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Provisional text

JUDGMENT OF THE COURT (Fifth Chamber)

30 April 2025 (*)

(Reference for a preliminary ruling – Consumer protection – Regulation (EC) No 1924/2006 – Nutrition and health claims made on foods – Article 10(1) and (3) – Specific conditions applicable to health claims – Articles 13 and 14 – Lists of authorised health claims – Article 28(5) and (6) – Transitional measures – Advertising promoting a food supplement using health claims relating to botanical substances contained in that supplement – Health claims the evaluation of which has been suspended by the European Commission – Applicability of Regulation No 1924/2006)

In Case C386/23,

REQUEST for a preliminary ruling under Article 267 TFEU from the Bundesgerichtshof (Federal Court of Justice, Germany), made by decision of 1 June 2023, received at the Court on 26 June 2023, in the proceedings

Novel Nutriology GmbH

v

Verband Sozialer Wettbewerb eV,

THE COURT (Fifth Chamber),

composed of I. Jarukaitis, President of the Fourth Chamber, acting as President of the Fifth Chamber, D. Gratsias and E. Regan (Rapporteur), Judges,

Advocate General: A. Rantos,

Registrar: N. Mundhenke, Administrator,

having regard to the written procedure and further to the hearing on 20 June 2024,

after considering the observations submitted on behalf of:

– Novel Nutriology GmbH, by T. Büttner, Rechtsanwalt,

– Verband Sozialer Wettbewerb eV, by D. Marquardt, Rechtsanwalt,

– the Greek Government, by V. Karra, E. Leftheriotou and A. Vasilopoulou, acting as Agents,

– the French Government, by M. de Lisi, H. Nunes da Silva and B. Travard, acting as Agents,

– the Italian Government, by G. Palmieri, acting as Agent, and by M. Di Benedetto, avvocato dello Stato,

– the European Commission, by B. Rous Demiri and E. Schmidt, acting as Agents,

after hearing the Opinion of the Advocate General at the sitting on 17 October 2024,

gives the following

Judgment

1 This request for a preliminary ruling concerns the interpretation of Article 10(1) and (3) and Article 28(5) and (6) of 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 2006 L 404, p. 9, and corrigendum OJ 2007 L 12, p. 3), as amended by Regulation (EC) No 109/2008 of the European Parliament and of the Council of 15 January 2008 (OJ 2008 L 39, p. 14) ('Regulation No 1924/2006').

2 The request has been made in proceedings between Novel Nutriology GmbH and Verband Sozialer Wettbewerb eV ('VSW') concerning the commercial advertising, carried out by Novel Nutriology, for the promotion of a food supplement using health claims relating to botanical substances contained in that supplement.

Legal context

European Union law

Directive 2002/46/EC

3 Article 2 of 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 (OJ 2002 L 183, p. 51) provides:

'For the purposes of this Directive:

(a) "food supplements" means foodstuffs the purpose of which is to supplement the normal diet and which are concentrated sources of nutrients or other substances with a nutritional or physiological effect, alone or in combination, marketed in dose form, namely forms such as capsules, pastilles, tablets, pills and other similar forms, sachets of powder, ampoules of liquids, drop dispensing bottles, and other similar forms of liquids and powders designed to be taken in measured small unit quantities;

…'

Regulation No 1924/2006

4 Recitals 1, 9, 14, 16, 17, 23, 24 and 35 of Regulation No 1924/2006 state:

'(1) An increasing number of foods labelled and advertised in the Community bear nutrition and health claims. In order to ensure a high level of protection for consumers and to facilitate their choice, products put on the market … should be safe and adequately labelled. …

…

(9) There is a wide range of nutrients and other substances including, but not limited to, vitamins, minerals including trace elements, amino-acids, essential fatty acids, fibre, various plants and herbal extracts with a nutritional or physiological effect that might be present in a food and be the subject of a claim. Therefore, general principles applicable to all claims made on foods should be established in order to ensure a high level of consumer protection, give the consumer the necessary information to make choices in full knowledge of the facts, as well as creating equal conditions of competition for the food industry.

…

(14) There is a wide variety of claims currently used in the labelling and advertising of foods in some Member States relating to substances that have not been shown to be beneficial or for which at present there is not sufficient scientific agreement. It is necessary to ensure that the substances for which a claim is made have been shown to have a beneficial nutritional or physiological effect.

…

(16) It is important that claims on foods can be understood by the consumer and it is appropriate to protect all consumers from misleading claims. …

(17) Scientific substantiation should be the main aspect to be taken into account for the use of nutrition and health claims and the food business operators using claims should justify them. A claim should be scientifically substantiated by taking into account the totality of the available scientific data, and by weighing the evidence.

