ECLI:EU:C:2020:693

Provisional text
JUDGMENT OF THE COURT (Tenth Chamber)
10 September 2020 (*)
(Reference for a preliminary ruling — Food safety — Nutritional and health claims concerning foodstuffs — Regulation (EC) No 1924/2006 — Articles 5 and 6 — Scientific substantiation for claims — Generally accepted scientific evidence — Article 10(1) — Article 28(5) — Transitional arrangements — Unfair business-to-consumer commercial practices in the internal market — Directive 2005/29/EC — Article 3(4) — Relationship between the provisions of Directive 2005/29 and other EU rules regulating specific aspects of unfair commercial practices)
In Case C-363/19,
REQUEST for a preliminary ruling under Article 267 TFEU from the Patent- och marknadsdomstolen vid Stockholms tingsrätt (Patent and Market Court, District Court, Stockholm, Sweden), made by decision of 2 May 2019, received at the Court on 7 May 2019, in the proceedings
Konsumentombudsmannen
v
Mezina AB,
THE COURT (Tenth Chamber),
composed of I. Jarukaitis, President of the Chamber, E. Juhász (Rapporteur) and M. Ilešič, Judges,
Advocate General: J. Kokott,
Registrar: A. Calot Escobar,
having regard to the written procedure,
after considering the observations submitted on behalf of:
– the Konsumentombudsmannen, by I. Nyström, acting as Agent,
– Mezina AB, by K. Ladenfors and S. Hanson, advokater,
– the Greek Government, by V. Karra, G. Papadaki and E. Tsaousi, acting as Agents,
– the European Commission, by K. Simonsson, B. Rous Demiri and G. Tolstoy, acting as Agents,
having decided, after hearing the Advocate General, to proceed to judgment without an Opinion, gives the following
Judgment
1 This request for a preliminary ruling concerns the interpretation of Articles 5 and 6, read in conjunction with Article 10(1) and Article 28(5), 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 107/2008 of the European Parliament and of the Council of 15 January 2008 (OJ 2008 L 39, p. 8) (‘Regulation No 1924/2006’), and Article 3 of Directive 2005/29/EC of the European

Parliament and of the Council of 11 May 2005 concerning unfair business-to-consumer commercial practices in the internal market and amending Council Directive 84/450/EEC, Directives 97/7/EC, 98/27/EC and 2002/65/EC of the European Parliament and of the Council and Regulation (EC) No 2006/2004 of the European Parliament and of the Council ('Unfair Commercial Practices Directive') (OJ 2005 L 149, p. 22).

2 The request has been made in the context of a dispute between the Konsumentombudsmannen (Consumer Ombudsman, Sweden; 'KO') and Mezina AB concerning the conformity with EU and national law of health claims used by Mezina.

Legal context

EU law

Regulation No 1924/2006

3 Recitals 14 and 17 of Regulation No 1924/2006 read as follows:

'(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.

...

(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.'

4 Article 1 of Regulation No 1924/2006, included in Chapter I of that regulation entitled 'Subject matter and scope', provides:

'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.

...'

5 Chapter II of Regulation No 1924/2006, entitled 'General principles', includes Articles 3 to 7 of that regulation.

6 Article 3 of the regulation, entitled 'General principles for all claims', provides:

'Nutrition and health claims may be used in the labelling, presentation and advertising of foods placed on the market in the [European Union] 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;

...'

7 Article 5 of that regulation, entitled 'General conditions', provides:

'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 be permitted only if the average consumer can be expected to understand the beneficial effects as expressed in the claim.
...'

8 Article 6 of that regulation, entitled 'Scientific substantiation for claims', states that

'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.

3. The competent authorities of the Member States may request a food business operator or a person placing a product on the market to produce all relevant elements and data establishing compliance with this regulation.'

9 Chapter IV of Regulation No 1924/2006, entitled 'Health claims', includes Articles 10 to 19 of that regulation.

10 Article 10 thereof, entitled 'Specific conditions', provides:

'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 be made only if accompanied by a specific health claim included in the lists provided for in Article 13 or 14.

...'

11 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

...

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 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 the [European Food Safety Authority (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.

...'

12 Article 28 of Regulation No 1924/2006, which is entitled 'Transitional measures', forms part of Chapter V, entitled 'General and final provisions', of that regulation and provides, in paragraph 5 thereof:

'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.'

