answer to question 2, first para.

32 Ibid., see answer to question 2, second para. We note in particular the Dutch, French and Hungarian versions of the NHCR.

33 We identified at least the Danish version of the NHCR supporting this interpretation. The German wording is also open to such interpretation, while the Belgian authorities have also acknowledged the absence of a clear wording within Art. 1(2) (supra note 29). In this respect, according to settled case-law "*[…] interpreting a provision of Union law involves a comparison of the language versions […]. Where there is divergence between the various language versions, the provision in question must be interpreted by reference to the purpose and general scheme of the rules of which it forms part […]*". See Case C-207/14 *Hotel Sava Rogaška, Gostinstvo, turizem in storitve, d.o.o. v Republika Slovenija* (24 June 2015), paras. 26-28. The CJ followed this approach in this case (see Section III.2.a).

34 We note that the AG, in his Opinion, referred to the existence of a German stream of scholarship precisely addressing alternative interpretations of Article 1(2) NHCR. However, the AG did not explicitly address this literature. Opinion of AG Saugmandsgaard Øe, supra note 4, para. 33.

2. Does the Judgment Set Limits to the Application of the NHCR to Health Professionals?

It is clear from the reading of the judgment that Article 1(2) NHCR applies to commercial communications that are exclusively addressed to health professionals. At first glance, therefore, food business operators will only be allowed to use nutrition and health claims in such commercial communications if those claims are compliant with the NHCR. This means that only claims that are scientifically substantiated and understandable by consumers would be permitted in commercial communications to health professionals.

However, a more careful reading of the judgment reveals that the CJ, be it purposefully or inadvertently, ruled that the NHCR does apply to commercial communications addressed to health professionals, although with some limitations. In particular, as discussed above,[35] the CJ stated that Article 5(2) NHCR, which subjects the use of claims to the average consumer understanding benchmark, applies if the claims are communicated *directly* to the final consumer, in order to enable him to make choices in full knowledge of facts.[36] This is a key qualification to the CJ's overall determination. It reveals that communication sent to health professionals would not be subject to Article 5(2) NHCR, and may thus include technical or scientific terminology not necessarily understandable as such by consumers. In the AG's words, this would be justified because health professionals would, where appropriate, "*[rephrase the information] if necessary*"[37] in order to ensure that consumers – in this case, patients – properly understand the benefit of the food as expressed in the claims.[38] In the CJ's mind, health professionals, in their capacity as experts, would contribute to guaranteeing that the dual objective of the NHCR – ensuring the effective functioning of the internal market while providing a high level of consumer protection – is duly preserved.[39]

Within this context, a fundamental question arises: to what extent does the NHCR *really* apply to commercial communications addressed to health professionals? In particular, how flexible is the margin for food business operators to communicate to health professionals beyond the boundaries of Article 5(2) NHCR? Are companies allowed to communicate any message expressed in scientific terms without restrictions when a commercial communication is directed to the health profession? A contextual and teleological reading of the NHCR and the judgment suggests that companies should be able to communicate commercial messages that reflect the content of nutrition and health claims that have been authorised by the European Commission using technical and scientific language. In this case, indeed, the need to ensure the scientific soundness of claims would be preserved while allowing a constructive scientific dialogue between the industry and the health profession which protects innovation and, through the filter of the health professional, also ensures appropriate consumer protection. To the contrary, commercial communication reflecting unauthorised claims would remain prohibited.

Independently of the above, food business operators remain free to share non-commercial information with health professionals, such information being outside the scope of the NHCR.[40]

35 See Section III.2.b.

36 The average consumer benchmark has been applied within the context of NHCR proceedings. See e.g. case T-100/15, *Dextro Energy GmbH & Co. KG v European Commission* (16 March 2016), where the General Court recalled that *"[a]s is apparent from recital 16 of Regulation No 1924/2006, in order to resolve the question whether a claim is misleading or not, it is necessary to refer to the presumed expectations in relation to that claim which an average consumer who is reasonably well informed, and reasonably observant and circumspect, would have […]"* (para. 66). See also Case C-609/12 *Ehrmann AG v Zentrale zur Bekämpfung unlauteren Wettbewerbs eV*. (10 April 2014), para. 40 *("[...] as Article 1 of Regulation No 1924/2006 states, the regulation aims to ensure the effective functioning of the internal market whilst providing a high level of consumer protection. In that regard, recitals 1 and 9 in the preamble to that regulation explain that it is necessary in particular to give the consumer the necessary information to make choices in full knowledge of the facts"*); case T-100/15, *Dextro Energy GmbH & Co. KG v European Commission* (16 March 2016), paras. 66 and 85; case C-157/14 *Société Neptune Distribution v Ministre de l'Économie et des Finances* (17 December 2015), para. 49; and case T-17/12, *Moritz Hagenmeyer and Andreas Hahn v European Commission* (30 April 2014), para. 105.