…

(23) Health claims should only be authorised for use in the Community after a scientific assessment of the highest possible standard. In order to ensure harmonised scientific assessment of these claims, the European Food Safety Authority [(EFSA)] should carry out such assessments. Upon request the applicant should be able to have access to his file to check the state of the procedure.

(24) There are many factors, other than dietary ones, that can influence psychological and behavioural functions. Communication on these functions is thus very complex and it is difficult to convey a comprehensive, truthful and meaningful message in a short claim to be used in the labelling and advertising of foods. Therefore, it is appropriate, when using psychological and behavioural claims, to require scientific substantiation.

…

(35) Adequate transitional measures are necessary to enable food business operators to adapt to the requirements of this Regulation.'

5 Article 1 of Regulation No 1924/2006, entitled 'Subject matter and scope', provides, in paragraphs 1 and 2 thereof:

'1. This Regulation harmonises the provisions laid down by law, regulation or administrative action in Member States which relate to nutrition and health claims in order to ensure the effective functioning of the internal market whilst providing a high level of consumer protection.

2. This Regulation shall apply to nutrition and health claims made in commercial communications, whether in the labelling, presentation or advertising of foods to be delivered as such to the final consumer.

…'

6 Article 2 of the regulation, entitled 'Definitions', establishes the following:

‘1. For the purposes of this Regulation:

…

(b) the definition of “food supplement” set out in Directive [2002/46] shall apply;

…

2. The following definitions shall also apply:

…

(5) “health claim” means any claim that states, suggests or implies that a relationship exists between a food category, a food or one of its constituents and health;

…’

7 Chapter II of that regulation, entitled ‘General principles’, comprises Articles 3 to 7 thereof.

8 Under Article 3 of that regulation, entitled ‘General principles for all claims’:

‘Nutrition and health claims may be used in the labelling, presentation and advertising of foods placed on the market in the Community only if they comply with the provisions of this Regulation.

Without prejudice to Directive 2000/13/EC [of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs (OJ 2000 L 109, p. 29)] and [Council] Directive 84/450/EEC [of 10 September 1984 relating to the approximation of the laws, regulations and administrative provisions of the Member States concerning misleading advertising (OJ 1984 L 250, p. 17)], nutrition and health claims shall not:

(a) be false, ambiguous or misleading;

…’

9 Article 5 of that regulation, entitled ‘General conditions’, is worded as follows:

‘1. The use of nutrition and health claims shall only be permitted if the following conditions are fulfilled:

(a) the presence, absence or reduced content in a food or category of food of a nutrient or other substance in respect of which the claim is made has been shown to have a beneficial nutritional or physiological effect, as established by generally accepted scientific evidence;

…

2. The use of nutrition and health claims shall only be permitted if the average consumer can be expected to understand the beneficial effects as expressed in the claim.

…’

10 Article 6 of that regulation, entitled ‘Scientific substantiation for claims’, provides in paragraphs 1 and 2 thereof:

‘1. Nutrition and health claims shall be based on and substantiated by generally accepted scientific evidence.

2. A food business operator making a nutrition or health claim shall justify the use of the claim.’

11 Chapter IV of Regulation No 1924/2006, relating to health claims, includes Articles 10 to 19 of that regulation.

12 As set out in Article 10 of that regulation, entitled ‘Specific conditions’:

‘1. Health claims shall be prohibited unless they comply with the general requirements in Chapter II and the specific requirements in this Chapter and are authorised in accordance with this Regulation and included in the lists of authorised claims provided for in Articles 13 and 14.

…

3. 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.

…’

13 Article 13 of that regulation, entitled ‘Health claims other than those referring to the reduction of disease risk and to children’s development and health’, provides:

‘1. Health claims describing or referring to:

(a) the role of a nutrient or other substance in growth, development and the functions of the body; or

(b) psychological and behavioural functions; or

…

which are indicated in the list provided for in paragraph 3 may be made without undergoing the procedures laid down in Articles 15 to 19, if they are:

(i) based on generally accepted scientific evidence; and

(ii) well understood by the average consumer.

2. Member States shall provide the [European] Commission with lists of claims as referred to in paragraph 1 by 31 January 2008 at the latest accompanied by the conditions applying to them and by references to the relevant scientific justification.

3. After consulting [EFSA], the Commission shall adopt, in accordance with the regulatory procedure with scrutiny referred to in Article 25(3), a Community list, designed to amend non-essential elements of this Regulation by supplementing it, of permitted claims as referred to in paragraph 1 and all necessary conditions for the use of these claims by 31 January 2010 at the latest.

