Case C-386/23

Summary of the request for a preliminary ruling pursuant to Article 98(1) of the Rules of Procedure of the Court of Justice

Date lodged:

26 June 2023

Referring court:

Bundesgerichtshof (Germany)

Date of the decision to refer:

1 June 2023

Defendant and appellant in the appeal on a point of law:

Novel Nutriology GmbH

Applicant and respondent in the appeal on a point of law:

Verband Sozialer Wettbewerb e.V.

Subject matter of the main proceedings

Action for an injunction prohibiting the advertising of a product containing plant or herbal substances with claims which the applicant considers to be impermissible health claims

Subject matter and legal basis of the request

Interpretation of EU law, Article 267 TFEU

Question referred for a preliminary ruling

May plant or herbal substances (‘botanicals’) be advertised with health claims (Article 10(1) of Regulation [EC] No 1924/2006) or with references to general, non-specific benefits of the nutrient or food for overall good health or health-related well-being (Art. 10(3) of Regulation [EC] No 1924/2006) without those claims being authorised under that Regulation and included in the list of authorised claims pursuant to Articles 13 and 14 of the Regulation (Article 10(1)

of the Regulation) or without those references being accompanied by a specific health claim contained in one of the lists referred to in Articles 13 or 14 of the Regulation (Article 10(3) of the Regulation), pending completion of the evaluation by the Authority and the examination by the Commission of the inclusion of the claims notified in respect of 'botanicals' in the Community lists referred to in Articles 13 and 14 of Regulation (EC) No 1924/2006?

Provisions of European Union law relied on

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, as amended by Commission Regulation (EU) No 1047/2012 of 8 November 2012, in particular Articles 10 and 28

Commission Regulation (EU) No 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 health, in particular recitals 10 and 11

Commission Regulation (EU) No 536/2013 of 11 June 2013 amending Regulation (EU) No 432/2012, in particular recitals 4 and 5

Provisions of national law relied on

Gesetz gegen den unlauteren Wettbewerb (German Law against unfair competition), in particular Paragraphs 3, 3a, 8 and 12

Succinct presentation of the facts and procedure in the main proceedings

1 The applicant, the Verband Sozialer Wettbewerb e.V., is a registered association whose responsibilities include the protection of the commercial interests of its members.

2 The defendant distributes the food supplement 'o'gaenics Adapto-Genie ANTI-STRESS-KOMPLEX'. It advertised that product on its website with the following claims about the substances 'saffron extract' and 'melon juice extract':

'1. mood-enhancing saffron extract.

2. The saffron extract Safr'Inside in Adapto-Genie was tested on 50 participants over a period of 30 days in an open study. With a dose of 30 mg of Safr'Inside per day, 77% of the subjects experienced an improvement in emotional balance, felt more optimistic and happier after only two weeks of use. 66% also felt more relaxed and dynamic. After 30 days, sleep quality improved in 11% of the subjects.

3. Melon juice extract with superoxide dismutase activity has been shown in studies to reduce feelings of stress and fatigue after four weeks. It also reduced irritability and fatigue by 63%, leading to a significant improvement in quality of life.'

3 The applicant considers those claims to be impermissible health claims pursuant to Article 10 of Regulation No 1924/2006. In a letter dated 23 October 2019 it therefore requested that the defendant issue an undertaking to desist. The defendant failed to comply with that request.

4 Thereupon, the applicant brought an action before the Landgericht (Regional Court, Germany) and claimed, inter alia, that the defendant should be prohibited from advertising the product 'o'gaenics Adapto-Genie ANTI-STRESS-KOMPLEX' in the course of business with the above-mentioned claims.

5 The Landgericht (Regional Court) upheld the action. The defendant's appeal against that was unsuccessful. The defendant then brought an appeal on a point of law before the referring court.

Succinct presentation of the reasoning in the request for a preliminary ruling

6 According to the referring court, the key issue in the present case is whether Article 10(1) and (3) of Regulation No 1924/2006 are applicable when plant or herbal substances ('botanicals') are advertised with health claims (Article 10(1) of Regulation No 1924/2006) or with references to general, non-specific benefits of the nutrient or food for overall good health or health-related well-being (Article 10(3) of Regulation No 1924/2006) as long as the evaluation by the Authority and the examination by the Commission on the inclusion of the claims notified for 'botanicals' in the Community lists pursuant to Article 13 and 14 of Regulation No 1924/2006 have not yet been completed (see paragraph 11 et seq. in that regard). If Article 10(1) and (3) of Regulation No 1924/2006 are not applicable, a breach of those provisions can be ruled out from the outset and the claims asserted are unmeritorious; if, on the other hand, Article 10(1) and (3) of Regulation No 1924/2006 are applicable, the claims asserted are justified on the merits because the claims complained of are in infringement of those provisions (see paragraph 22 et seq. in that regard).

