European Journal of Risk Regulation (2026), 1–8
doi:10.1017/err.2026.10099

CAMBRIDGE UNIVERSITY PRESS

CASE NOTES

SALUS Case: Organic Medicinal Herbal Teas Cannot be Labelled as Organic

Alexandra Molitorisová[1,2] and Aleksandra Hubar-Kołodziejczyk[1]

[1]Chair of Food Law, University of Bayreuth, Germany and [2]Faculty of Law, University of Passau, Germany

Corresponding author: Alexandra Molitorisová; Email: alexandra.molitorisova@uni-bayreuth.de

Abstract

A medicinal herbal tea classified as a traditional herbal medicinal product cannot, in principle, be marketed with the organic logo. The position may be otherwise where such an indication on the packaging has been approved by the competent authority on account of the beneficial effect of the organic production on the therapeutic characteristics of the medicinal product.

Keywords: Labelling; organic production; traditional herbal medicinal product

Legislation

Article 1(29), Article 16a, Article 62 Directive 2001/83/EC on the Community Code Relating to Medicinal Products for Human Use, last amended by Directive 2004/27/EC, OJ L – 311, of 28.11.2004, pp. 67–128, Article 2(1), Article 33 Regulation (EU) 2018/848 of the European Parliament and of the Council of 30 May 2018 on organic production and labelling of organic products and repealing Council Regulation (EC) No 834/2007, OJ L 105 14.11.2018, pp. 1-92.

I. Facts

The dispute[1] arose in private enforcement proceedings (the so-called *Unterlassungsklage*) under the German *Gesetz über den Verkehr mit Arzneimitteln* (Arzneimittelgesetz, "AMG") (Law on the Marketing of Medicinal Products), which transposes Directive 2001/83/EC on the Community code relating to medicinal products for human use ("Directive").[2] Two companies, SALUS and Twardy, market traditional herbal medicinal products. SALUS's products include sage leaves as well as *Alchemilla* (the so-called lady's mantle plant), the outer packaging of which featured the EU official organic production logo, the control body number,[3] and information indicating that the product originates from non-EU agriculture or EU farming.

Twardy brought an action against SALUS before the *Landgericht Düsseldorf*, alleging a violation of the fifth sentence of Article 10(1) AMG and seeking an order prohibiting SALUS

[1] Case C-618/23 *SALUS* [2025] ECLI:EU:C:2025:485.

[2] 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, OJ L 311 28.11.2001, pp 67–128.

[3] On this a recent case Case C-745/24 Verband Sozialer Wettbewerb eV v GLOBUS Handelshof GmbH & Co. KG. ECLI:EU:C:2025:1030.

from marketing medicinal herbal teas bearing indications of the organic origin of the plants. The *Landgericht Düsseldorf* granted the requested order, but SALUS appealed the judgment to the *Oberlandesgericht Düsseldorf* (Higher Regional Court, Düsseldorf, Germany).

The *Oberlandesgericht* referred several questions to the Court of Justice of the European Union ("CJEU") concerning the relationship between the Directive and the Organic Production Regulation. First, the referring court asked whether plant-based traditional herbal preparations within the meaning of Article 2(1) of the Organic Production Regulation include medicinal herbal teas.[4] The referring court observed that the scope of the Organic Production Regulation extends beyond food or feed. More specifically, it asked whether information on the production methods of medicinal products, including medicinal herbal teas, could be regarded as useful to patients within the meaning of Article 62 of the Directive, in light of the importance EU law attaches to organic production. The referred question is, however, complicated by the fact that the wording of the fifth sentence of Article 10(1) AMG is closer to the original version of Article 62 of Directive 2001/83, which permitted indications that are "useful for health education," a narrower formulation than the current wording of Article 62. The referring court admitted that the interpretation adopted by the German courts, which permits only information directly useful for patients' health, "may prove to be too narrow."[5]

The case thus raised essentially two questions: one concerning further clarification of the regime governing borderline medicinal and other products, and the other concerning the application of the cumulative test for permissible information on the outer packaging and leaflets of medicinal products under Article 62 of the Directive.

