HEALTH CLAIMS` NOTION IN THE CASE LAW OF THE EUROPEAN COURT OF JUSTICE

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Abstract

Although an area traditionally reserved to the Member States, health policy is increasingly influenced by European Union regulatory framework and by the Court of Justice of European Union case law. This article surveys the Court of Justice of European Union jurisprudence that clarifies the health claims concept, in the light of the interactions with fundamental rights, public health and consumer protection.

Keywords: *health claims, Court of Justice of European Union, consumer protection, health policy, food law.*

1. Introduction

Health policy is traditionally an area with no or very little EU involvement. It is an area where the national interests prevails, and where member states have been reluctant to transfer competences to EU. Increasingly, however, member states 'health policy are influenced by EU, especially when the policy is linked to the single market[1].

The concept of "health claims" is one area where we can spot the interaction between the consumer interests, public health, free movement of goods and the interest of food and pharmaceutical business sector. This article surveys the Court of Justice of European Union jurisprudence that clarifies the health claims concept, in the light of this interactions.

Certain studies suggest that a multidisciplinary approach need to be carried out, using insights from food technological and medical, economic, legal and managerial sciences. The main finding is that the costs and uncertainties attached to health claims are important factors impacting the innovation efforts of companies, the willingness-to-pay of consumers and the effectiveness of public policy[2].

Besides, the field of European Union competences is closely related to the concept of supra-nationality[3].

Moreover, some analyses asserts that European legislation on foods and medicine has failed to keep pace with the developments in nutrition and medical science that now recognise many important contributions that diet and individual foods may make to the promotion and maintenance of health. EU food law prevents the communication of these benefits to consumers, whilst the law on medicinal products is established on a very broad basis that also encompasses foods making preventive, therapeutic or curative claims[4].

The opportunities for product innovation arising from this new legislation combined with protection of consumer interest in respect of controlling misleading advertising, while at the same time promoting public health, are noteworthy. Whether this legislation is driving product innovation and the development of health and nutritional food or whether it is a barrier to such developments is an area in need of investigation[5].

The present paper will place the concept of health claims in the framework of European Union (EU) legislation (Capitol 2) and then will survey the Court of Justice of European Union jurisprudence that attempts to clarify the issue (Capitol 3).

2. Regulatory framework

Rules for nutrition and health claims made on foods across the European Union are harmonized by the Regulation No1924/2006 ("The Regulation") of the European Parliament and of the Council of 20 December 2006. According to the Regulation, the Commission can authorises different health claims provided they are based on scientific evidence[6]. The European Food Safety Authority (EFSA) is responsible for evaluating the scientific evidence supporting health claims.

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[1] Carsten Stroby Jensen in Cini, Michelle, and Nieves Pérez-Solórzano Borragán. 2016. *European Union Politics*. Oxford University Press, pg.58.

[2] Bremmers, H. J., B. M. J. van der Meulen, and K. Purnhagen. 2013. "Multi-Stakeholder Responses to the European Union Health Claims Requirements." *Journal on Chain and Network Science* 13 (2): 161–72.

[3] Fuerea, Augustin, Dreptul Uniunii Europene -principii, actiuni, libertati- Universul Juridic, Bucuresti, 2016, p.36.

[4] Coppens, Patrick, Marlene Bijlsma, Neville Craddock, Inneke Herreman, Eva Hurt, Yves Le Bail-Collet, and Peter Loosen. 2001. "Are Foods Bearing Health Claims Medicinal Products?" *Scandinavian Journal of Nutritiod/ Näringsforskning* 45(1): 140–45.

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[6] Commission Regulation (EU) No 432/2012 established the list of permitted health claims, which is regularly updated.

The Regulation No1924/2006 is part of an extensive legal framework governing food[7], such as labelling, presentation and advertising of foodstuffs [8], food supplements[9], the addition of vitamins and minerals and of certain other substances to foods[10], foods intended for use in energy-restricted diets for weight reduction[11], exploitation and marketing of natural mineral waters[12], drinking water[13] or foodstuffs intended for particular nutritional uses[14].

