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How the European Court of Justice's judgement on Case 19/15ⁱ single-handedly changed the EU's food information policy

Sobre cómo el Tribunal de Justicia de la Unión Europea transformó la política comunitaria de información nutricional con el Caso 19/15ⁱ

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ⁱ Case C-19/15, Verband Sozialer Wettbewerb eV v Innova Vital GmbH, ECLI:EU:C:2016:563 (not yet published in ECR).

Abstract

The European Court of Justice is asked by the German courts to determine if the European Union's legal framework on the use of nutrition and health claims in the advertising of food products applies to commercial communication that is directly forwarded by food business operators to health professionals. According to this ruling, because these professionals are not in a position to review all upcoming scientific studies and because of the complexity of the claims, they need to be protected from misleading claims as much as the average consumer. It is the author's view that this Judgment opens the door for the European Commission to define clear rules on how food businesses can approach health professionals when advertising their products.

Keywords: food information; food safety; misleading claims; public health; Regulation 1924/2006; health claims; nutrition claims; health professionals.

Resumen

El Tribunal de Justicia de la Unión Europea responde ante la cuestión preliminar remitida por los tribunales alemanes relativa al alcance del Reglamento comunitario sobre el uso de declaraciones nutricionales y de propiedades saludables en la publicidad de los productos alimenticios. En particular, interpreta que la publicidad dirigida a los profesionales sanitarios queda sujeta a dicho Reglamento, puesto que estos profesionales no están en condiciones de examinar todos los estudios científicos publicados debido a su número y complejidad. Esta sentencia abre la puerta para que la Comisión Europea defina reglas claras que impongan límites a la actuación de las empresas cuando comunican con los profesionales de la salud.

Palabras clave: información alimentaria; seguridad alimentaria; confusión al consumidor; salud pública; Reglamento 1924/2006; declaración nutricional; declaración de propiedades saludables; profesionales sanitarios.

On the 14th July 2016, while most public officials based at the European Union's institutions and lobbyist were still on summer break, the Third Chamber of the European Court of Justice "ECJ" issued its judgment on Case 19/15 in the framework of a request for a preliminary ruling under Article 267 TFEU from the Landgericht München I (Regional Court, Munich I, Germany), in the proceedings between Verband Sozialer Wettbewerb eV „VSW” versus Innova Vital GmbH “INNOVA”. While the general press failed to report on this ruling, the publication of this judgement meant the end of vacation for too many policy professionals in Brussels and abroad. Was it possible that the rumour was true? Did the ECJ together with the Advocate General Saugmandsgaard Øe disregard all political pressure from both policy officers and private stakeholders? Indeed, this judgment immediately became the example of how the ECJ can be a significant game-changer when it comes to the European Union's public policies.

According to the European Commission's own data¹, “the food and drink industry is the EU's biggest manufacturing sector in terms of jobs and value added. It's also an asset in trade with non-EU countries. The EU boasts an important trade surplus in trade in food and EU food specialities are well appreciated overseas. In the last 10 years, EU food and drink exports have doubled, reaching over €90 Billion and contributing to a positive balance of almost €30 Billion.” Also, as stated by Cann (2014), agribusiness lobbyist are the largest and more active lobby prowling around EU institutions, as “food multinationals, agri-traders and seed producers have had more contacts with the Commission's trade department (DG Trade) than lobbyists from the pharmaceutical, chemical, financial and car industry put together.” Given the power of the food and drink industry in the EU, the fact that the Court did not yield to its demands increases the significance of the European Court of Justice's decision.

But, what happened?

Case 19/15 deals with the definition of the scope of Regulation 1924/2006, of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods (“Regulation 1924/2006”)². As described in this article, the ECJ was to assess if nutrition and health

¹ See EU Commission's website, “Growth by sector” section, accessible here: https://ec.europa.eu/growth/sectors/food_en.

