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CASE NOTES

Health Claims on Botanical Substances Prohibited Pending Commission Evaluation: Case C–386/23, Novel Nutriology [2025] ECLI:EU:C:2025:304

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Abstract

The Court of Justice of the European Union (CJEU) ruled that health claims relating to botanical substances cannot be used in commercial advertising without prior authorisation, even during the prolonged suspension of the European Commission's evaluation process. In Case C-386/23, Novel Nutriology, the Court clarified that Article 10(1) and (3) of Regulation (EC) No 1924/2006 (Nutrition and Health Claims Regulation, NHCR) maintains its prohibition on unauthorised health claims regardless of administrative delays in the assessment process. The judgment provides guidance for food business operators marketing botanical products and highlights ongoing regulatory challenges in balancing consumer protection with commercial interests. This case note examines the Court's reasoning, situates the decision within broader CJEU case law, and explores potential regulatory reforms to address the persistent impasse surrounding botanical health claims in European Union (EU) food law.

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, pp. 9–25

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I. Facts

Novel Nutriology is a German company that marketed a food supplement containing saffron extract and melon juice extract.[1] The company advertised this product on its website using specific health-related claims about these botanical substances. The disputed claims included "mood-enhancing saffron extract," detailed assertions about a study showing that 77 per cent of subjects experienced improved emotional balance and felt more optimistic after two weeks of using 30 mg of Safr'Inside daily, and claims that melon juice extract with superoxide dismutase activity reduced stress and fatigue by 63 per cent after four weeks.[2]

Verband Sozialer Wettbewerb eV (VSW), a German trade association with the statutory task of defending its members' commercial interests, challenged these marketing practices. On 23 October 2019, VSW gave Novel Nutriology formal notice to cease using

[1] Case C-386/23 *Novel Nutriology GmbH v Verband Sozialer Wettbewerb eV* [2025] ECLI:EU:C:2025:304, para 24.
[2] Ibid.

these claims, arguing that they violated Article 10 of the Regulation (EC) No 1924/2006 (Nutrition and Health Claims Regulation, NHCR).[3] VSW contended that Article 10 prohibits health claims unless they are included in the lists of authorised claims established under Articles 13 and 14 of the NHCR.

Importantly, the evaluation process for botanical substance health claims has been suspended by the European Commission for several years. Although Article 13(3) of the NHCR required the Commission to consult the European Food Safety Authority (EFSA) and adopt lists of authorised health claims by 31 January 2010, the Commission acknowledged that "the evaluation of health claims relating to botanical substances has been suspended and the list of such claims has not yet been drawn up."[4]

When Novel Nutriology failed to comply with the formal notice, VSW brought proceedings before the Landgericht Hamburg (Regional Court, Hamburg) seeking an injunction to prohibit the company from promoting its product using the contested claims.[5] The Regional Court upheld the action, and Novel Nutriology's subsequent appeal to the Oberlandesgericht Hamburg (Higher Regional Court, Hamburg) was dismissed.[6]

During the subsequent court proceedings, lower German courts ruled against Novel Nutriology declaring their health claims illegal.[7] The case then moved up to Germany's highest court, which sought guidance from the Court of Justice of the European Union (CJEU, hereinafter also referred to as the Court). Essentially, the German court asked whether companies could use health claims for plant-based products without official approval while waiting for EFSA's assessment and the European Commission's review for inclusion on approved lists.[8]

In his Opinion of 17 October 2024, Advocate General Rantos recommended the Court respond to this question in the negative, except where claims might qualify for temporary use under Article 28 of the NHCR.[9] Rantos reasoned that the NHCR establishes a complete framework requiring scientific validation and official approval before health claims can appear in marketing materials.

In particular, Rantos argued that the European Commission's decision to pause reviewing botanical claims does not free companies from regulatory obligations.[10] While this regulatory standstill deserves criticism and could potentially lead to legal action against the Commission for inaction,[11] the Advocate General pointed out that the NHCR contains interim measures permitting certain claims to remain in use during the evaluation period.[12]

In this respect, Article 28(6) allows health claims beyond those describing "a nutrient's or substance's role in growth, development and bodily functions" (Article 13) to continue if they were previously approved by a Member State and, crucially, if applications were filed before 19 January 2008. Although the national court must ultimately decide if these conditions apply to this particular case, Rantos observed that one claim was filed too late (2009) and the other was never submitted, suggesting these interim provisions do not apply here.[13]

[3] Ibid [25].
[4] Ibid [55].
[5] Ibid [26].
[6] Ibid [27].
[7] Ibid.
[8] Ibid [42].
[9] Case C-386/23 *Novel Nutriology GmbH v Verband Sozialer Wettbewerb eV*, Opinion of AG Rantos [2024] ECLI:EU:C:2024:897, para 54.
[10] Ibid [38–39].
[11] Ibid [36].
[12] Ibid [45].
[13] Ibid [50–51].