37 Opinion of AG Saugmandsgaard Øe, supra note 4, para. 54.

38 In this respect, as the AG stated, *"it is irrelevant whether professionals pass on 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*." Ibid., para. 44.

39 The CJ recalled this dual objective sought by the NHCR, stating that health protection is among the principal aims of the NHCR, in many instances. See e.g. case T-17/12, *Moritz Hagenmeyer and Andreas Hahn v European Commission* (30 April 2014), para. 105; and case T-100/15, *Dextro Energy GmbH & Co. KG v European Commission* (16 March 2016), paras. 33 and 85.

40 *Verband Sozialer Wettbewerb eV v Innova Vital GmbH*, supra note 2, paras. 52-53. See also supra Section III.2.c.

3. Implications for the Industry

The AG acknowledged the significant practical implications of this judgment.[41] To date, open communication between companies and health professionals represented generally accepted market practice within the industry, partly due to the commonly perceived uncertainty in the interpretation of Article 1(2) NHCR. The CJ ruling puts an end to this decade of uncertainty and sets forth the standard – although not free from open questions – for what should be considered accepted practice when companies communicate with health professionals. From this point onwards, food business operators will need to take further precautionary steps to ensure that any information that they communicate to health professionals either (i) qualifies as non-commercial or (ii) complies with the NHCR.[42]

Regarding the first option, it can be inferred from the judgment that information that is objective, focuses on scientific developments, uses technical terminology, and is presented in a non-promotional context may qualify as non-commercial. Such a scenario was already envisaged by Recital 4 NHCR. In that respect, the CJ seems to clarify that the non-commercial nature of a communication must be analysed by considering not only its content but also the context in which said communication is put in place. In the absence of further detailed guidance by the CJ on what characterises "objective" or "non-commercial" communications, companies may consider turning to guidelines for publications in medical and scientific reviews in order to minimise risks. Furthermore, they may consider limiting their communication to channels only targeting health professionals, such as scientific journals, and where content is not easily accessible by consumers, such as access-restricted websites protected by credentials issued by the relevant professional body.

With respect to the second route, it seems that compliance with the NHCR would not preclude food business operators from addressing health professionals with commercial communications including technical or scientific terminology not necessarily understandable as such by consumers. As mentioned above,[43] health professionals would, where appropriate, rephrase the terminology to ensure that their patients properly understand the benefit of the food as expressed in the authorised claims. Consequently, in practical terms, the judgment does not seem to have revolutionary implications on the industry practice. Nonetheless, regulators may be inclined to scrutinise carefully whether the scientific or technical information contained in a commercial communication addressed to health professionals accurately reflects the science behind an authorised claim, particularly in view of the "significant influence" that health professionals may exert on patients as a result of their relationship of trust.

It remains to be seen what the Regional Court will rule based on the judgment of the CJ. A preliminary analysis anticipates that the Document would qualify as "commercial communication" under the NHCR. Indeed, all of the following elements point towards the promotional nature of such communication: (i) use of expressions inviting professionals to recommend or even purchase the food product ("*For that reason, I have given my son the recommended formula [...]. You can find out how to place direct orders and obtain free information material for your surgery by calling [...]*");[44] (ii) use of images and terms referring to the branded product – as opposed to only scientific terms; and (iii) use of business related contents such as the selling price ("*with a selling price of EUR 26.75, your patients are investing EUR 0.11 per day for balanced vitamin D_3 supplement*").[45] On this basis, as the communication was addressed to health professionals, the Regional Court will likely find that the Document could not have lawfully included unauthorised health claims, ordering Innova to refrain from using such claims in further commercial communications targeting health professionals.

41 Opinion of AG Saugmandsgaard Øe, supra note 4, para. 32.

42 While this judgment relates to communications to health professionals, food business operators should take it into account when communicating with other professionals ('business-to-business') as well to minimise risks.

43 Sections III.2.b and IV.2.

44 *Verband Sozialer Wettbewerb eV v Innova Vital GmbH*, supra note 2, para. 14.

45 Ibid., para.15. See also Opinion of AG Saugmandsgaard Øe, supra note 4, para. 17.