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).

claims included in commercial communications from food businesses³ to health professionals needs to comply with Regulation 1924/2006 mandatory particulars and prohibitions.

1. About the relevance of Regulation 1924/2006 when it comes to protecting consumers from misleading claims

Regulation 1924/2006 is at the core of the EU's food information policy, a policy that as set in its first article seeks to harmonise "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."

Before Regulation 1924/2006 came into force, nutrition and health claims were accepted in the labelling and advertising of food products provided that they were supported by scientific data and did not generate confusion in the average consumer⁴. Nutrition and health claims did not need to be validated by competent authorities before used in commercial communications.

Under Regulation 1924/2006, the European Commission understands that—in order not to mislead consumers—the only nutrition or health claims that can be included in food products' advertising or labelling are the ones that have undergone the authorisation process its Regulation establishes. The authorized nutrition claims—as well as their conditions of use—are analyzed, validated or rejected and then listed in the Annex of Regulation 1924/2006, while health claims are included in the Annex of Commission Regulation (EU) n° 432/2012, of 16 May 2012, establishing a list of permitted health claims made on foods, other than those referring to the reduction of disease risk and to children's development and health⁵.

The process requires from food business operators to provide the EU Commission and the European Food Safety Authority "EFSA" with extensive scientific data supporting a claim that once

³ Food business operators are, according to Article 3 No. 3 of Regulation 178/2002, "the natural or legal persons responsible for ensuring that the requirements of food law are met within the food business under their control."

⁴ There is extensive ECJ jurisprudence on what the concept of "average consumer" means both in general and in the field of food information. As set by the Court and analyzes Szakács (2015), the average consumer is "a reasonably circumspect critical person when making his or her market decision, and who informs himself or herself about the products well in advance. It can also be noted that social, cultural and linguistic factors must be considered. As the Court stated in the Mars case, a reasonably circumspect consumer is someone who does not believe that the size of a promotional marking on a package corresponds to the promotional increase in the size of the product."

⁵ The updated list of authorised and rejected claims to be made on foods can be easily accessed through the EU's register through this link: <http://ec.europa.eu/nuhclaims/>.

approved will be legally used by any food business operator in the market. This –together with the fact that completing the process requires from extensive funds and can take several years– has resulted in the food and drink industry constantly criticizing⁶ the system since it was first launched. And even before that, branches of the EU Commission itself advocated for amending the proposed regulation in a firm manner: “it is sufficient if, instead of an expensive authorisation procedure, it is ensured that the health claims asserted are scientifically verifiable.”⁷

But the idea behind that new EU's nutrition and health claims system is still today that only when consumers are given clear and complete information about foodstuffs will they be able to avoid unnecessary risks for their health while also ensuring that their food choices meet their ethical, social or political concerns. As indicated in article 3 of Regulation (EU) n^o 1169/2011 on the provision of food information to consumers⁸, legislative provisions on food information's first objective is to “pursue a high level of protection of consumers' health and interests by providing a basis for final consumers to make informed choices and to make safe use of food, with particular regard to health, economic, environmental, social and ethical considerations.”

As both Regulation 1169/2011 and Regulation 1924/2006 illustrate and is inferred from the above, when it comes to ensuring that consumers have clear and complete information on food, the EU focuses on the role of food operators as food information providers.

However, by focussing only on information provided directly by food operators to the final consumer, the EU is failing to acknowledge a societal phenomenon that has significantly diminished the effectiveness of EU regulations on information about the nutrition and health properties of specific foods such as food supplements and other functional foods: while remaining at the heart of the EU policy on food information, food business operators are not the main source of food information for the final consumer anymore. On the contrary, as the EU funded project

⁶ See, among many others, MJ Deschamps coverage on the 11 August 2011, accessible here: http://www.just-food.com/analysis/mixed-verdict-on-eu-health-claims-process_id116286.aspx.

