Case C-363/19

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

Date lodged:

7 May 2019

Referring court:

Patent- and marknadsdomstolen (Sweden)

Date of the decision to refer a request for a preliminary ruling:

2 May 2019

Claimant:

Konsumentombudsmannen (KO)

Defendant:

Mezina AB

Subject matter of the proceedings before the national court

Action for an injunction prohibiting, the use of certain health claims in the marketing of food supplements, non-compliance with which is punishable by a fine.

Purpose and legal basis of the request for a preliminary ruling

Interpretation of EU law. Article 267 TFEU.

Questions referred 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 Article 3(a) of the regulation) and Directive 2005/29 can be applied together in the proceedings before the national court?

Provisions of EU law and case-law of the Court of Justice relied upon

Regulation (EC) No 1924/2006 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), point (a) of the second paragraph of Article 3, Articles 5(1)(a), 5(1)(b), 5(1)(d), 6, 10(1) and 28(5).

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 (OJ 2005L 149, p. 22), recitals 10, 18 and 21 and Articles 3(4) and 12.

Judgment of 23 November 2017, *Bionorica and Diapharm* v *Commission* (C-596/15 P and C-597/15 P, EU:C:2017:886)

Judgment of 15 October 2015, *Nike European Operations Netherlands* (C-310/14, EU:C:2015:690)

Judgment of 21 January 2016, *Eturas and Others* (C-74/14, EU:C:2016:42)

Judgment of 16 July 2015, *Abcur* (C-544/13 and C-545/13, EU:C:2015:481)

Judgment of 16 March 2016, *Dextro Energy* v *Commission* (T-100/15, EU:T:2016:150)

Judgment of 8 June 2017, *Dextro Energy* v *Commission* (C-296/16 P, EU:C:2017:437)

National provisions relied upon

Marknadsföringslagen (2008:486) (Law (2008:486) on marketing practices; 'MFL') which transposes Directive 2005/29 into Swedish law:

Paragraph 5 Marketing shall be consistent with good marketing practice.

Paragraph 6 Marketing that violates good marketing practice on the basis of Paragraph 5 shall be deemed to be improper if, to a significant extent, it affects or is likely to affect the recipient's ability to make a well-founded business decision.

Paragraph 8 Marketing that is misleading on the basis of any of the provisions in Paragraphs 9, 10 or 12 to 17 shall be deemed to be improper if it affects or is likely to affect the recipient's ability to make a well-founded business decision.

Paragraph 10 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,

2. the product's origin, use and risks such as the impact on health and the environment.

Brief presentation of the facts and procedure in the case before the national court

1 Mezina AB (Mezina) is engaged in the development, evidence-gathering, research and marketing of natural remedies, medicines and food supplements.

2 Mezina has marketed the products Movizin complex, Macoform and Vistavital. Those products are classified as food supplements and contain plants or plant extracts, known as botanicals (referred to below as 'botanical substances'). The products come within the definition of food. Movizin complex contains ginger, rose hip and boswellia. Macoform contains artichoke and dandelion. Vistavital contains blueberries. In its marketing, Mezina has made certain claims to the effect that the products in question or the botanical substances they contain have positive effects on, inter alia, joints in the body, digestion and function of the intestines as well as eyesight and the eyes. The parties agree that those claims are health claims.

3 The Konsumentombudsmannen (Swedish Consumer Ombudsman (KO)) has brought proceedings against Mezina before the Patent- and marknadsdomstolen (Patent and Market Court). KO has requested the Patent- och marknadsdomstolen (Patent and Market Court) to issue an injunction, non-compliance with which to be punishable by a fine, ordering Mezina to refrain, in the marketing of the products at issue, from using the abovementioned claims or other claims having essentially the same content.

4 Mezina has objected to the injunction being issued.

5 KO and Mezina agree that the claims about the botanical substances are what are known as specific health claims, all of which also are to be deemed to be consistent with the claims covered by relevant applications submitted to the European Commission for a statement of its adopted position with regard to Article 13(2) of Regulation No 1924/2006.

6 The Commission has not adopted a position on any of the abovementioned health claims and EFSA [European Food Safety Authority] has assessed only one of them and has concluded that the scientific evidence that EFSA has had available to it has not shown a link between the substance and the claim made about it.

7 KO and Mezina disagree as to whether the claims about the products as such are specific or non-specific health claims. Unlike the claims about the botanical substances, those claims do not appear in any of the applications submitted to the Commission.

Principal arguments of the parties

8 KO asserts that the claims about the products as such are primarily specific health claims which are contrary to Article 10(1) of Regulation No 1924/2006. The claims are not permitted, since there are no authorised claims on the Community list of authorised health claims concerning the products Movizin complex, Macoform and Vistavital. Nor are there any applications involving health claims about the products Movizin complex, Macoform and Vistavital. Since the claims are contrary to the regulation, they are also contrary to Paragraph 5 of the MFL.

9 KO makes the following submissions in regard to Mezina's claims made about the botanical substances. The claims are to be deemed to be consistent with the claims covered by relevant applications submitted to the European Commission for its adopted position. The claims do not, however, otherwise satisfy the requirements laid down in Article 28(5) of Regulation No 1924/2006, as they are contrary to point (a) of the second paragraph of Article 3 and Articles 5 and 6 of the regulation, and also to Paragraphs 5 and 10 of the MFL. The claims may therefore not be used.