4. Any changes to the list referred to in paragraph 3, based on generally accepted scientific evidence and designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 25(3), after consulting [EFSA], on the Commission’s own initiative or following a request by a Member State.

5. Any additions of claims to the list referred to in paragraph 3 based on newly developed scientific evidence and/or which include a request for the protection of proprietary data shall be adopted following the procedure laid down in Article 18, except claims referring to children’s development and health, which shall be authorised in accordance with the procedure laid down in Articles 15, 16, 17 and 19.

14 Article 14 of that regulation, entitled ‘Reduction of disease risk claims and claims referring to children’s development and health’, is worded as follows:

‘1. Notwithstanding Article 2(1)(b) of Directive [2000/13], the following claims may be made where they have been authorised in accordance with the procedure laid down in Articles 15, 16, 17 and 19 of this

Regulation for inclusion in a Community list of such permitted claims together with all the necessary conditions for the use of these claims:

(a) reduction of disease risk claims;

(b) claims referring to children's development and health.

2. In addition to the general requirements laid down in this Regulation and the specific requirements of paragraph 1, for reduction of disease risk claims the labelling or, if no such labelling exists, the presentation or advertising shall also bear a statement indicating that the disease to which the claim is referring has multiple risk factors and that altering one of these risk factors may or may not have a beneficial effect.'

15 Article 15 of Regulation No 1924/2006, entitled 'Application for authorisation', provides in paragraph 3 thereof:

'The application shall include the following:

…

(c) a copy of the studies, including, where available, independent, peer-reviewed studies, which have been carried out with regard to the health claim and any other material which is available to demonstrate that the health claim complies with the criteria provided for in this Regulation;

…

(e) a copy of other scientific studies which are relevant to that health claim;

(f) a proposal for the wording of the health claim for which authorisation is sought including, as the case may be, specific conditions for use;

…'

16 Article 16 of that regulation, entitled 'Opinion of [EFSA]', provides in paragraphs 3 and 5 thereof:

'3. In order to prepare its opinion, [EFSA] shall verify:

(a) that the health claim is substantiated by scientific evidence;

(b) that the wording of the health claim complies with the criteria laid down in this Regulation.

…

5. [EFSA] shall forward its opinion to the Commission, the Member States and the applicant, including a report describing its assessment of the health claim and stating the reasons for its opinion and the information on which its opinion was based.'

17 Article 17 of that regulation, entitled 'Community authorisation', provides in paragraphs 1 and 5 thereof:

'1. Within two months after receiving the opinion of [EFSA], the Commission shall submit to the Committee referred to in Article 23(2) a draft decision on the lists of permitted health claims, taking into account the opinion of [EFSA], any relevant provisions of Community law and other legitimate factors relevant to the matter under consideration. Where the draft decision is not in accordance with the opinion of [EFSA], the Commission shall provide an explanation for the differences.

…

5. Health claims included in the lists provided for in Articles 13 and 14 may be used, in conformity with the conditions applying to them, by any food business operator, if they are not restricted for use in accordance with the provisions of Article 21.

…'

18 Article 18 of that regulation, entitled 'Claims referred to in Article 13(5)', is worded as follows:

'1. A food business operator intending to use a health claim not included in the list provided for in Article 13(3) may apply for the inclusion of the claim in that list.

…

3. The valid application, in line with the guidance referred to in Article 15(5), and any information supplied by the applicant shall be sent without delay to [EFSA] for a scientific assessment as well as to the Commission and the Member States for information. …

…'

19 Under Article 28 of that regulation, entitled 'Transitional measures':

'…

5. Health claims as referred to in Article 13(1)(a) may be made from the date of entry into force of this Regulation until the adoption of the list referred to in Article 13(3), under the responsibility of food business operators provided that they comply with this Regulation and with existing national provisions applicable to them, and without prejudice to the adoption of safeguard measures as referred to in Article 24.

6. Health claims other than those referred to in Article 13(1)(a) and in Article 14(1)(a), which have been used in compliance with national provisions before the date of entry into force of this Regulation, shall be subject to the following:

(a) health claims which have been the subject of evaluation and authorisation in a Member State shall be authorised as follows:

(i) Member States shall communicate to the Commission, by 31 January 2008 at the latest, such claims accompanied by a report evaluating the scientific data in support of the claim;

(ii) after consulting [EFSA], the Commission shall, in accordance with the regulatory procedure with scrutiny referred to in Article 25(3), adopt a decision concerning the health claims authorised in this way and designed to amend non-essential elements of this Regulation by supplementing it.