⁷ Opinion of the Committee on Industry, Research and Energy issued on the 18th March 2005, for the Committee on the Environment, Public Health and Food Safety on the proposal for a regulation of the European Parliament and of the Council on nutrition and health claims made on foods (COM(2003)0424 – C5-0329/2003 – 2003/0165(COD)).

⁸ Regulation (EU) n^o 1169/2011 of the European Parliament and the Council, of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) 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/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004 (hereinafter “Regulation 1169/2011”).

TRUSTINFOOD⁹ reflected, health professionals as well as general media and specific Internet sources are generally more trusted by consumers, and as such more likely to be influencing consumers' food choices in a more definite manner.

While the European Commission is still tip-toeing when it comes to adapting to this social behaviour, food operators have already reacted and have changed their strategy when it comes to advertising the nutrition and health-related properties of their products. Instead of navigating through a long and expensive procedure to get nutrition and health claims approved, business is now communicating with health professionals as well as other so called "food & health influencers" assuming that they will later convey their message to final consumers. That way, operators escape the legal framework set by Regulation 1924/2006.

One must then wonder if the information that the final consumer gets is clear, complete and, most of all, not misleading. Are health professionals or other relevant actors such as journalists or digital "influencers" able to distinguish between reliable scientific studies and commercially driven communication?

In a digital and social media era that has given so called "food and health" bloggers a tremendous influence over their followers' food choices and that has made massively accessible the most varied non-peer review journals and websites, ensuring that those who hold consumers' trust are not misled by commercial communication becomes tremendously important.

In this context, the European Court of Justice's judgement "Verband Sozialer Wettbewerb eV v Innova Vital GmbH"¹⁰ analyzed in this article becomes the game-changer that consumer organizations were praying for.

2. Case 15/19: the facts

The European Court of Justice "ECJ" issues this judgment on the 14 July 2016 in the framework of a request for a preliminary ruling under Article 267 TFEU from the Landgericht München I (Regional Court, Munich I, Germany), in the proceedings between Verband Sozialer Wettbewerb eV „VSW“ versus Innova Vital GmbH „INNOVA.“ The German Court is to decide on a possible

⁹ Full Project name: Consumer trust in food: A European study of the social and institutional conditions for the production of trust. Contract No.: QLK1-CT-2001-00291. Project Collaborators: The National Institute for Consumer Research, (FI), University of Bologna, (IT), Royal Veterinary, and Agricultural University (DK), University of Manchester (UK), University of Porto (PT), Federal Research Centre for Nutrition (DE). 2003.

¹⁰ Case C-19/15, Verband Sozialer Wettbewerb eV v Innova Vital GmbH, ECLI:EU:C:2016:563 (not yet published in ECR).

unlawful commercial practice conducted by INNOVA, when its director forwarded in November 2013 a written document to named doctors advertising the firm's nutritional supplement Innova Mulsin® D³.

The document included the following statements:

"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."

"Benefits of Mulsin® emulsions:

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

According to VSW, the forwarding of the document constitutes an unlawful practice because the above-mentioned two statements should be considered health claims prohibited by Article 10 n° 1 of Regulation (EC) 1924/. On the other hand, INNOVA argues that its practice is lawful because commercial communication between a business operator and health professionals do not fall in the scope of that Regulation.

The German Court's request for a preliminary ruling focuses on the following question:

"Must Article 1 No.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?"

3. The judgment

The ECJ ruled that Article 1(2) of Regulation (EC) 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."

It is relevant to highlight at this point that there is discordance between the German Court's question and the ECJ Court's judgment. While the German Court required the preliminary ruling to

establish whether commercial communication directed to professionals in general fall within the scope of the Regulation, the later fingers "health professionals" in particular.