A. General considerations

7 Article 10(1) of Regulation No 1924/2006 provides that health claims are to be prohibited unless they comply with the general requirements in Chapter II and the specific requirements in that Chapter and are authorised in accordance with that Regulation and included in the lists of authorised claims provided for in Articles 13 and 14 of Regulation No 1924/2006. Article 10(3) of Regulation No 1924/2006 provides that reference to general, non-specific benefits of the nutrient or food for overall good health or health-related well-being may only be

made if accompanied by a specific health claim included in the lists provided for in Article 13 or 14 of Regulation No 1924/2006.

8 Article 10(3) of Regulation No 1924/2006, as with Article 10(1) of Regulation No 1924/2006, requires a health claim; references to general, non-specific benefits of the nutrient or food for health in general or health-related well-being constitute a specific form of health claim.

9 The contested claims 'mood enhancing', 'improvement of emotional balance', 'felt more optimistic and happy', 'felt … more relaxed and dynamic', 'improved … sleep quality', 'feelings of stress and fatigue [decreased] …', 'irritability and fatigue [were] reduced by 63%' and 'significant improvement in quality of life' are health claims within the meaning of Article 1(2), points 1 and 5, Article 10(1) and (3) of Regulation No 1924/2006.

10 The distinction between Article 10(1) of Regulation No 1924/2006, on the one hand, and Article 10(3) of Regulation No 1924/2006, on the other, depends on whether the claim establishes a direct causal relationship between a food category, a food or one of its constituents and a function of the human organism, the scientific substantiation of which can be verified in an authorisation procedure (in which case it is a specific health claim within the meaning of Article 10(1) of Regulation No 1924/2006) or whether such verification is not possible (in which case it is a non-specific health claim within the meaning of Article 10(3) of Regulation No 1924/2006).

B. Applicability of Article 10(1) and (3) of Regulation No 1924/2006

11 The saffron and melon juice extracts in question are substances known as 'botanicals'. This term is commonly used to refer to plant or herbal substances (see recital 10 of Regulation No 432/2012; recital 4 of Regulation No 536/2013). The Commission of the European Union has not yet decided on the inclusion of health claims referring to 'botanicals' in the Community list of permitted claims within the meaning of Article 13(3) of Regulation No 1924/2006, but considers a further examination and consultation to be necessary (cf. recital 10 of Regulation No 432/2012; recitals 4 and 5 of Regulation No 536/2013). It is unclear whether Article 10(1) and (3) of Regulation No 1924/2006 is applicable to health claims on plant and herbal substances before the Authority's evaluation and the Commission's examination of the inclusion of the claims made regarding 'botanicals' in the Community lists pursuant to Articles 13 and 14 of Regulation No 1924/2006 have been completed.

12 However, the application of Article 10(3) of Regulation No 1924/2006 is in principle not precluded by the fact that the lists pursuant to Articles 13 and 14 of the Regulation have not yet been drawn up in full. The dissenting view is hardly compatible with the wording of Article 10(3) of Regulation No 1924/2006 or with the spirit and purpose of that provision. Moreover, it is precluded by the fact that additions are admissible in accordance with Article 13(5) of Regulation

No 1924/2006 (see Opinion of Advocate General Bobek in Case C-177/15, *Nelsons*, EU:C:2016:474, point 75 et seq.). The same applies to the application of Article 10(1) of Regulation No 1924/2006.

13 However, it is uncertain whether Article 10(1) and (3) of Regulation No 1924/2006 applies to claims whose evaluation by the Authority or examination by the Commission is on hold and not yet finalised, such as claims referring to the effects of plant or herbal substances commonly referred to as 'botanicals' and certain other health claims on whose inclusion in the list of permitted claims the Commission has not yet taken a final decision. It is not possible to give a clear answer to that question.