II. Judgment

In the first part of the judgment, the Court addressed the question of whether traditional herbal medicinal products can simultaneously be regarded as plant-based traditional herbal preparations. The CJEU clarified that products classified as "traditional herbal medicinal products" within the meaning of Article 16a(1) of the Directive cannot simultaneously be regarded as "plant-based traditional herbal preparations" within the meaning of Annex I to the Organic Production Regulation, even though the latter regulation also covers products closely linked to agricultural products. Relying on Article 2(2) of the Directive, the Court confirmed that, in cases of overlap between the definition of a medicinal product and that of a product governed by other EU legislation, the medicinal product regime takes precedence, by reason of its higher requirements and in line with the objective of ensuring a high level of protection of human health under Article 168 Treaty on the Functioning of the European Union (TFEU).

The Court added that the broad and non-targeted wording of recital 10 of the Organic Production Regulation, which extends its scope to products closely linked to agriculture, cannot be interpreted as expressing an intention to include medicinal products within that regulation in the absence of an express derogation from the exclusive regime established by the Directive. In that regard, the generic nature of the term "plant-based traditional herbal preparations" does not suffice to bring medicinal products within the scope of the Organic Production Regulation.

Furthermore, by interpreting Articles 2(4) and 2(5) of the Organic Production Regulation, read in conjunction with recital 16 thereof, the Court specified that the Directive constitutes "other specific Union law relating to the placing of products on the

[4] Regulation (EU) 2018/848 of the European Parliament and of the Council of 30 May 2018 on organic production and labelling of organic products and repealing Council Regulation (EC) No 834/2007, OJ L 105 14.11.2018, pp 1–92.

[5] Case C-618/23 *SALUS* [2025] ECLI:EU:C:2025:485, para. 34.

market," even though it is not expressly listed in Article 2(5) of that regulation. Consequently, the Organic Production Regulation applies without prejudice to the medicinal products framework. The Court also underlined that economic operators cannot rely on concurrent classifications or choose the regulatory framework most advantageous for marketing purposes.[6] Where a product falls within the concept of a medicinal product under the Directive, it must comply exclusively with that Directive and is excluded from the scope of the Organic Production Regulation.

The second part of the judgment was devoted to answering the question of whether information relating to the organic production of the active substances of traditional herbal medicinal products can be regarded as "useful to the patient" and as not being "of a promotional nature." The CJEU clarified that Article 62 of the Directive establishes a strict, cumulative test for the inclusion of optional information on the outer packaging of medicinal products.[7] This test requires that the information is reconcilable with the summary of product characteristics (SPC), useful to the patient and free of promotional elements.[8]

Furthermore, the concepts of information "useful to the patient" and "element of a promotional nature" constitute autonomous concepts of EU law, which must be interpreted uniformly in light of the wording, context and objectives of the Directive.[9] The CJEU specified that information "useful to the patient" serves to inform patients about the correct use of medicinal products, thereby contributing to the protection of public health, while excluding information liable to expose patients to irrelevant material or marketing.[10]

According to the CJEU, given the strict pre-approval regime governing the information appearing on medicinal product packaging, Article 62 must be interpreted strictly so as to exclude information that was not submitted to and approved by the competent authorities in the context of the marketing authorisation procedure. The fact that traditional herbal medicinal products are subject to a simplified registration procedure does not justify a broader interpretation of Article 62.[11] Nonetheless, the CJEU indicated that, in principle, information relating to organic production could be authorised if a producer opts for the marketing authorisation procedure and the competent authority approves a statement that organic production has beneficial effects on the medicinal product's therapeutic characteristics.[12]