Directive 2005/29

13 Under recital 10 of Directive 2005/29:

‘It is necessary to ensure that the relationship between this directive and existing [EU] law is coherent, particularly where detailed provisions on unfair commercial practices apply to specific sectors. ... This directive accordingly applies only in so far as there are no specific [EU] law provisions regulating specific aspects of unfair commercial practices, such as information requirements and rules on the way the information is presented to the consumer. It provides protection for consumers where there is no specific sectoral legislation at [EU] level and prohibits traders from creating a false impression of the nature of products. ... This directive ... complements the [EU] *acquis*, which is applicable to commercial practices harming consumers’ economic interests.’

14 Article 2 of that directive, entitled ‘Definitions’, provides:

‘For the purposes of this directive:

...

(d) “business-to-consumer commercial practices” (hereinafter also referred to as commercial practices) means any act, omission, course of conduct or representation, commercial communication including advertising and marketing, by a trader, directly connected with the promotion, sale or supply of a product to consumers;

...’

15 Article 3 of that directive, entitled ‘Scope’, provides:

‘1. This directive shall apply to unfair business-to-consumer commercial practices, as laid down in Article 5, before, during and after a commercial transaction in relation to a product.

...

3. This directive is without prejudice to [EU] or national rules relating to the health and safety aspects of products.

4. In the case of conflict between the provisions of this directive and other [EU] rules regulating specific aspects of unfair commercial practices, the latter shall prevail and apply to those specific aspects.

...’

16 Article 5 of that directive, entitled ‘Prohibition of unfair commercial practices’, provides:

‘1. Unfair commercial practices shall be prohibited.

2. A commercial practice shall be unfair if:

(a) it is contrary to the requirements of professional diligence, and

and

(b) it materially distorts or is likely materially to distort the economic behaviour with regard to the product of the average consumer whom it reaches or to whom it is addressed, or of the average member of the group when a commercial practice is directed to a particular group of consumers.

3. Commercial practices which are likely materially to distort the economic behaviour only of a clearly identifiable group of consumers who are particularly vulnerable to the practice or the underlying product because of their mental or physical infirmity, age or credulity in a way which the trader could reasonably be expected to foresee, shall be assessed from the perspective of the average member of that group. This is without prejudice to the common and legitimate advertising practice of making exaggerated statements or statements which are not meant to be taken literally.

4. In particular, commercial practices shall be unfair which:

(a) are misleading as set out in Articles 6 and 7,

or

(b) are aggressive as set out in Articles 8 and 9.

5. Annex I contains the list of those commercial practices which shall in all circumstances be regarded as unfair. The same single list shall apply in all Member States and may be modified only by revision of this directive.’

Swedish provisions

17 Paragraph 5 of the marknadsföringslagen (2008:486) (Law on commercial practices (2008:486); 'the MFL'), which transposed Directive 2005/29 into Swedish law, states that 'marketing shall be consistent with good marketing practice'.

18 Paragraph 10 of that law provides:

'In marketing, a trader may not make use of incorrect claims or other statements that are misleading in relation to the trader's own or someone else's business activity.

The first paragraph shall apply especially in respect of statements relating to:

1. the product's presence, nature, quantity, quality and other distinctive properties,

...'

19 It is apparent from the information provided by the referring court that, in accordance with settled national case-law, the burden of proof relating to the truthfulness of promotional claims rests on the trader concerned and that the level of proof required, as regards nutrition and health claims, is 'relatively high'.

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

20 Mezina is active in the production and marketing of natural remedies and food supplements, including Movizin complex, which contains ginger, rosehip and boswellia; Macoform, which contains artichoke and dandelion; and Vistavital, which contains blueberries.

21 In the marketing of these products, which fall within the category of 'foodstuffs' within the meaning of Regulation No 1924/2006, Mezina uses the following health claims respectively: 'Movizin complex — for your joints'; 'Ginger can help to maintain joint mobility and add energy and vitality'; 'Rosehip can help to maintain joint mobility'; 'Rosehip can help me to protect my joints and help to keep them strong'; 'Boswellia — the resin of this tree has long been used, particularly in India, to support natural joint mobility and flexibility'; 'I make sure to take a daily dose of Movizin, which contains boswellia to help to maintain joint comfort'.