Art. 2(5) of the Regulation provides the following definition for health claims: "any claim that states, suggests or implies that a relationship exists between a food category, a food or one of its constituents and health".

The Regulation distinguishes between three types of health claims which has to follow different procedures for authorization.

First, *the Article 13 claims* ('Function Health Claims') [15] are health claims describing or referring to: the growth, development and functions of the body; psychological and behavioral functions and slimming or weight-control[16].

Second, *Article 14(1)(a) claims (*'Risk Reduction Claims') [17] are health claims on reducing a risk factor in the development of a disease. The 'reduction of disease risk claim', definition provided by art.2(6) of the Regulation, means any health claim that states, suggests or implies that the consumption of a food category, a food or one of its constituents significantly reduces a risk factor in the development of a human disease.

The last one are the claims provided in *Article 14(1)(b)* (Health 'Claims referring to children's development')[18].

3. Case law

The Court of Justice of European Union case law considering health claims concept is approached pointing on the impact on fundamental rights, consumer protection and the definition of health claims.

3.1. Fundamental rights

In the case *Deutsches Weintor*[19], the reference to the Court has been made in proceedings between Deutsches Weintor, a German winegrowers' cooperative, and the department responsible for supervising the marketing of alcoholic beverages in the *Land* of Rhineland-Palatinate concerning the description of a wine as 'easily digestible' ('bekömmlich'), indicating reduced acidity levels. The German authority objected to the use of the description 'easily digestible' on the ground that it is a 'health claim', which, pursuant to the regulation 1924/2006, is not permitted for alcoholic beverages.

The court was asked to interpret whether the prohibition from using a health claim for alcoholic beverages, is compatible with Article 15(1) of the Charter, according to which everyone has *the right to engage in work and to pursue a freely chosen or accepted occupation*, and to Article 16 of the Charter, which guarantees the *freedom to conduct a business*.

In this regard, the court pointed out that a *high level of human health protection* has to be ensured in the definition and implementation of all the European Union's policies and activities, according to Article 35 of the Charter. It also underlies that health protection is among the principal aims of regulation 1924/2006, as this is present in recitals 1 and 18 in the preamble.

It follows that, the Court needed to reconcile the requirements of the protection of those various fundamental rights protected by the Union legal order, and striking a fair balance between them[20].

Accordingly, the Court determines, first, that the total prohibition of a health claim of the kind at issue is regarded as being necessary to ensure compliance with the requirements of human health protection provided in the Charter.

Secondly, as regards the freedom to choose an occupation and the freedom to conduct a business the

[7] 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.

[8] Regulation (EU) No 1169/2011 of the European Parliament and of 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.

[9] Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements.

[10] Regulation (EC) No 1925/2006 of the European Parliament and of the Council of 20 December 2006 on the addition of vitamins and minerals and of certain other substances to foods.

[11] Commission Directive 96/8/EC of 26 February 1996 on foods intended for use in energy-restricted diets for weight reduction.

[12] Directive 2009/54/EC of the European Parliament and of the Council of 18 June 2009 on the exploitation and marketing of natural mineral waters.

[13] Council Directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption.

[14] Regulation (EU) No 609/2013 of the European Parliament and of the Council of 12 June 2013 on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control and repealing Council Directive 92/52/EEC, Commission Directives 96/8/EC, 1999/21/EC, 2006/125/EC and 2006/141/EC, Directive 2009/39/EC of the European Parliament and of the Council and Commission Regulations (EC) No 41/2009 and (EC) No 953/2009.

[15] For example: "Walnuts contribute to the improvement of the elasticity of blood vessels".

[16] Without prejudice to Commission Directive 96/8/EC of 26 February 1996 on foods intended for use in energy-restricted diets for weight reduction.