The CJEU ruled that labelling elements related to organic production, as defined in the Organic Production Regulation, are to be considered promotional because they lack health value, do not align with any information in the SPC, and pertain to non-prescription medicinal products intended for direct patient use. Such information may directly influence purchasing decisions and therefore cannot be considered "useful to the patient" under Article 62 of the Directive. Accordingly, the Court concluded that information regarding the organic production of active ingredients in traditional herbal medicinal products is not useful to patients and is promotional in nature.[13]

[6] Ibid [46].
[7] Ibid [52].
[8] Ibid [52].
[9] Ibid [51].
[10] Ibid [59].
[11] Ibid [56, 60].
[12] Ibid [57].
[13] Ibid [61, 62].

III. Comment

Some herbal teas derived from the same plant may be classified as either medicinal products or foods, but they cannot fall under both categories at the same time. The Directive distinguishes broadly between two types of medicinal products: those by virtue of their presentation and those by virtue of their function.[14] These definitions are to be broadly construed.[15] The classification, therefore, depends on multiple factors, including presentation, composition, scientifically observed pharmacological properties (restoring, correcting or modifying physiological functions, significantly affecting metabolism), manner of use, extent of distribution, familiarity to consumers and risks that its use may entail.[16] As regards medicinal products by function, the mere presence of medicinal herbs (that can be used both in medicinal products and food) in the product does not prove that the product has pharmacological properties.[17] As such, peppermint tea may be considered a medicinal product by function, and marketed following an application for licensing, but may also be marketed as a food, that is, as a regular herbal tea.[18] Data important for classification are based on Community and national herbal monographs, which contain scientific opinions on the safety and efficacy of herbal substances intended for medicinal use.[19] The case-by-case assessments of the borderline products, however, may lead to divergent opinions of Member States.[20]

If a product is a food product, it clearly falls within the scope of the Organic Production Regulation. The Court's conclusion that medicinal herbal tea cannot be regarded as a product of organic production within the scope of the Organic Production Regulation should have brought the reasoning to an end. Under Article 33(1) of that regulation, the EU organic production logo may be used only in the labelling, presentation and advertising of products that comply with the regulation, that is, products falling within its scope. However, neither the Court nor the Advocate General engages with the implications of that provision. Despite the exclusive nature of the respective regulatory regimes and in light of the referring court raising the issue in a separate question, the Court found it necessary to address the use of the organic label on medicinal products.

Unlike an "original" herbal medicinal product, which must undergo an authorisation procedure, a producer of a traditional herbal medicinal tea must register the product before placing it on the market.[21] In both cases, whether an "original" herbal medicinal product or a traditional herbal medicinal product, the products have outer packaging and a leaflet. However, only in the case of the authorisation procedure does all information appearing on the packaging and leaflet require prior approval and may not be changed freely unless the producer supports the change with relevant data. A tea derived from the same plant may thus be subject to three markedly different regulatory regimes, differing

[14] Art. 1(2)(a) and (b) Directive.

[15] Case C-112/89 *Upjohn* [1991] ECR I-1703, para. 16.

[16] Case C-319/05, *Commission v Germany*, EU:C:2007:678, C-140/07, *Hecht-Pharma*, ECLI:EU:C:2009:5.

[17] Case C-88/07 *Commission v Kingdom of Spain* [2009] EU:C:2009:123, paras. 73–5.

[18] This normally depends on the strength and posology of the intended product with active markers. Depending on the product other biopharmaceutical aspects may also need to be considered. Also, national guidance lists may be applicable to determine the status of the product, such as the Swedish list of plants and plant parts unsuitable for use in food (*Förteckning över växter och växtdelar som är olämpliga I Livsmedel* (VOLM)), updated in 2010.

[19] European Medicines Agency, "European Union Monographs List Entries" <https://www.ema.europa.eu/en/human-regulatory-overview/herbal-medicinal-products/european-union-monographs-list-entries> (accessed 13 February 2026).