'Macoform — Stomach balance'; 'Artichoke can contribute to normal digestion and support stomach comfort'; 'Dandelion can support the body's pH balance and help normal bowel function'.

'Vistavital — maintain normal vision'; 'Blueberry promotes blood supply to the eye, supports retinal function and helps to maintain normal eye function'; 'Blueberry — helps to maintain normal retinal function'.

22 The KO brought an action before the Patent- och marknadsdomstolen vid Stockholms tingsrätt (Patents and Market Court, District Court, Stockholm, Sweden) seeking an order from that court prohibiting Mezina from using those health claims in marketing the products at issue in the main proceedings.

23 As regards, first, health claims referring to a particular substance (ginger, rosehip, boswellia, artichoke, dandelion and blueberry), the KO points out that those fall under the transitional arrangements referred to in Article 28(5) of Regulation No 1924/2006, since the Commission has not yet defined its position on the applications for the inclusion of such claims in the list provided for in Article 13(3) of that regulation. However, the KO submits that those claims, some of which have, moreover, been the subject of an unfavourable opinion by EFSA, do not meet the requirements of Article 28(5) of that regulation, since they are contrary not only to point (a) of the second paragraph of Article 3, and Articles 5 and 6 of that regulation, but also to the relevant national provisions, in this case Paragraphs 5 and 10 of the MFL.

24 Mezina has not shown that the presence of the nutrients in the products at issue in the main proceedings has a beneficial physiological effect, as established by generally accepted scientific evidence, within the meaning of Article 5(1)(a) of Regulation No 1924/2006, nor has it put forward scientific evidence to prove compliance with the provisions of that regulation, in accordance with Article 6(1) thereof, nor even established that the health claims are not inaccurate, ambiguous or misleading, in the light of point (a) of the second paragraph of Article 3 of that regulation.

25 With regard, second, to health claims which do not refer to a particular substance ('Movizin complex — for your joints', 'Macoform — stomach balance' and 'Vistavital — maintain normal vision'), the KO submits, principally, that they constitute specific claims, such that, since they have

not been the subject of any application for inclusion in the list provided for in Article 13(3) of Regulation No 1924/2006, they cannot be authorised. In the alternative, if those claims were to be regarded as general, non-specific health claims within the meaning of Article 10(3) of that regulation, they still could not be authorised, since they would not be accompanied by specific health claims authorised under Article 13(3) of that regulation or under Article 28(5) of that regulation.

26 In defence, Mezina contends that the action should be dismissed.

27 As regards health claims referring to a particular substance, Mezina submits that health claims falling under the transitional measures in Article 28(5) of Regulation No 1924/2006 cannot, contrary to the KO's submission, be subject to higher evidential requirements than those which are to be met by health claims which are authorised by the Commission. In particular, it would not be reasonable to require a food business operator to submit, for health claims falling under those transitional measures, a scientific dossier other than that on the basis of which the application for inclusion in the list provided for in Article 13(3) of that regulation was submitted.

28 As for health claims which do not refer to a particular substance, Mezina submits that they are non-specific claims and that, since they are accompanied by specific claims which must be authorised under Article 28(5) of Regulation No 1924/2006, they comply with the conditions laid down in Article 10(3) of that regulation.

29 In that regard, the referring court notes that, as regards health claims which describe or refer to the role of a nutrient or other substance in growth, development and the functions of the body, such as those at issue in the main proceedings, Article 13 of Regulation No 1924/2006 provides that such claims, where they are included in the list drawn up by the Commission, may be made without prior authorisation, provided that they are based on generally accepted scientific evidence and are well understood by the average consumer.

30 Since the list of authorised claims which was to be drawn up by the Commission had not been completed by 31 January 2010, as laid down in Article 13(3) of Regulation No 1924/2006, the referring court seeks clarification as regards the burden of proof of the veracity of and the standard of proof required in respect of such claims which have not yet been included in that list.

31 The referring court considers that, in the context of the transitional arrangements provided for in Article 28(5) of Regulation No 1924/2006, the wording of Article 6 of that regulation appears to suggest that the burden of proof of the veracity of a health claim lies with the food business operator or the party responsible for placing the product on the market. It points out, in that regard, that the use in Article 5(1)(a) of that regulation of the expression 'has been shown' suggests that that regulation governs the burden of proof, without, however, designating the person who must prove the veracity of the claims.