This circumstance makes uncertain the real scope of the judgement of the ECJ. Are only health professionals affected by the judgement? Does it also apply to other professionals or business-to-business relations? While many argue that the Courts' position makes Regulation 1924/2006 applicable to B2B relations along the food chain, the arguments provided by the Court gainsay this position because it justifies that advertising to health professionals falls within the scope of the Regulation on the grounds that those professionals "exercise significant influence over [their patients]" as they benefit from a relationship based on trust and have an aura of independence.

In particular, the judgment indicates 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." The later suggests that professionals may become mere intermediaries between the company and the final consumer when it comes to transmitting information about the nutrition or health-related properties of the foodstuff. Because health professionals are privileged information providers to the final consumer, making sure that they are not "misled by nutrition or health claims which are false, deceptive or even mendacious" is a must.

The Court also insists on the fact that health 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," therefore when subject to commercial communication should receive the same protection than the final consumer as a way to protect the later.

Finally, the judgment indicates that there are no provisions or recitals that gainsay the Court's interpretation because the fact 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" makes it clear that "it is the product itself, and not the communication of which it is the subject matter, which must necessarily be aimed at consumers."

It may be noted at this point that the Judgment of the European Court of Justice cannot be repealed and must be noted by competent authorities and any food business operator that introduces food products in the EU internal market.

4. A proposal for a new legal framework for the advertising of food supplements and functional foods

Case 19/15 has made visible the fact that food supplements —and functional foods in general— are frequently recommended to consumers by health professionals in the framework of a medical visit. Health professionals today recommend the intake of a specific nutritional food product through the same process as they would have recommended a medicine that requires no prescription.

Thus, recommending a specific food supplement and other functional foods has become part of the doctor-patient relationship. This is relevant, because the patient-consumer perceives the food product —that often appears as a pill or similar format— as having an impact on health in a similar way as medicines do, even when the label does not include any claim that suggests so.

In this context, when the health professional receives commercial communication about the alleged nutrition or health-related properties of a food product he is left alone to decide if his or her patients could benefit from adding it to their diet. But, if the ECJ's Third Chamber is right and "health 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," is making them stand alone before aggressive commercial communication the best idea?

Let's take now into account that in the proceedings between "VSW" and "INNOVA", commercial communication was forwarded via e-mail to named doctors in such a manner that the health professional was saluted individually by its author, resembling what could have been considered by its recipient private advice or correspondence. Moreover, the author even claimed to share a certain degree of intimate information with the recipient to increase trust, indicating that the food supplement was being used by his own family: "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."

In accordance with the Courts' ruling, it is my view that health professionals should be protected from such communications. But mostly, given that commercial communications such as INNOVA's go unnoticed by public officials because they are transmitted through private communication channels such as e-mail, it is not enough to consider that nutrition and health claims should comply with Regulation 1924/2006. The European Commission needs to make a stand and go further protecting professionals and consumers from aggressive and dishonest commercial initiatives from the food and drinks industry just as it did before regarding the pharmaceutical industry.

Taking the above into consideration, it may be advisable to consider establishing a new framework for the advertising of food supplements and functional foods, which goes further in the protection of health professionals as privileged actors when it comes to protecting final consumers from receiving misleading information.

It is my view that a system similar to the one established for the advertising of medicines that do not require a medical prescription in Directive 2001/83/EC of the European Parliament and the Council of 6 November 2001 on the Community code relating to medicinal products for human use, could significantly upgrade consumer protection in this field.

The definition of clear rules regarding how operators can approach health professionals when dealing with food supplements or functional foods should respect the same principles used when dealing with non-prescription drugs. Especially, it should be taken into consideration the possibility of implementing the Directive's measures prohibiting giving, offering or promising premiums, pecuniary advantages or benefits to any kind to health professionals when advertising food supplements or functional foods. Also, making it mandatory to provide professionals with a legally-defined dossier on the characteristics of the product would improve their capacity to make accurate recommendations to patients.

Finally, because of their role as trusted sources of food & health information, these rules should also apply when advertising to other professionals that also exercise significant influence over the final consumer, when dealing with the same substances.

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