II. Judgment

The CJEU delivered its judgment on 30 April 2025, ruling that health claims about botanical substances cannot be made without authorisation pending Commission evaluation, unless permitted under transitional provisions. The judgment opens by reconstructing the normative framework created by the NHCR. It confirms that Article 10(1) "lays down a prohibition in principle of health claims, with the exception of those included in the lists of authorised claims referred to in Article 13 or 14 of that regulation."[14] Furthermore, Article 10(3) requires that "any reference to general, non-specific health benefits of a nutrient or food must be accompanied by a specific health claim included in the lists provided for in Article 13 or 14 of that regulation."[15]

The Court emphasised that this creates a binary system where "the use of a specific health claim is permitted only if it is included in one of the lists of authorised health claims provided for in Article 13(3) and Article 14(1) of that regulation, whereas any general health claim must be accompanied by such a specific claim."[16]

Addressing the central question, the Court acknowledged that the Commission had suspended the evaluation process. At the same time, it held that this did not exempt botanical substance claims from regulatory requirements. The Court noted that "health claims the consideration of which has not yet been completed will remain published on the website of Commission and may continue to be used in accordance with the transitional measures provided for in Article 28(5) and (6) of the NHCR."[17]

However, the Court held that Novel Nutriology cannot benefit from these transitional provisions. Under Article 28(6)(b), health claims describing psychological or behavioural functions "may continue to be used provided that an application was submitted in accordance with that regulation before 19 January 2008."[18] Since Novel Nutriology had submitted one claim late and no application for the other, "the use of claims such as those at issue in the main proceedings cannot be permitted under the transitional regime provided for in Article 28(6)."[19]

The Court grounded its interpretation in the NHCR's objectives, stating that it "seeks to ensure the effective functioning of the internal market while providing a high level of consumer protection, in particular against misleading claims."[20] The Court emphasised that "the use of health claims should only be authorised in the European Union after a scientific assessment of the highest possible standard" conducted by EFSA.[21]

Regarding potential interference with freedom to conduct business under Article 16 of the Charter, the Court acknowledged this concern yet holds that such freedom "is not absolute but must be viewed in relation to its social function."[22] Crucially, the Court stated that "the objective of the protection of health takes precedence over economic considerations, the importance of that objective being such as to justify even substantial negative economic consequences."[23]

The Court held that the prohibition achieves "a fair balance between the fundamental rights which must be reconciled, without disproportionately impairing the legitimate right of economic operators in the food sector to pursue their entrepreneurial activity."[24]

[14] *Novel Nutriology* (n 1), para 47.
[15] Ibid [48].
[16] Ibid [50].
[17] Ibid [56].
[18] Ibid [59].
[19] Ibid [61].
[20] Ibid [63].
[21] Ibid [65].
[22] Ibid [68].
[23] Ibid [75].
[24] Ibid [76].

The restriction is justified because it merely prohibited promotion through unauthorised health claims rather than preventing the marketing of botanical products entirely.[25]

III. Comment

Prior to this judgment, the Commission's prolonged suspension of botanical substance evaluations had created a legal vacuum that different national courts were interpreting inconsistently. In the German legal system, in particular, two competing interpretations of the NHCR's requirements had emerged. The first interpretation, adopted by some German courts, argued that Article 10(3) is not applicable in such circumstances. This is because the Commission and EFSA have indefinitely suspended the examination of health claims relating to botanical substances, making it impossible for food business operators (FBOs) to obtain decisions on specific health claims.[26]

Conversely, the second interpretation, predominant among German courts,[27] maintained that Article 10(3) remains applicable to botanical substances. This view emphasises that completely exempting botanical substances from these restrictions would risk consumer confusion between food supplements and medicinal products, allowing the continued use of untested health claims.

This regulatory uncertainty created problematic consequences for consumer understanding. The scale of this problem becomes apparent when considering that Member States submitted approximately 44,000 health claim proposals by January 2008, which, after removing duplications, resulted in about 4,600 unique proposals requiring evaluation.[28] The botanical claims constitute a significant portion of the unresolved cases from this massive submission.[29]

This regulatory uncertainty also risked distorting market competition. FBOs dealing with botanical substances faced an environment where compliance strategies could vary significantly between Member States, undermining the NHCR's goal of creating a level playing field across the EU.