32 The referring court adds that the reference made by those provisions to '… accepted scientific evidence' suggests that Regulation No 1924/2006 also governs the level of proof required in respect of health claims.

33 It points out that the regulation does not, however, contain specific provisions on the procedure to be followed when it is applied in national proceedings, in particular as regards questions relating to the taking of evidence and the probative value of evidence produced. In such a case and by virtue of the procedural autonomy of the Member States, it would then be for the internal legal order of the Member States to remedy the silence of the texts, while observing the principles of equivalence and effectiveness.

34 The referring court entertains doubts, furthermore, as to whether the national rules applicable to unfair commercial practices, adopted in the context of the transposition of Directive 2005/29, could be applicable, even though Regulation No 1924/2006 contains special rules which take precedence over and apply to those specific aspects of unfair commercial practices, as the Court has held in relation to the regulation of medicinal products (judgment of 16 July 2015, *Abcur*, C-544/13 and C-545/13, EU:C:2015:481, paragraphs 80 and 81).

35 In that regard, it states that, even where a health claim is based on generally accepted scientific evidence, such a claim may contain an ambiguous or contradictory message which is not likely to be authorised, with the result that health claims which fall under the transitional arrangements referred to in Article 28(5) of Regulation No 1924/2006 cannot be presumed to comply with the provisions of that regulation and those of Directive 2005/29.

36 In those circumstances, the Patent- och marknadsdomstolen vid Stockholms tingsrätt (Patent and Market Court, District Court, Stockholm) decided to stay the proceedings and to refer the following questions to the Court of Justice for a preliminary ruling:

'(1) Do Articles 5 and 6, read in conjunction with Articles 10(1) and 28(5) of Regulation No 1924/2006, regulate the burden of proof when a national court is determining whether unpermitted health claims have been made in a situation where the health claims in question correspond to a claim covered by an application under Article 13(2) of Regulation No 1924/2006, but where the application has not yet led to a decision on authorisation or non-authorisation, or is the burden of proof determined according to national law?

(2) If the answer to question 1 is that the provisions of Regulation No 1924/2006 regulate the burden of proof, does the burden of proof lie with the trader making a given health claim or with the authority requesting the national court to prohibit the trader from continuing to make the claim?

(3) In a situation such as that described in question 1, do Articles 5 and 6, read in conjunction with Articles 10(1) and 28(5) of Regulation No 1924/2006, regulate the evidentiary requirements when a national court is determining whether unpermitted health claims are being made, or are the evidentiary requirements determined according to national law?

(4) If the answer to question 3 is that the provisions of Regulation No 1924/2006 regulate the evidentiary requirements, what are the evidentiary requirements imposed?

(5) Is the answer to questions 1–4 affected by the fact that Regulation No 1924/2006 (including [point (a) of the second paragraph of Article 3] of the regulation) and Directive 2005/29 can be applied together in the proceedings before the national court?'

Consideration of the questions referred

The first to fourth questions

37 As a preliminary point, it must be noted, first, that, while the dispute in the main proceedings concerns both health claims making no reference to a particular substance ('Movizin complex — for your joints', 'Macoform — stomach balance' and 'Vistavital — maintain normal vision') and health claims making reference to a particular substance (ginger, rosehip, boswellia, artichoke, dandelion and blueberry), only the latter health claims gave rise to an application for inclusion in the list provided for in Article 13(3) of Regulation No 1924/2006 and are the subject of the referring court's first four questions referred for a preliminary ruling.

38 Second, the referring court takes as its basis the premiss that health claims referring to a particular substance constitute specific health claims, within the meaning of Article 10(3) of Regulation No 1924/2006, and that they fall within the category of those which describe or refer to the role of a nutrient or other substance in growth, development and the functions of the body, within the meaning of Article 13(1)(a) of that regulation. It is therefore in the light of that premiss, which it will nevertheless be for the referring court to ascertain, that the Court will answer the first four questions referred for a preliminary ruling.

39 In those circumstances, it must be held that, by its first to fourth questions, which it is appropriate to examine together, the referring court is asking, in essence, whether Article 5(1), Article 6(1) and (2), Article 10(1) and Article 28(5) of Regulation No 1924/2006 are to be interpreted as meaning that, under the transitional arrangements provided for in the latter provision, the burden of proof and the standard of proof required in respect of the health claims referred to in Article 13(1)(a) of that regulation are governed by that regulation and, if so, what requirements flow therefrom.