Health claims not authorised under this procedure may continue to be used for six months following the adoption of the Decision;

(b) health claims which have not been the subject of evaluation and authorisation in a Member State: such claims may continue to be used provided an application is made pursuant to this Regulation before 19 January 2008; health claims not authorised under this procedure may continue to be used for six months after a decision is taken pursuant to Article 17(3).'

Regulation (EU) No 432/2012

20 Recitals 10 and 11 of 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 (OJ 2012 L 136, p. 1), state:

‘(10) The Commission has identified a number of claims submitted for evaluation, referring to effects of plant or herbal substances, commonly known as “botanical” substances, for which [EFSA] has yet to complete a scientific evaluation. In addition, there are a number of health claims for which either a further evaluation is required before the Commission is able to consider their inclusion or otherwise in the list of permitted claims, or which have been evaluated, but due to other legitimate factors consideration cannot be completed by the Commission at this time.

(11) Claims whose evaluation by [EFSA] or whose consideration by the Commission has not yet been completed will be published on the website of the Commission and may continue to be used pursuant to Article 28(5) and (6) of Regulation [No 1924/2006].’

Regulation (EU) No 536/2013

21 Recital 9 of Commission Regulation (EU) No 536/2013 of 11 June 2013 amending Regulation (EU) No 432/2012 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 (OJ 2013 L 160, p. 4), states:

‘ In order to ensure transparency and legal security for all interested parties, claims the consideration of which has not yet been completed will remain published on the website of the Commission and may continue to be used pursuant to paragraphs 5 and 6 of Article 28 of Regulation [No 1924/2006].’

German law

22 Paragraph 3 of the Gesetz gegen den unlauteren Wettbewerb (Law against unfair competition) of 3 July 2004, in the version applicable to the dispute in the main proceedings, entitled ‘Prohibition of unfair commercial practices’, provides:

‘(1) Unfair commercial practices shall be prohibited.

(2) Commercial practices addressed to or reaching consumers are unfair where they do not meet the level of diligence required of undertakings and are likely to materially distort the economic behaviour of consumers.

…’

23 Paragraph 3a of that law, entitled ‘Infringement of the law’, provides:

‘A person shall be considered to be acting unfairly where he or she infringes a statutory provision that is also intended to regulate market behaviour in the interests of market participants and the infringement is liable to have a significantly adverse effect on the interests of consumers, other market participants or competitors.’

The dispute in the main proceedings and the question referred for a preliminary ruling

24 Novel Nutriology markets a food supplement (‘the product concerned’), which it advertised on its website, using the following claims relating to the ‘saffron extract’ and the ‘melon juice extract’ contained in that product:

‘1. Mood-enhancing saffron extract.

2. The saffron extract Safr’Inside in [the product concerned] 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 2 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.'

25 Taking the view that those claims are prohibited under Article 10 of Regulation No 1924/2006, VSW, a trade association governed by German law which, according to its articles of association, has the task, inter alia, of defending the commercial interests of its members, gave Novel Nutriology formal notice, by letter of 23 October 2019, to declare that it would undertake to refrain from using those claims.

26 Since Novel Nutriology did not comply with that letter of formal notice, VSW brought an action before the Landgericht Hamburg (Regional Court, Hamburg, Germany) seeking an order prohibiting Novel Nutriology, subject to a penalty payment, from promoting the product concerned in the course of trade by using the claims at issue in the main proceedings.

27 After that court upheld that action, Novel Nutriology brought an appeal against the judgment of that court before the Oberlandesgericht Hamburg (Higher Regional Court, Hamburg, Germany), which was dismissed.

28 Novel Nutriology brought an appeal on a point of law against the judgment of that court before the Bundesgerichtshof (Federal Court of Justice, Germany), which is the referring court.

29 The referring court notes, first, that, under Article 10(1) of Regulation No 1924/2006, health claims are prohibited unless they meet the general requirements set out in Chapter II of that regulation and the specific requirements set out in Chapter IV thereof, are authorised under that regulation and are included in the list of authorised claims provided for in Articles 13 and 14 thereof.

30 Second, under Article 10(3) of Regulation No 1924/2006, references to general, non-specific benefits of a nutrient or food for overall good health or health-related well-being are permitted only if that reference is accompanied by a specific health claim included in the lists of authorised claims provided for in Articles 13 and 14 of that regulation.

31 In that regard, after noting that the Oberlandesgericht Hamburg (Higher Regional Court, Hamburg) did not err in law in holding that the claims at issue in the main proceedings constituted 'health claims' within the meaning of point 5 of Article 2(2) and Article 10(1) and (3) of Regulation No 1924/2006, the referring court nevertheless states that the question whether the provisions of Article 10(1) and (3) of that regulation are applicable to health claims relating to botanical substances has not been settled, since EFSA and the Commission have not completed the examination of those claims for the purposes of their possible inclusion in the lists referred to in Articles 13 and 14 of that regulation.