Against this backdrop, the judgment provides much-needed clarity. The judgment establishes that the NHCR's prohibition on unauthorised health claims operates independently of the Commission's administrative progress in completing evaluations. The Court's overall reasoning is consistent with its previous case law in this area. The judgment echoes the rigorous approach taken in Case C-524/18, *Dr. William Schwabe*, where the Court strictly interpreted the requirements for linking generic and specific health claims.[30] Similarly, the principle that public health considerations take precedence over economic interests reflects the Court's position in cases such as C-452/20, *Agenzia delle dogane e dei monopoli*,[31] and C–151/17, *Swedish Match*.[32]

[25] Ibid [71].

[26] *Novel Nutriology*, Opinion of AG Rantos (n 9), para 20.

[27] Ibid [22].

[28] H Verhagen and H van Loveren, "Status of Nutrition and Health Claims in Europe by mid 2015" (2016) 56 Trends in Food Science & Technology 39.

[29] Ibid.

[30] Case C-524/18 Dr. Willmar Schwabe GmbH & Co. KG v Queisser Pharma GmbH & Co. KG [2020] ECLI:EU:C:2020:60. H Schebesta, "On Legal Value of Implementing Acts at the CJEU Case Note on Schwabe/Queisser Pharma (C-524/18)" (2020) 6 Journal of European Consumer and Market Law 248.

[31] Case C-452/20 *PJ v Agenzia delle dogane e dei monopoli — Ufficio dei monopoli per la Toscana* [2022] ECLI:EU:C:2022:111. F Masci, "Il bilanciamento tra diritto alla salute e libertà d'iniziativa economica nell'ordinamento dell'UE, ovvero della nuova gerarchia di valori disegnata dalla CGUE in conformità al Trattato di Lisbona" (2022) 52(2) DPCE Online.

[32] Case C-151/17 *Swedish Match AB v Secretary of State for Health* [2018] ECLI:EU:C:2018:938. V Delhomme, "The Ban on Tobacco for Oral Use Upheld by the Court of Justice: On Subsidiarity and Proportionality in EU Lifestyle Risks

The Court's commitment to consumer protection and the maintenance of high scientific standards for health claims is commendable. This strict interpretation reflects the core function of the NHCR, which was designed to eliminate the information asymmetry between producers and consumers. The NHCR establishes that all claims concerning nutritional or health benefits must be authorised before any use, with all unauthorised claims being prohibited regardless of available supporting literature. According to the Court, allowing unauthorised claims during administrative delays would undermine the entire regulatory framework and potentially expose consumers to misleading or unsubstantiated health claims.

The Court's reasoning reflects the application of the precautionary principle, which allows regulatory authorities to take protective measures when scientific evidence is incomplete but potential risks to health exist.[33] Under this principle, regulators may restrict activities even when scientific uncertainty persists, provided that the measures are proportionate to the potential risk and subject to review as new evidence emerges.[34] In the context of botanical health claims, the precautionary principle supports maintaining the prohibition on unauthorised claims until proper scientific evaluation can be completed, protecting consumers from potentially misleading information.

However, the judgment highlights a regulatory problem that has persisted throughout the history of the NHCR. The prolonged failure of the Commission to finalise the evaluation of health claims on botanical substances arguably serves neither economic nor public health purposes optimally. The Regulatory Fitness and Performance Programme (REFIT) evaluation identified the botanical claims issue as one of the two main reasons why the NHCR currently fails to completely reach its objectives.[35]

This regulatory *impasse* stems from challenges in applying conventional evidence standards to botanical products. The scientific requirements established by EFSA demand that health claims be substantiated by the "highest scientific standard," typically requiring "placebo-controlled randomised control trials."[36] Research shows that foods often work in subtle ways and affect multiple parts of the body at once.[37] Current testing methods focus on one ingredient affecting one specific area, but food products may actually help the body in several different ways. Because these benefits are often mild, scientific studies might not detect them even though people notice positive effects when they eat these foods regularly.[38]

Additionally, current evidence requirements may create financial barriers for small and medium enterprises seeking authorisation for botanical health claims.[39] This economic dimension may exclude smaller companies from the market for authorised health claims,[40] contributing to market concentration that serves neither innovation nor consumer choice.

Policy: Case C-151/17, *Swedish Match AB v Secretary of State for Health*" (2019) 1 European Journal of Risk Regulation 227.

[33] Commission, "Communication from the Commission on the Precautionary Principle" COM (2000) 1 final, section 3.

[34] Ibid.

[35] A de Boer, "Fifteen Years of Regulating Nutrition and Health Claims in Europe: The Past, the Present and the Future" (2021) 13(5) Nutrients 1725.