40 In the present case, since the Commission has not yet defined its position on the applications for entry of the health claims at issue in the main proceedings in the list referred to in Article 13(3)

of Regulation No 1924/2006, those claims are subject to the transitional arrangements laid down in Article 28(5) of that regulation (see, to that effect, judgment of 23 November 2017, *Bionorica and Diapharm* v *Commission*, C-596/15 P and C-597/15 P, EU:C:2017:886, paragraph 88).

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

42 As regards the requirement that health claims falling under the transitional arrangements of Article 28(5) of Regulation No 1924/2006 comply with that regulation, it is necessary to recall that Article 10(1) of the regulation provides that health claims are prohibited unless they comply with, inter alia, the general requirements in Chapter II of that regulation.

43 However, under Article 5(1) of Regulation No 1924/2006, which forms part of Chapter II of that regulation, the use of a health claim is authorised, inter alia, only where the presence 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'.

44 Similarly, Article 6(1) of Regulation No 1924/2006 states that health claims must be 'based on and substantiated by generally accepted scientific evidence'.

45 Thus, by providing, in both Article 5(1) and Article 6(1) of Regulation No 1924/2006, that health claims must be substantiated by 'generally accepted scientific evidence', the EU legislature has determined the standard of proof required in that regard.

46 The use of the expression 'generally accepted scientific evidence' means that such evidence should not be limited to beliefs, hearsay derived from popular wisdom, or the observations or experiences of persons outside the scientific community.

47 On the contrary, the use of such an expression means that health claims should be based on objective and scientific evidence and that, in particular, there should be sufficient scientific agreement as to the benefits of the substances to which the health claims relate, as stated in recital 14 of Regulation No 1924/2006. In addition, and as required in recital 17 of that regulation, health claims must be 'scientifically substantiated by taking into account the totality of the available scientific data and by weighing the evidence'.

48 As regards the burden of proof, it should be noted, first, that Article 28(5) of Regulation No 1924/2006 provides that, until the adoption of the list referred to in Article 13(3) of that regulation, health claims are to be made 'under the responsibility of food business operators' and, secondly, that Article 6(2) of that regulation provides that 'a food business operator making a nutrition or health claim shall justify the use of the claim'.

49 The defendant in the main proceedings submits, however, that Regulation No 1924/2006 cannot be interpreted as requiring the food business operator concerned to produce its own evidence and prepare scientific studies itself or have them prepared by the appropriate institutions.

50 In that regard, it must be noted that, although Article 5(1) and Article 6(2) of Regulation No 1924/2006 do not impose such a requirement, they nonetheless require the food business operator concerned to be able to justify the health claim it uses.

51 The evidence put forward may be that contained in the file prepared in support of the application for entry in the list provided for in Article 13(3) of Regulation No 1924/2006 or come from other sources, provided that that evidence is of sufficient scientific value.

52 Thus, in the context of the transitional arrangements laid down in Article 28(5) of Regulation No 1924/2006, a food business operator which decides to use a health claim must, under its responsibility, be aware of the effects on health of the substance in respect of which the claim is made (see, to that effect, judgment of 10 April 2014, *Ehrmann*, C-609/12, EU:C:2014:252, paragraph 43), which means that it must be able to prove the genuineness of those effects and that the burden of proof lies with that operator.

53 Furthermore, although Regulation No 1924/2006 governs the burden of proof and standard of proof required as regards the health claims referred to in Article 13(1)(a) of that regulation, the regulation does not govern how evidence is to be provided or the methods of obtaining that evidence. It follows therefrom, as the referring court has noted, that it remains the national law which governs those questions, subject to the application of the principles of equivalence and effectiveness.

54 In the light of the foregoing, the answer to the first to fourth questions is that Article 5(1), Article 6 (1) and (2), Article 10(1) and Article 28(5) of Regulation No 1924/2006 must be interpreted as meaning that, under the transitional arrangements provided for in the latter provision, the burden of proof and standard of proof in respect of the health claims referred to in Article 13(1)(a) of that regulation are governed by that regulation, which requires the food business operator concerned to be able to justify, by means of generally accepted scientific evidence, the claims which it uses. Those claims must be based on objective evidence which has sufficient scientific agreement.