[20] See on the borderline issues R. Warda, K. Purnhagen and M. Molitorisová, "Has Mutual Recognition in the EU Failed? – A Legal-Empirical: Analysis on the Example of Food Supplements Containing Botanicals and Other Bioactive Substances" (2024) 47 Journal of Consumer Policy 425–44.

[21] Case C-618/23 *SALUS* [2025] ECLI:EU:C:2025:485, para 56.

in data requirements and manufacturers' obligations: a food, a traditional herbal medicinal product or an herbal medicinal product.

Although the Court held that the organic origin of the plant may not feature on the packaging or leaflet of traditional herbal medicinal teas, it appears to suggest that producers could pursue a full marketing authorisation procedure to benefit from the organic logo. This procedure, typically intended for innovative (including herbal) medicinal products, would allow them to seek approval for a claim relating to the health relevance of organic production. In practice, this is a highly unrealistic scenario, notably given further restrictions on marketisation of medicinal products. The regulatory costs associated with medicinal products are significantly higher than those incurred in the marketisation of traditional herbal medicinal products. Take, for example, the regimes governing the sale of traditional herbal medicinal teas, which are also regulated under national law. In Germany, for example, teas prepared from plants listed in the relevant legislation and marketed as chest tea, stomach tea, etc., may be sold outside pharmacies (*Verordnung für den Arzneimittelverkauf*).[22] As a result, in a supermarket, there may be tea marketed as food next to tea marketed as a medicinal product. Traditional herbal medicinal teas may also be sold in organic shops specialising in organic food products. Last but not least, they can be sold online alongside organic teas and food supplements.[23]

To complicate matters further, certain teas classified as food are intended to be marketed with health claims. However, EFSA has currently put on hold the assessment of a wide range of functional claims, including those relating to teas, pending final consideration by the Commission and the Member States.[24] As a result, botanicals[25] may not include health claims that are awaiting Commission authorisation or that fall outside a narrow transitional regime.[26] This potential avenue for the marketisation of organic teas, which are not medicinal products, may open in the future; for now, however, as suggested by the Court,[27] manufacturers of traditional herbal medicinal teas may undergo an authorisation procedure. However, as manufacturers may not opt between the organic production regulatory framework and that pertaining to pharmaceuticals, they may equally not be in a position to switch between registration and authorisation procedure, as it may be up to competent authorities only to judge whether a traditional herbal medicinal product fulfils the criteria for authorisation in accordance with Article 6 of the Directive.[28] The Court's suggestion suffers from another problem, namely, whether

[22] Verordnung über apothekenpflichtige und freiverkäufliche Arzneimittel in der Fassung der Bekanntmachung vom 24. September 1988 (BGBl. I S. 2150; 1989 I S. 254), die zuletzt durch Artikel 3 der Verordnung vom 21. Oktober 2020 (BGBl. I S. 2260) geändert worden ist.

[23] Cf. Case C-604/24 *FARMAKEIO YZ & SIA O.E.* [2025] ECLI:EU:C:2025:1007. Opinion of Advocate General Szpunar delivered on 18 December 2025.

[24] A Parziale "Health Claims on Botanical Substances Prohibited Pending Commission Evaluation: Case C–386/23, Novel Nutriology [2025] ECLI:EU:C:2025:304" (2025) 16(3) European Journal of Risk Regulation 1178–84. https://doi.org/10.1017/err.2025.10038.

[25] EU law does not provide a legal definition of "botanicals" or "botanical substances." EFSA describes them as follows: Botanicals and derived preparations made from plants, algae, fungi or lichens have become widely available on the EU market in the form of food supplements. Examples include ginkgo, garlic and ginseng. Such products are typically labelled as natural foods and a variety of claims are made regarding their possible health benefits. They can be bought over the counter in pharmacies, supermarkets, specialist shops and via the internet. While most of these products have a long history of use in Europe, some concerns exist about their safety and quality. These include the risk of chemical or microbiological contamination and the need to ensure that concentrations of active substances are within safe limits. See European Food Safety Authority, "Botanicals", <https://www.efsa.europa.eu/en/topics/topic/botanicals#efsa-page-title> (accessed on 13 February 2026).