[36] "As risk assessor, EFSA is responsible for ensuring the highest scientific standard in risk assessment. At this point, placebo-controlled randomised control trials are considered to be the highest scientific standard" (KGM Lenssen, A Bast and A de Boer, "Should Botanical Health Claims Be Substantiated with Evidence on Traditional Use? Reviewing the Stakeholders' Arguments" (2020) 14 PharmaNutrition 100232).

[37] A de Boer, E Vos and A Bast, "Implementation of the Nutrition and Health Claim Regulation–The Case of Antioxidants" (2014) 68 Regulatory Toxicology and Pharmacology 475.

[38] A Bast, W Briggs and E Calabrese, "Scientism, Legalism and Precaution-Contending with Regulating Nutrition and Health Claims in Europe" (2013) 6 European Food and Feed Law Review 401.

[39] Ibid.

[40] Ibid.

Furthermore, a regulatory anomaly exists where botanical substances may be evaluated under different evidential frameworks depending on their regulatory classification. Traditional herbal medicinal products under Directive 2001/83/EC may rely on traditional use evidence under certain circumstances,[41] while identical botanical substances in food products face stricter evidentiary requirements under the NHCR. This creates inconsistency in how traditional knowledge is valued across different regulatory domains.

These regulatory and economic considerations have prompted stakeholders to debate whether well-documented traditional knowledge should receive some recognition in the health claims authorisation process. The European Commission's REFIT consultation process exposed significant divisions among stakeholders, with industry associations largely supporting traditional use evidence while consumer protection groups and pharmaceutical representatives opposing it.[42]

Stakeholders supporting traditional use evidence argue that withholding information about traditional benefits may not serve consumer interests, whereas opponents contend that claims not substantiated by controlled trials may mislead consumers.[43] Consumer research indicates that the reality is more nuanced than either position suggests.[44] Consumers demonstrate limited understanding of health claims generally,[45] highlighting the need for clearer communication strategies regardless of the evidential basis for claims.

Based on these considerations, the analysis points towards developing more nuanced regulatory approaches. Examples of alternative frameworks can be found in several non-European legal systems. For instance, Japan's Food for Specified Health Uses (FOSHU) system, established in 1991, evaluates foods and supplements making health claims through a process that considers both scientific evidence and traditional usage patterns,[46] where substances with established historical use may require less extensive clinical testing than novel ingredients.[47] Similarly, Canada's Natural Health Products Regulations establish requirements for botanicals and other natural health products that are "proportionate to the nature of the products and their historical use patterns."[48] The United States allows qualified health claims based on credible scientific evidence that may include various forms of research, accompanied by disclaimers indicating the quality of supporting evidence.[49] These diverse approaches suggest that addressing the regulatory impasse

[41] See Article 16a(1) of Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use, as amended.

[42] Lenssen, Bast and de Boer (n 36). M Christodoulou, "Study Supporting the Evaluation of: a) Regulation (EC) No 1924/2006 on Nutrition and Health Claims Made on Food with Regard to Nutrient Profiles and Health Claims Made on Plants and Their Preparations, and of b) the General Regulatory Framework for Their Use in Foods" (Agra CEAS Consulting, July 2018) 5.

[43] Lenssen, Bast and de Boer (n 36).

[44] L Lähteenmäki, "Claiming Health in Food Products" (2013) 27(2) Food Quality and Preference 196; JM Wills and Others, "European Consumers and Health Claims: Attitudes, Understanding and Purchasing Behaviour" (2012) 71(2) Proceedings of the Nutrition Society 229; KG Grunert, J Scholderer and M Rogeaux, "Determinants of Consumer Understanding of Health Claims" (2011) 56(2) Appetite 269; S Khedkar, L Carraresi and S Bröring, "Food or Pharmaceuticals? Consumers' Perception of Health-Related Borderline Products" (2017) 5(4) PharmaNutrition 133.

[45] Lenssen, Bast and de Boer (n 36).

[46] Verhagen and van Loveren, "Status of Nutrition and Health Claims in Europe by mid 2015" (n 28) 39.

[47] Ibid.

[48] A Kušar and Others, "Comparison of Requirements for Using Health Claims on Foods in the European Union, the USA, Canada, and Australia/New Zealand" (2021) 20(2) Comprehensive Reviews in Food Science and Food Safety 1307.

[49] Since wordings of such disclaimers are complex, their usefulness for consumers is questionable (CM Hasler, "Health Claims in the United States: An Aid to the Public or a Source of Confusion?" (2008) 138(6) Journal of Nutrition 1216S).

surrounding botanical health claims may require comprehensive reconsideration of how EU food law can accommodate different forms of evidence while maintaining consumer protection.

Competing interests. The author(s) declare none.

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