Status of the dispute

– *First view: Article 10(3) of Regulation No 1924/2006 is not applicable*

14 According to one view, Article 10(3) of Regulation No 1924/2006 is not applicable as long as the specific claims relating to 'botanicals' have not been evaluated by the Authority and examined by the Commission. One argument in support of that view is that the legislator considered a general ban on general, non-specific health claims to be too far-reaching. It therefore enacted only a limited prohibition. Accordingly, general health-related claims are prohibited only if they are made without the addition of specific claims contained in a list pursuant to Article 13 or 14 of Regulation No 1924/2006. However, that limited prohibition requires those lists to be drawn up. Otherwise, contrary to the intention of the legislator, which is also clearly expressed in the transitional provisions of Article 28 of Regulation No 1924/2006, the Regulation would initially contain stricter provisions than it would eventually do. Due to the suspension of the evaluation of claims for 'botanicals' by the Authority and the Commission, it is currently impossible for the advertiser to obtain a decision on specific health claims; therefore, no such claims can be added to a non-specific claim within the meaning of Article 10(3) of Regulation No 1924/2006. The deliberate decision of the legislator not to impose a general ban on non-specific health claims but only to link them to the addition of listed specific claims would be reversed by the mere decision of the Commission to refrain from drawing up lists for an entire class of substances. If that were the case, merely by refraining from drawing up the lists and not dealing with applications for registration in respect of plant or herbal substances, the resulting legal position would be one that the legislator had not intended to enact. That is why the wording of Article 10(3) of Regulation No 1924/2006 alone could not be the decisive factor. Instead, it is to be assumed that the use of general health-related claims for 'botanicals' is not regulated by the Regulation as long as the Commission remains inactive. Those principles also apply even if the advertiser has not made an application for registration of specific claims. Such an application would have no chance of success in the foreseeable future because the treatment of health claims on 'botanicals' has been put 'on hold' by the competent bodies.

15 A further argument in favour of the inapplicability of the conditions for permissibility pursuant to Article 10(1) and (3) of Regulation No 1924/2006 could be that the Commission's inaction over a number of years could be seen as a disproportionate restriction of the freedom of the undertakings concerned to conduct a business within the meaning of Article 16 of the Charter of Fundamental Rights of the European Union as well as unjustified unequal treatment compared to the advertising opportunities of competitors whose applications for the inclusion of health claims in the Community list concern substances that are being evaluated by the Authority and examined by the Commission. The Commission's failure to act for a number of years could result in the conditions for permissibility under Article 10(1) and (3) of Regulation No 1924/2006 being maintained, which could be seen as a disproportionate interference with the legally protected interests of the undertakings concerned (see judgment of the Court of Justice of 23 November 2017, *Bionorica and Diapharm* v *Commission*, C-596/15 P and C-597/15 P, EU:C:2017:886, paragraph 91 et seq.).

16 If one were to take that view, Article 10(1) and (3) of Regulation No 1924/2006 are not applicable in the present case, and the contested use of the claims at issue here is not precluded by the fact that they are not authorised under that Regulation and included in the list of authorised claims pursuant to Article 13 and 14 of Regulation No 1924/2006 (Article 10(1) of Regulation No 1924/2006) or that they are not accompanied by specific health claims included in one of the lists provided for in Article 13 or 14 of Regulation No 1924/2006 (Article 10(3) of Regulation No 1924/2006).

– *Second view: Article 10(3) of Regulation No 1924/2006 is applicable*

17 By contrast, the predominant view is that Article 10(3) of Regulation No 1924/2006 must also be applied to 'botanicals', but with the proviso that its requirements are also met if a general, non-specific reference within the meaning of that provision is accompanied by a specific health claim which, according to the Commission, has been put 'on hold' and may continue to be used subject to the conditions of Article 28(5) and (6) of Regulation No 1924/2006.

18 That view is supported by the fact that the wording of Article 10(1) and (3) of Regulation No 1924/2006 covers non-specific health claims without differentiating whether or not the claims refer to 'botanicals'.

19 Furthermore, the purpose of Article 10(1) and (3) of Regulation No 1924/2006 would seem to militate against fully exempting advertising with non-specific health claims relating to 'botanicals' from the restrictions of those provisions without first completing a scientific evaluation of the specific health claims (to be attached). According to recital 23 of the Regulation, health claims should only be authorised for use in the Community after a scientific assessment of the highest possible standard which is to be carried out by the European Food Safety Authority in order to ensure consistency. It should be taken into account that there

is a risk that consumers will not be able to distinguish between food supplements and plant or herbal medicinal products in particular and that – contrary to the intention of the legislator – the use of food supplements with untested health claims may continue to pose a health risk to patients.