[26] Case C-386/23 *Novel Nutriology GmbH v Verband Sozialer Wettbewerb eV* [2025] ECLI:EU:C:2025:304.

[27] Case C-618/23 *SALUS* [2025] ECLI:EU:C:2025:485, 57.

[28] Art. 16a(3) of the Directive.

claims concerning the therapeutic effects of the organic origin of a herbal tea would be successful in an actual authorisation procedure.[29]

Another issue unrecognised by the Court's judgment is the distinction between packaging/labelling and advertising under the Directive. As regards packaging, the Directive requires that information on the outer packaging and the leaflet be compatible with the SPC, useful to the patient, and not promotional in nature. The Court affirmed that such information may be more extensive than the SPC itself, as set out in Article 59(1), and the mandatory particulars prescribed by Article 54 of the Directive. However, the content must be reconcilable with the information conveyed by the SPC,[30] meaning there must be a substantive relationship between information on the packaging and that contained in the SPC. This requirement is further reinforced by the criteria of usefulness to the patient and absence of promotional character.[31]

This reasoning leads the Court to a restrictive interpretation, under which permissible information "must be information which serves to inform patients as to the correct use of medicinal products."[32] All other information may be regarded as unnecessary and therefore not useful to the patient. This would also suggest that the interpretation of German courts in similar cases, which the referring court questioned, follows the correct logic. The Court justifies this interpretation by the need to protect patients from information overload and commercial advertising, which is framed as a public health concern.[33] At the same time, perhaps despite concerns about information overload, which could lead to "purchase paralysis," the Court seems worried that consumers may be enticed by the perceived virtues of organic labelling to purchase more traditional herbal tea products than they actually need.[34] Such public health framing is significant for medicinal products available only on prescription, where medical supervision ensures appropriate use.[35] The Court now appears to extend this protective logic not only to over-the-counter medicinal products designed for use without medical supervision,[36] but also to products that national laws allow to be sold outside pharmacies.

Nonetheless, it must be acknowledged that striking an abstract balance between information that is "too much" and genuinely useful information for patients is inherently difficult.[37] The Directive does not require certain information, such as therapeutic indications, to appear in the SPC of traditional herbal medicinal products. At the same time, it requires that any advertising for such products should include a statement that they are intended for use in specified indications, based solely on long-standing use. A similar situation exists with homoeopathic medicinal products.[38]

As noted above, the provisions governing medicinal product packaging and leaflets have horizontal applicability across different classes of medicinal products. By contrast, the Directive differentiates, in the context of advertising, between medicinal products available only on prescription, whose advertising is prohibited, and other medicinal products, whose advertising is permitted only to the extent that it encourages rational use

[29] Art. 1(28a) of the Directive.
[30] Case C-618/23 *SALUS* [2025] ECLI:EU:C:2025:485, para. 52.
[31] Ibid [59].
[32] Ibid.
[33] Ibid.
[34] Ibid [60, 61].
[35] Case C-530/20 *'EUROAPTIEKA' SIA* [2022] ECLI:EU:2022:1014, para. 41.
[36] Art. 16a(1)(a) of the Directive.
[37] See also A Hubar-Kołodziejczyk and A Molitorisová, "Op-Ed: "Can the EU Organic Label Be Used on Medicinal Products Marketed in the EU? SALUS (C-618/23)" *EU Law Live*, 9 July 2025.
[38] Art. 16c(1)(a)(iii) and Article 69 of the Directive; Case C-101/19 *DHU Arzneimittel* [2020] ECLI:EU:2020:304, para. 46.

through objective presentation and without exaggerating their properties.[39] Although the Court did not address advertising directly, a question arises as to whether, for example, the placement of a traditional herbal medicinal tea in an organic shop could amount to impermissible promotion that encourages consumption beyond what is rational.[40]