[17] For example: "Sugar-free chewing gum helps reduce tooth demineralisation. Tooth demineralisation is a risk factor in the development of dental caries".

[18] For example:"Vitamin D contributes to the normal function of the immune system in children".

[19] Judgment of 6 September 2012, Deutsches Weintor, Case C–544/10, ECLI:EU:C:2012:526.

[20] Judgment of the Court (Grand Chamber) of 29 January 2008, *Promusicae*, Case C-275/06, ECLI:EU:C:2008:54.

courts indicates its case-law, underling the possibility to restrict *the exercise* of those freedoms, if those restrictions correspond to objectives of general interest pursued by the European Union and do not constitute, with regard to the aim pursued, a disproportionate and intolerable interference, impairing the very substance of those rights[21]. The courts affirms that the prohibition at issue does not in any way affect the *actual substance* of the freedom to choose an occupation or of the freedom to conduct a business[22].

In *Neptune Distribution*[23], the national court is asking essentially whether EU law must be interpreted as meaning that it precludes packaging, labels or advertising for natural mineral waters from containing claims or indications leading consumers to believe that the waters concerned are low or very low in sodium or salt[24]. Neptune Distribution sells and distributes the natural sparkling mineral waters denominated 'Saint-Yorre' and 'Vichy Célestins'. French authorities asked Neptune to remove any statement leading the consumer to believe that the waters in question are low or very low in salt or in sodium.

The court examines whether the need to ensure that the consumer has the most accurate and transparent information possible concerning the characteristics of goods is closely related to the protection of human health. The court concludes that *protection of human health is a question of general interest which may justify limitations on the freedom of expression and information of a person carrying on a business or his freedom to conduct a business*[25].

3.2. Consumer protection

Consumer protection was the main question in the case *Verband Sozialer Wettbewerb*[26], which concerned health claims communication addressed exclusively to health professionals. In this case, Innova Vital marketed a nutritional supplement in Germany known as 'Innova Mulsin® Vitamin D3' which is administered in the form of drops. Innova Vital sent exclusively to named doctors a written document presenting the nutritional supplement.

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.

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 was interpreted as a major breakthrough as 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[27].

Thus, the Court first analyzed the concept of a 'commercial communication' as the regulation does not contain a definition. For this purpose, the court used definitions present in other areas of EU law, used as a guide in order to ensure consistency of EU law[28]. The court conclude that 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[29]. Such a communication may also take the form of an *advertising document which food business operators address to health professionals*[30]. In addition, the court affirmed that the regulation *makes no distinction according to whether that addressee is a final consumer or a health professional*[31].

Another reason was that health professionals risk forwarding, in all good faith, incorrect information on foods which are the subject of a commercial communication to final consumers[32].

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[33].

Some authors question whether it is possible to communicate scientific information without falling foul of Regulation No 1924/2006? Although the judgment in question allows economic operators to communicate objective information about new scientific advances to health professionals if such communications are of a non-commercial nature, it does not offer any criteria for use in defining the meaning of "objective information", or in which cases

[21] Judgment of 6 September 2012, Deutsches Weintor, Case C–544/10, ECLI:EU:C:2012:526, para 54.
[22] Ibid, para. 58.
[23] Judgment of 17 December 2015, Neptune Distribution, Case C-157/14, ECLI:EU:C:2015:82.
[24] Ibid para 37.
[25] Ibid. para 74.
[26] Judgment of 14 July 2016, *Verband Sozialer Wettbewerb eV v Innova Vital GmbH*, C-19/15, ECLI:EU:C:2016:563.
[27] Morpurgo, M., & Botana, P. (2016). The Nutrition and Health Claims Regulation Applies to Commercial Communications Addressed to Health Professionals. European Journal of Risk Regulation, 7(3), 634-641.
[28] Judgment of the Court of 14 July 2016, Innova Vital GmbH, Case C-19/15, ECLI:EU:C:2016:563, para.25.
[29] Ibid, para.29.
[30] Ibid, para.30.
[31] Ibid, para.31.
[32] Ibid. para 45.
[33] Judgment of the Court of 14 July 2016, Innova Vital GmbH, Case C-19/15, ECLI:EU:C:2016:563, para.47.

industry communications to health professionals are of a "commercial nature"[34].