The fifth question

55 By its fifth question, the referring court asks, in essence, which provisions are to apply in the event of a conflict between the rules laid down in Regulation No 1924/2006 and those in Directive 2005/29.

56 In that regard, it is clear from Article 3(1) of Directive 2005/29 that that directive is to apply to unfair business-to-consumer commercial practices, as defined in Article 5, before, during and after a commercial transaction in relation to a product. Article 2(d) of that directive defines 'commercial practices' as 'any act, omission, course of conduct or representation, commercial communication including advertising and marketing, by a trader, directly connected with the promotion, sale or supply of a product to consumers'.

57 As the Court has consistently held, Directive 2005/29 is characterised by a particularly broad material scope, extending to any commercial practice which has a direct link with the promotion, sale or supply of a product to consumers (judgment of 16 July 2015, *Abcur*, C-544/13 and C-545/13, EU:C:2015:481, paragraph 74 and the case-law cited).

58 It must be noted, however, that, in accordance with Article 3(3) of Directive 2005/29, that directive 'is without prejudice to [EU] or national rules relating to the health and safety aspects of products' and that, under Article 3(4) of that directive, 'in the case of conflict between the provisions of this directive and other [EU] rules regulating specific aspects of unfair commercial practices, the latter shall prevail and apply to those specific aspects'.

59 It thus follows from those provisions that Directive 2005/29 applies only in the absence of, on the one hand, specific EU or national provisions on health and safety aspects of products and, as follows from recital 10 of that directive, on the other, specific EU provisions regulating specific aspects of unfair commercial practices, such as information requirements and rules on the way the information is presented to the consumer. Moreover, that recital specifies that Directive 2005/29 provides protection for consumers where there is no specific sectoral legislation at EU level and prohibits traders from creating a false impression of the nature of products.

60 Since Regulation No 1924/2006 contains specific rules on health claims which appear on the labelling, in the presentation of foodstuffs placed on the European Union market and in the advertising for those products, that regulation constitutes a special rule as compared with the general rules concerning protection of consumers against unfair commercial practices by undertakings towards them, such as those set out in Directive 2005/29 (see, by analogy, judgment of 16 July 2015, *Abcur*, C-544/13 and C-545/13, EU:C:2015:481, paragraph 80 and the case law cited).

61 It follows that, in the event of conflict between the provisions of Directive 2005/29 and those of Regulation No 1924/2006, in particular those set out in Chapter II of that regulation, the provisions of Regulation No 1924/2006 take precedence and apply to those specific aspects of

unfair commercial practices (see, by analogy, judgment of 16 July 2015, *Abcur*, C-544/13 and C-545/13, EU:C:2015:481, paragraph 81).

62 Consequently, the answer to the fifth question is that, in the event of conflict between the provisions of Regulation No 1924/2006 and those of Directive 2005/29, the provisions of that regulation take precedence and apply to unfair commercial practices in relation to health claims, within the meaning of that regulation.

Costs

63 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 (Tenth Chamber) hereby rules:

1. **Article 5(1), Article 6(1) and (2), Article 10(1) and Article 28(5) 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 107/2008 of the European Parliament and of the Council of 15 January 2008, must be interpreted as meaning that, under the transitional arrangements provided for in the latter provision, the burden of proof and standard of proof in respect of the health claims referred to in Article 13(1)(a) of that regulation are governed by Regulation No 1924/2006, which requires the food business operator concerned to be able to justify, by means of generally accepted scientific evidence, the claims which it uses. Those claims must be based on objective evidence which has sufficient scientific agreement.**

2. **In the event of conflict between the provisions of Regulation No 1924/2006, as amended by Regulation No 107/2008, and those of Directive 2005/29/EC of the European Parliament and of the Council of 11 May 2005 concerning unfair business-to-consumer commercial practices in the internal market and amending Council Directive 84/450/EEC, Directives 97/7/EC, 98/27/EC and 2002/65/EC of the European Parliament and of the Council and Regulation (EC) No 2006/2004 of the European Parliament and of the Council (Unfair Commercial Practices Directive), the provisions of that regulation take precedence and apply to unfair commercial practices in relation to health claims, within the meaning of that regulation.**

[Signatures]

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* Language of the case: Swedish.