32 The answer to that question is decisive in enabling the referring court to rule on the case in the main proceedings in so far as, in its view, if Article 10(1) and (3) of Regulation No 1924/2006 were applicable, VSW's request that Novel Nutriology be prohibited from promoting the product concerned by using the claims at issue in the main proceedings should be upheld on the ground that those claims are prohibited under that regulation.

33 The referring court states that, according to the interpretation adopted by some of the German courts, Article 10(3) of Regulation No 1924/2006 is not applicable in circumstances such as those in the main proceedings. The EU legislature provided only for a limited prohibition of general and non-specific health claims, under which general references to health are prohibited only if they are not accompanied by specific claims included in the lists provided for in Articles 13 and 14 of that regulation, which presupposes that those lists have been drawn up.

34 However, as a result of the suspension of the examination of health claims relating to 'botanical substances' by EFSA and the Commission, it is impossible for a food business operator to obtain a decision on specific health claims and, consequently, to be able to accompany a reference to general health by such health claims.

35 The inapplicability of those provisions for as long as the Commission's inaction continues also concerns the situation in which the person concerned has not submitted any application for the inclusion of health claims in the lists provided for in Articles 13 or 14 of Regulation No 1924/2006, since such an application would have no prospect of succeeding in the near future as a result of the suspension of the examination of health claims relating to botanical substances.

36 A further argument in favour of the inapplicability of Article 10(1) and (3) of Regulation No 1924/2006 is that the Commission's inaction over several years could be regarded as a disproportionate restriction of the freedom to conduct a business enshrined in Article 16 of the Charter of Fundamental Rights of the European Union ('the Charter'), and as an unjustified difference in treatment compared with the advertising opportunities available to competitors whose applications for the inclusion of health claims in the lists provided for in Articles 13 and 14 of that regulation concern substances evaluated by EFSA and examined by the Commission.

37 According to a second interpretation, described by the referring court as 'predominant' among the German courts, Article 10(3) of Regulation No 1924/2006 is applicable to botanical substances. However, the requirements of that provision should be regarded as being satisfied where a reference to the general benefits of such a substance is accompanied by a specific health claim which may be used under the conditions laid down in Article 28(5) and (6) of that regulation.

38 That interpretation is supported by the fact that the wording of Article 10(1) and (3) of that regulation does not make a distinction according to whether or not the health claims relate to 'botanical substances'.

39 In addition, a teleological interpretation precludes advertising using non-specific health claims relating to 'botanical substances' from being completely exempted from the restrictions laid down in Article 10(1) and (3), in the absence of a full scientific assessment of the specific health claims that must accompany them. There is a risk that consumers would not be able to distinguish between food supplements and plant-based medicinal products, and that, contrary to the intention of the EU legislature, the use of food supplements with untested health claims may continue to pose a health risk to patients.

40 Furthermore, the legitimate interest of food business operators in being able to use health claims relating to 'botanical substances' could have been sufficiently taken into account given that, in recital 11 of Regulation No 432/2012 and in recital 9 of Regulation No 536/2013, the Commission stated that health claims the consideration of which has not yet been completed will remain indicated on its website and may continue to be used pursuant to Article 28(5) and (6) of Regulation No 1924/2006.

41 Lastly, the referring court considers that the health claims at issue in the main proceedings, which relate to psychological functions, within the meaning of Article 13(1)(b) of that regulation, cannot continue to be used pursuant to Article 28(6)(b) thereof since Novel Nutriology did not submit any application for authorisation under that regulation before 19 January 2008. The Oberlandesgericht Hamburg (Higher Regional Court, Hamburg) found, without being challenged in the appeal on a point of law, that, as regards the melon juice extract contained in the product concerned, no application had been submitted by that company and that the application relating to the saffron extract used in that product dated from 13 January 2009.

42 In those circumstances, the Bundesgerichtshof (Federal Court of Justice) decided to stay the proceedings and to refer the following question to the Court of Justice for a preliminary ruling:

‘May plant or herbal substances (“[botanical substances]”) be 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) without those claims being authorised under that regulation and included in the list of authorised claims pursuant to Articles 13 and 14 of [that regulation] (Article 10(1) of [Regulation No 1924/2006]) 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 [that regulation] (Article 10(3) of [Regulation No 1924/2006]), pending completion of the evaluation by [EFSA] and the examination by the Commission of the inclusion of the claims notified in respect of “[botanical substances]” in the Community lists referred to in Articles 13 and 14 of Regulation No 1924/2006?’