20 Moreover, the Commission has indicated in recital 9 of Regulation No 536/2013 and in recital 11 of Regulation No 432/2012 that claims whose evaluation by the Authority or examination by the Commission has not yet been completed will be published on the Commission's website and may continue to be used in accordance with Article 28(5) and (6) of Regulation No 1924/2006. Thus, the legitimate interests of the advertising company in the use of health claims for 'botanicals' could have been taken into account to a sufficient degree.

21 If one were to take that view, Article 10(1) and (3) of Regulation No 1924/2006 are applicable in the present case and preclude the contested use of the claims at issue here.

C. Infringement of Article 10(1) and (3) of Regulation No 1924/2006 if applicable

I. In the event that Article 10(1) of Regulation No 1924/2006 is applicable

22 If the contested claims are to be classified as references to general, non-specific benefits of the nutrient or food for health in general or health-related well-being, they are in infringement of Article 10(3) of Regulation No 1924/2006 because they are not accompanied by a specific health claim, that is to say neither a claim included in one of the lists pursuant to Article 13 or 14 of Regulation No 1924/2006 nor a claim that has been put 'on hold' by the Commission and may continue to be used pursuant to Article 28(5) or (6) of Regulation No 1924/2006.

II. In the event that Article 10(3) of Regulation No 1924/2006 is applicable

23 If the contested claims are to be regarded as health claims within the meaning of Article 10(1) of Regulation No 1924/2006, they are in infringement of that provision for the very reason that they are neither authorised under that Regulation and included in the list of authorised claims pursuant to Articles 13 and 14 of Regulation No 1924/2006, nor are they claims that have been put 'on hold' by the Commission and allowed to continue to be used under Article 28(5) or (6) of Regulation No 1924/2006.

24 Article 28(5) of Regulation No 1924/2006 provides that, so long as the list referred to in Article 13(3) of Regulation No 1924/2006 has not been adopted, the health claims provided for in Article 13(1)(a) of Regulation No 1924/2006 may be made under the responsibility of food business operators provided that they comply with that Regulation and with existing national provisions applicable to them.

25 According to Article 28(6)(b) of Regulation No 1924/2006, health claims not covered by Article 13(1)(a) of Regulation No 1924/2006 and Article 14 of Regulation No 1924/2006 (such as claims referring to psychological or behavioural functions pursuant to Article 13(1)(b) of Regulation No 1924/2006) and which were used in compliance with national law before the entry into force of that Regulation and have not been the subject of evaluation and authorisation in a Member State, may continue to be used for six months after a decision has been taken pursuant to Article 17(3) of Regulation No 1924/2006, provided that an application under that Regulation was submitted before 19 January 2008.

26 The functions advertised are not physiological functions within the meaning of Article 13(1)(a) of Regulation No 1924/2006, but rather psychological functions within the meaning of Article 13(1)(b) of Regulation No 1924/2006. Thus, the transitional provision of Article 28(6) of Regulation No 1924/2006 is applicable. All the functions advertised in the present case have in common that they concern the emotional world. This does not count as a physiological function but rather as a psychological function.

27 An application under the Regulation within the meaning of Article 28(6)(b) of Regulation No 1924/2006 can only mean an application under Article 13(5) in conjunction with Article 18(1) of Regulation No 1924/2006. According to that provision, any food business operator intending to use a health claim not included in the Community list of permitted claims referred to in Article 13(3) of Regulation No 1924/2006 may apply for the inclusion of the claim in that list. Pursuant to Article 18(4) of Regulation No 1924/2006, a decision on that application is to be taken by the Commission after obtaining the opinion of the Authority. The reference in Article 28(6)(b) of Regulation No 1924/2006 to Article 17(3) of Regulation No 1924/2006 is probably an error on the part of the legislator.

28 In the present case, the defendant did not file an application before 19 January 2008. The defendant did not file an application for melon juice extract at all and the application filed for saffron is dated 13 January 2009.

29 It is irrelevant whether Article 28(6)(b) of Regulation No 1924/2006 must be interpreted as meaning that an application by a food business operator is not required if the claim is contained in the list provided by a Member State pursuant to Article 13(2) of Regulation No 1924/2006. The lower court found that there were no claims that were still to be examined.