Thus, the EU regulation is regarded as focusing relatively strongly on precaution and consumer understanding. The extent to which this hampers food innovations is in dispute[35].

In the case *Herbaria Kräuterparadies*[36], the relevant question was whether the EU law required minerals and vitamins to be *added to foodstuffs labelled as having a specific nutritional and health function*.

Herbaria manufactures 'Herbaria Blutquick — Eisen + Vitamine', a fruit juice mixture with herbal extracts which contains, in addition to plant ingredients of organic agricultural origin, non-organic vitamins and ferrous gluconate. Blutquick is advertised and marketed as a food supplement containing iron and vitamins, and its label bears a reference to organic production, together with the claim: 'Iron supports the normal formation of red blood cells and haemoglobin'.

The competent Bavarian authorities ordered Herbaria to remove the reference to organic farming in the labelling, advertising and marketing of Blutquick[37]. Herbaria took the view that Regulation No 1924/2006, required minerals and vitamins to be added to foodstuffs labelled as having a specific nutritional function. The stated purpose of a food supplement was the basis for the legal obligation to achieve the corresponding minimum values and that if those values could be achieved only by addition of substances, the addition was legally required[38].

However, the Court decide that it is for economic operators to determine the composition of their products and to decide how they want to portray them for marketing purposes. If they wish to market those products as a food supplement coming under Directive 2002/46, with nutrition or health claims as covered by Regulations 1924/2006 and 432/2012, or as a foodstuff intended for a particular nutritional use coming within the scope of Directive 2009/39 and Regulation No 953/2009, they must fulfil the relevant obligations laid down by the applicable EU rules. EU law does not guarantee that an economic operator will be allowed to market its products using any terms it finds to be most advantageous for promoting them[39].

In the light of the fact that the marketing of a foodstuff as a food supplement with nutrition or health claims is optional the Court rejected Herbaria arguments.

3.3. Definition of health claims

The definition of health claims was examined in cases *Deutsches Weintor*[40], *Green-Swan Pharmaceuticals*[41]*and Nelsons v. Ayonnax Nutripharm, Bachblütentreff*[42].

It is worth noting that the court sets as the starting-point for the definition of a 'health claim' within the meaning of that regulation the *relationship* that must exist between a *food or one of its constituents and health*.

On the one hand, that definition provides no information as to whether that relationship must be direct or indirect, or as to its intensity or duration. In those circumstances, the court understand the term '*relationship*' in a broad sense[43]. On the other hand, the concept of a 'health claim' must cover not only a relationship implying an *improvement* in health as a result of the consumption of a food, but also any relationship which implies the absence or reduction of effects that are adverse or *harmful* to health and which would otherwise accompany or follow such consumption, and, therefore, the mere preservation of a good state of health despite that potentially harmful consumption[44].

Accordingly, the concept of a 'health claim' is deemed to refer not only to the *effects* of the consumption – in a specific instance – of a precise quantity of a food which is likely, normally, to have only *temporary* or fleeting effects, but also to those of the *repeated, regular, even frequent* consumption of such a food, the effects of which are, by contrast, not necessarily only temporary and fleeting[45].

In case *Green-Swan Pharmaceuticals*, the court considered that a 'health claim' within the meaning of Article 2(2)(5) of Regulation No 1924/2006 on nutrition and health claims made on foods is the relationship that must exist between a food or one of its constituents and health; that definition provides no information as to whether that relationship must be direct or indirect, or as to its intensity or duration, so that the term 'relationship' must be understood in a broad sense.