Consideration of the question referred

43 By its question, the referring court asks, in essence, whether Article 10(1) and (3) of Regulation No 1924/2006 must be interpreted, in the context of commercial advertising of a food supplement composed of ‘botanical substances’ within the meaning of Regulation No 432/2012, as meaning that it is not permitted, until the Commission has completed its examination of health claims relating to botanical substances for the purposes of their inclusion in the lists of authorised health claims provided for in Articles 13 and 14 of Regulation No 1924/2006, to use specific health claims relating to such substances or to make reference to the general, non-specific benefits of such a substance for overall good health and health-related well-being without that reference being accompanied by a specific health claim included in those lists.

44 Under Article 1(2) thereof, Regulation No 1924/2006 applies to nutrition and health claims made in commercial communications of foods to be delivered as such to the final consumer, including, as is apparent from Article 2(1)(b) of that regulation, read in conjunction with Article 2(a) of Directive 2002/46, to food supplements.

45 In accordance with the first paragraph of Article 3 of Regulation No 1924/2006, such health claims may be used in the labelling, presentation and advertising of foods placed on the EU market only if they comply with the provisions of that regulation.

46 In that context, it should be noted, in the first place, that the specific requirements applicable to health claims are set out in Chapter IV of Regulation No 1924/2006, which includes Article 10(1), under which health claims are prohibited unless, first, they comply with the general requirements laid down in Chapter II of that regulation and with the specific requirements laid down in Chapter IV and, second, they are authorised in accordance with that regulation and are included in the lists of authorised claims provided for in Articles 13 and 14 thereof.

47 Article 10(1) of Regulation No 1924/2006 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 (judgment of 30 January 2020, *Dr. Willmar Schwabe*, C524/18, EU:C:2020:60, paragraph 37).

48 Furthermore, Article 10(3) of Regulation No 1924/2006 provides 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.

49 Article 10 of that regulation thus draws a distinction between two categories of health claims, namely, on the one hand, the specific health claim referred to in paragraph 1 of that article and, on the other hand, the ‘general’ health claim constituting a reference to general, non-specific benefits for overall good health, referred to in paragraph 3 of that article (see, to that effect, judgment of 30 January 2020, *Dr. Willmar Schwabe*, C524/18, EU:C:2020:60, paragraph 38 and the case-law cited).

50 It follows from the foregoing considerations that 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.

51 In the second place, it must be pointed out that the inclusion of specific health claims in those lists is subject to various authorisation procedures designed, inter alia, to ensure, as is apparent from Article 6 of that regulation, read in the light of recital 23 thereof, that those claims are scientifically substantiated.

52 As regards, in particular, health claims describing or referring to psychological or behavioural functions, which the referring court considers to be the category of claims to which the claims at issue in the main proceedings belong, Article 13(1)(b) of Regulation No 1924/2006, read in the light of recital 24 of that regulation, permits the use of such claims provided that certain conditions are met, including, first, that those claims are based on generally accepted scientific evidence and, second, that they are well understood by the average consumer.

53 The requirement that the authorised health claims describing or referring to psychological or behavioural functions be included in the list provided for in Article 13 of Regulation No 1924/2006 is therefore justified by the need to ensure that health claims are scientifically substantiated and that such claims made in commercial communications of foods to be delivered as such to final consumers are well understood.

54 In the third place, it should be noted that, in accordance with Article 13(3) of that regulation, the Commission was required to consult EFSA with a view to adopting, by 31 January 2010 at the latest, the list of authorised health claims provided for in paragraph 1 of that article.

55 However, as the Commission acknowledged at the hearing before the Court, the evaluation of health claims relating to botanical substances has been suspended and the list of such claims has not yet been drawn up.

56 In addition, recital 9 of Regulation No 536/2013 states, in essence, 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 Regulation No 1924/2006.

57 As regards, in particular, the health claims referred to in Article 13(1)(b) of Regulation No 1924/2006, which describe or refer to psychological or behavioural functions, they fall within the scope of Article 28(6) of Regulation No 1924/2006, provided that they were used in accordance with the national provisions applicable before the date of entry into force of that regulation.

58 In the present case, as is apparent from paragraph 41 of the present judgment, the referring court starts from the premiss that the specific health claims at issue in the main proceedings fall, under the transitional regime, within the scope of Article 28(6)(b) of Regulation No 1924/2006.

59 Under that provision, the health claims referred to, inter alia, in Article 13(1)(b) of Regulation No 1924/2006 which have not been the subject of an evaluation and authorisation in a Member State may continue to be used provided that an application was submitted in accordance with that regulation before 19 January 2008.