Finally, the judgment raises the broader issue of the relationship between human health and organic farming methods used in the production of food and other products. The Court appears to reject any relevant connection between organic production and human health, thereby undermining the health-related arguments associated with such production methods, at least in the context of the medicinal products' labelling framework under Article 62 of the Directive. This conclusion may be supported by the legal text, as the Organic Production Regulation contains only sparse references to human health, limited primarily to general principles of non-harm.[41] However, the organic production movement has long emphasised its potential health benefits, particularly those associated with the absence of pesticides permitted in conventional farming. The Commission authorises and establishes lists of substances that may be used in organic production, which must comply with the principles of organic farming. Although these principles are primarily linked to environmental, plant and animal health considerations, the Court implicitly rejects a broader *One Health* perspective, which recognises the interconnectedness of these dimensions with human health. Finally, it might have been possible for the Court to engage with scientific evidence concerning the health value of organic production, whether by referring to existing studies demonstrating direct health benefits[42] or those examining the influence of organic food consumption on subjective well-being, even while discounting placebo effects.[43] The implications of the Court's judgments could seem at odds with some of the national courts' judgments, for example, those permitting the use of "organic" for ordinary mineral water.[44]

Altogether, the judgment codifies a long-standing position adopted in 2000 by the European Medicines Agency's Committee of Herbal Medicinal Products that "accreditation logos," such as "Kosher," "Halal" or "organic" are not acceptable as they are not "health information." Unless the legislature explicitly permits it, traditional herbal medicinal products of organic agricultural origin cannot be marketed as organic. As for now, the only permitted expressions, symbols and pictograms in some Member States appear in the so-called "blue box" and are listed in an Annex to the Commission's Guideline on the packaging information of medicinal products for human use authorised by the Community.[45] They also include a recycling green dot (*der Grüne Punkt*), as in Austria, and pictograms warning about the dangers of driving while using the medicinal product, *Amostra gratuita* (free sample), identification of generic medicinal products (MG) in Portugal, or doping in Italy, which, too, however, may seem of questionable health value.

Acknowledgments. The authors would like to thank anonymous reviewers for their valuable comments.

[39] Arts. 87(3) and 88(1)(a) of the Directive; Case C-618/23 *SALUS* [2025] ECLI:EU:C:2025:485, para. 61.

[40] Case C-618/23 *SALUS* [2025] ECLI:EU:C:2025:485, paras. 60–61.

[41] Art. 5(d) of the Organic Production Regulation.

[42] D Kumar, K Narendran V D Rajput, S Shanthakumr, M Banerjee, D Srivastava and M Shamim, "Organic Production Systems and Certification Approaches for Organic Foods, " in D Kumar, K Narendran and A Panghal (eds.) *Organic Agribusiness and Management*, Apple Academic Press (2025).

[43] V Paolaza, P Hartmann, C D'Souza, and C M. López. "Eat Organic – Feel Good? The Relationship between Organic Food Consumption, Health Concern and Subjective Wellbeing" (2018) 63 Food Quality and Preference 51–62. https://doi.org/10.1016/j.foodqual.2017.07.011.

[44] Judgment of the Federal Court of Justice of Germany (BGH) of 13 September 2012 – I ZR 230/11 – Biomineralwasser.

[45] European Commission *Guideline on the Packaging Information of Medicinal Products for Human Use Authorised by the Union*, September 2023.

Competing interests. The authors declare none.

Declaration of use of artificial intelligence. The authors used ChatGPT5 for proofreading the text. The authors reviewed and edited the content, and they take full responsibility for the content of the publication.

Cite this article: A Molitorisová and A Hubar-Kołodziejczyk, "SALUS Case: Organic Medicinal Herbal Teas Cannot be Labelled as Organic". *European Journal of Risk Regulation*. https://doi.org/10.1017/err.2026.10099