In that context, in order to be considered a 'reduction of disease risk claim', a health claim need

[34] Luis González Vaqué, Silvia Bañares Vilella And Sebastián Romero Melchor. 2016. "The European Court of Justice Declares That Regulation No 1924/2006 Applies to Health Claims Directed at Health Professionals: The Verband Sozialer Wettbewerb eV Judgment (Case C-15/19)." *European Food and Feed Law Review* 11 (6): 508–19.

[35] Aschemann-Witzel, Jessica. 2011. "The EU Health Claim Regulation in International Comparison: Review of the Possible Impact on Food Marketing and Consumer Protection." *CAB Reviews: Perspectives in Agriculture, Veterinary Science, Nutrition and Natural Resources* 6 (33): 1–7.

[36] Judgment of the Court of 5 November 2014, *Herbaria Kräuterparadies*, Case C-137/13, ECLI:EU:C:2014:2335.

[37] Ibid, para 19-21.

[38] Ibid, para 22.

[39] Judgment of the Court of 5 November 2014, Herbaria Kräuterparadies, Case C-137/13, ECLI:EU:C:2014:2335, para 46.

[40] Judgment of 6 September 2012, Deutsches Weintor, Case C–544/10, ECLI:EU:C:2012:526.

[41] Judgment of the Court of 18 July 2013, Green-Swan Pharmaceuticals, Case C‑299/12, ECLI:EU:C:2013:501.

[42] Judgment of 23 November 2016, Nelsons v. Ayonnax Nutripharm, Bachblütentreff, Case C 177/15, ECLI:EU:C:2016:888.

[43] Judgment of 6 September 2012, Deutsches Weintor, Case C–544/10, ECLI:EU:C:2012:526, para. 34.

[44] Ibid, para. 35.

[45] Judgment of 6 September 2012, Deutsches Weintor, Case C–544/10, ECLI:EU:C:2012:526, para. 36.

not necessarily expressly state that the consumption of a category of food, a food or one of its constituents 'significantly' reduces a risk factor in the development of a human disease[46].

4. Concluding remarks

It is evident form the Court case law, that in striking a fair balance between various fundamental rights protected by the Union legal order, it favors both health and consumer protection. As regards the freedom to choose an occupation and the freedom to conduct a business the court reveals the possibility to restrict *the exercise* of those freedoms, if those restrictions correspond to objectives of general interest pursued by the European Union and do not constitute, with regard to the aim pursued, a disproportionate and intolerable interference, impairing the very *substance* of those rights.

Moreover, the court concludes that protection of human health is a question of general interest which may justify limitations on the freedom of expression and information of a person carrying on a business or his freedom to conduct a business

In one interesting decision, the court affirmed that the regulation makes no distinction according to whether that addressee is a final consumer or a health professional. Accordingly the EU regulation is regarded as focusing relatively strongly on precaution and consumer understanding.

It is worth noting that the definition of a 'health claim' within the meaning of that regulation is the relationship that must exist between a food or one of its constituents and health. The definition provides no information as to whether that relationship must be direct or indirect, or as to its intensity or duration In those circumstances, the court understand the term 'relationship' in a broad sense.

The literature affirms that the application of EU law to areas traditionally reserved to the Member States may produce a spillover effect[47] Member states have carefully isolated health services and policy from the EU since its inception, granting only narrow responsibilities and weak tools relevant to marginal areas of policy. Yet, today, the EU is emerging as one of the formative influences in health policy. The result is systematic encroachments on health policy by the EU, driven by the Court and justified by internal market rules and decisions.[48]

The case law in the field of health claims can be consider a contribution to the analysing of the theories of European integration and the role the Court plays.

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[46] Judgment of the Court of 18 July 2013, Green-Swan Pharmaceuticals, Case C‑299/12, ECLI:EU:C:2013:501, operative part 1.

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- Council Directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption;
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