60 In the present case, however, as is apparent from paragraph 41 of the present judgment, the referring court states that one of the two claims at issue in the main proceedings was the subject of a late application under Article 28(6)(b) of Regulation No 1924/2006, whereas, for the other claim, no application has been submitted.

61 Consequently, 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) of Regulation No 1924/2006 and can be permitted only under Article 10(1) and (3) of Regulation No 1924/2006. It follows that the use of such claims cannot be permitted until the Commission has completed its examination of them.

62 Such an interpretation is all the more justified since the EU legislature expressly provided, in Article 28 of that regulation, for transitional measures which, as stated in recital 35 thereof, are intended to enable food business operators to adapt to the requirements of that regulation.

63 That interpretation is supported by the purpose of Regulation No 1924/2006, which, as stated in Article 1(1) thereof, seeks to ensure the effective functioning of the internal market while providing a high level of consumer protection, in particular against misleading claims, by facilitating his or her choice by placing safe and adequately labelled products on the market. Furthermore, according to the Court's case-law, the protection of health is among the principal aims of that regulation (judgment of 30 January 2020, *Dr. Willmar Schwabe*, C524/18, EU:C:2020:60, paragraphs 35 and 55 and the case-law cited).

64 In order to fulfil the objectives of ensuring a high level of consumer protection and protection of human health, consumers should, in particular, be given the necessary information to make a choice in full knowledge of the facts (see, to that effect, judgment of 14 July 2016, *Verband Sozialer Wettbewerb*, C19/15, EU:C:2016:563, paragraph 39 and the case-law cited).

65 Therefore, as stated in recital 23 of Regulation No 1924/2006, the use of health claims should only be authorised in the European Union after a scientific assessment of the highest possible standard which, in order to ensure a harmonised assessment, must be carried out by EFSA (see, to that effect, judgment of 30 January 2020, *Dr. Willmar Schwabe*, C524/18, EU:C:2020:60, paragraph 55).

66 In those circumstances, Article 10(1) and (3) of Regulation No 1924/2006 must be interpreted as precluding a food business operator from using health claims relating to botanical substances until the Commission has completed its examination of those claims for the purposes of their inclusion in the lists of authorised health claims, unless such use is permitted under the transitional measures laid down in that regulation.

67 That interpretation is not called into question by the principle of freedom to conduct a business, enshrined in Article 16 of the Charter.

68 In that regard, it should be recalled, first of all, that that principle, which protects the freedom to pursue an economic or commercial activity, the freedom to use, within the limits of its liability for its own acts, the economic, technical and financial resources at an undertaking's disposal and the freedom of contract (judgment of 27 June 2024, *Gestore dei Servizi Energetici*, C148/23, EU:C:2024:555, paragraph 62 and the case-law cited), is not absolute but must be viewed in relation to its social function (see, to that effect, judgment of 29 February 2024, *cdVet Naturprodukte*, C13/23, EU:C:2024:175, paragraph 38 and the case-law cited).

69 Next, Article 52(1) of the Charter accepts that limitations may be imposed on the exercise of rights and freedoms enshrined by it as long as the limitations are provided for by law, respect the essence of those rights and freedoms, and, subject to the principle of proportionality, are necessary and genuinely meet objectives of general interest recognised by the European Union or the need to protect the rights and freedoms of others.

70 Lastly, when several rights protected by the EU legal order clash, the assessment of those limitations must be carried out in accordance with the need to reconcile the requirements of the protection of those various rights and striking a fair balance between them (judgment of 29 February 2024, *cdVet Naturprodukte*, C13/23, EU:C:2024:175, paragraph 40 and the case-law cited).

71 In the present case, it should be noted, first, that the requirement that specific health claims must have been authorised in advance and that they be included in the lists provided for in Articles 13 and 14 of Regulation No 1924/2006 does not prevent food business operators marketing foods containing botanical substances from placing such foods on the market entirely, but merely prohibits them being promoted by means of health claims which have not been evaluated and authorised in advance in accordance with that regulation.

72 Furthermore, the fact that health claims relating to botanical substances cannot be the subject of such authorisation until the Commission has completed its examination of them with a view to a possible inclusion in the lists of authorised health claims does not have the effect of preventing all use of those claims. As is apparent from paragraphs 57 to 59 of the present judgment, the EU legislature has provided for transitional measures designed to grant such operators the possibility of using such claims. That is the case, in particular, for health claims which, like those at issue in the main proceedings, describe or refer to psychological or behavioural functions and which may continue to be used pursuant to Article 28(6) of Regulation No 1924/2006 subject to compliance by the operator concerned with the conditions laid down in that provision.

73 In those circumstances, as the Advocate General observed in point 43 of his Opinion, the application of Article 10(1) and (3) of Regulation No 1924/2006 to health claims relating to botanical substances which describe or refer to psychological or behavioural functions does not adversely affect the very substance of the freedom to conduct a business.

74 Second, as has been stated in paragraphs 63 to 66 of the present judgment, the prohibition on promoting foods containing botanical substances by means of health claims which have not been evaluated and authorised in advance in accordance with that regulation meets the objective of protecting human health and protecting consumers.

75 In accordance with settled case-law, 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 (judgment of 24 February 2022, *Agenzia delle dogane e dei monopoli and Ministero dell'Economia e delle Finanze*, C452/20, EU:C:2022:111, paragraph 50 and the case-law cited).

76 In the present case, it must therefore be held, as the Advocate General stated, in essence, in point 44 of his Opinion, that the prohibition on promoting foods containing botanical substances by means of health claims which describe or refer to psychological or behavioural functions, which have not been evaluated and authorised in advance in accordance with Regulation No 1924/2006, and which are also not authorised under the transitional measures provided for by that regulation, ensures 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.

77 Nor can the principle of equal treatment lead to an interpretation different from that adopted in paragraph 66 of the present judgment.

78 That principle, which is enshrined in Article 20 of the Charter, requires that comparable situations must not be treated differently and that different situations must not be treated in the same way unless such treatment is objectively justified. A difference in treatment is justified if it is based on an objective and reasonable criterion, that is, if the difference relates to a legally permitted aim pursued by the legislation in question, and it is proportionate to the aim pursued by the treatment concerned (judgment of 23 November 2023, *Seven.One Entertainment Group*, C260/22, EU:C:2023:900, paragraph 45 and the case-law cited).

79 In accordance with the case-law of the Court, the assessment as to whether situations are comparable for the purpose of determining whether that general principle has been observed must be made in the light of the objective pursued by the act containing the provision in question (see, to that effect, judgment of 29 July 2024, *HDI Global and MS Amlin Insurance*, C771/22 and C45/23, EU:C:2024:644, paragraph 84 and the case-law cited).

80 As stated in paragraph 63 of the present judgment, the objective of Regulation No 1924/2006 is to attain a high level of consumer and human health protection. Article 10(1) and (3) of that regulation contributes to achieving that objective by guaranteeing to consumers that health claims intended to promote foods have been scientifically verified in order to enable them to make their choice in full knowledge of the facts.

81 Consequently, in the light of that objective, the comparison of food business operators wishing to use health claims in order to promote the foods which they market must be established in the light of the scientifically substantiated nature of such claims.

82 It follows that, in accordance with the principle of equal treatment, all food business operators must comply with the provisions contained in Article 10(1) and (3) of Regulation No 1924/2006.

83 In the light of all the foregoing considerations, the answer to the question referred is that Article 10(1) and (3) of Regulation No 1924/2006 must be interpreted, in the context of commercial advertising of a food supplement composed of 'botanical substances' within the meaning of Regulation No 432/2012, as meaning that it is not permitted, until the Commission has completed its examination of health claims relating to botanical substances for the purposes of their inclusion in the lists of authorised health claims provided for in Articles 13 and 14 of Regulation No 1924/2006, to use specific health claims relating to such substances and describing or referring to psychological or behavioural functions, or to make reference to the general, non-specific benefits of such a substance for overall good health and health-related well-being without that reference being accompanied by a specific health claim included in those lists, unless the use of such claims is permitted under Article 28(6) of that regulation.

Costs

84 Since these proceedings are, for the parties to the main proceedings, a step in the action pending before the referring court, the decision on costs is a matter for that court. Costs incurred in submitting observations to the Court, other than the costs of those parties, are not recoverable.

On those grounds, the Court (Fifth Chamber) hereby rules:

Article 10(1) and (3) of 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 Regulation (EC) No 109/2008 of the European Parliament and of the Council of 15 January 2008,

must be interpreted, in the context of commercial advertising of a food supplement composed of 'botanical substances' within the meaning of 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, as meaning that it is not permitted, until the European Commission has completed its examination of health claims relating to botanical substances for the purposes of their inclusion in the lists of authorised health claims provided for in Articles 13 and 14 of Regulation No 1924/2006, as amended, to use specific health claims relating to such substances and describing or referring to psychological or behavioural functions, or to make reference to the general, non-specific benefits of such a substance for overall good health and health-related well-being without that reference being accompanied by a specific health claim included in those lists, unless the use of such claims is permitted under Article 28(6) of that regulation.

[Signatures]

* Language of the case: German.