10 KO submits that the health claims about the botanical substances are not permitted since they do not fulfil the requirements laid down in Article 5(1)(a), 5(1)(b) and

5(1)(d) of Regulation No 1924/2006. Since Mezina has not submitted evidence showing that the regulation's requirements are satisfied, the company has failed to show that it has based the health claims on generally accepted scientific evidence in accordance with Article 6 of the regulation.

11 Under Article 6, it is incumbent upon Mezina to demonstrate that its claims are authoritative (that is to say, are not inaccurate, ambiguous or misleading) under point (a) of the second paragraph of Article 3. As the company has not submitted any evidence at all, either previously to the Konsumentverket (Swedish Consumer Agency)/KO or now to the Patent- och marknadsdomstolen (Patent and Market Court), in support of its claims, Mezina has failed to demonstrate that the claims are authoritative. The claims are therefore misleading under point (a) of the second paragraph of Article 3 of the Regulation.

12 As Mezina has not substantiated the claims as authoritative, they are also misleading and not permitted under Paragraph 10 of the MFL.

13 Given that the claims are not permitted under the Regulation, they are also contrary to Paragraph 5 of the MFL.

14 In the alternative, KO submits, with regard to the claims about the products as such, that they are general, non-specific health claims under Article 10(3) of Regulation No 1924/2006. The claims are not permitted, as they are not accompanied by either authorised health claims under the regulation or by specific claims about the botanical substances, which are permitted under the transitional provisions laid down in Article 28(5) of the regulation. Should the Patent- och marknadsdomstolen (Patent and Market Court) conclude that the claims about the botanical substances are permitted under Article 28(5) of the regulation, KO submits that those health claims are not accompanied by specific claims.

15 KO takes the view that the marketing target group cannot be deemed to have detailed knowledge about the health aspects discussed in the marketing materials. Nor can people in the target group be deemed to be accustomed internet users or well-informed with regard to self-care. The average consumer does not have detailed knowledge about the health aspects discussed in the marketing materials.

16 Mezina, for its part, has emphasised that the Commission has not yet adopted a position on the applications concerning the claims about the botanical substances. The Commission might conclude that the requirements on which EFSA took as its basis for its assessment were too stringent. This is one of the reasons why the assessment has been put on hold, that is to say, a determination is being made as to whether so-called botanicals are to be assessed in the same manner as vitamins and minerals and/or whether the substances are to be covered by separate legislation. Those circumstances must be taken into account in the assessment of the requirements relating to the responsibility of food operators provided for in Article 28(5) of the regulation.

17 Mezina takes the view that it is unreasonable and goes beyond what is covered by 'the responsibility of food operators' as provided for in Article 28(5) of the regulation to require Mezina to be able to present self-produced evidence as proof that the presence of the substance to which the claim relates has a nutritional or physiological effect on the basis of generally accepted scientific evidence and that the substance is present in a quantity that gives the nutritional and physiological effect which is claimed. There is a transitional period under Article 28(5) and legislation is not in place. The Commission has not assessed the basis used by EFSA basis in accordance with the regulation or adopted a decision on the claims in question. Nor has it been decided that botanicals are to be covered by any other legislation with different requirements. Accordingly, it must be sufficient for Mezina to be able to rely on the information submitted to EFSA and to use the health claims in question in a wording that is compatible with the application made in respect of the claim. That standpoint must be viewed in the light of the fact that food operators are not allowed to use their own scientific evidence in support of permitted health claims but are bound by the evidence submitted to EFSA.

18 The requirement for generally accepted scientific evidence under Articles 5 and 6 of the regulation refers to that evidence which is relied upon in support of the health claim for which authorisation is sought. Therefore, in Mezina's submission, the veracity assessment under point (a) of the second paragraph of Article 3 and Articles 5 and 6 of the regulation should be conducted with reference to the requirements laid down in the regulation and be based on the scientific evidence submitted in support of the claims for which authorisation is sought.

19 As Mezina understands KO's action, KO considers that Mezina should present self-produced evidence in support of the claims for which authorisation is sought in order to comply with the requirements of the responsibility of food business operators and generally accepted scientific evidence.

20 KO's position means that more stringent requirements are placed on food business operators with regard to the use of health claims covered by the transitional provisions under Article 28(5) of the regulation than for the use of health claims authorised by the Commission, since, under the regulation, food business operators are not allowed to refer to studies other than those forming the basis for an authorised health claim. In that light, it is unreasonable to require food business operators to present scientific support for the claims in question for which authorisation is sought and which are covered by the transitional provisions other than that which forms the basis of the application. That would also lead to food business operators' use of the claims for which authorisation is sought being assessed differently in the various Member States, which is contrary to the purpose of the regulation. A corresponding requirement of 'generally accepted scientific evidence' imposed by the regulation in respect of authorised health claims should also apply to claims covered by the transitional provisions laid down in Article 28(5) of the regulation in order for the 'the responsibility of food business operators' to be deemed to be fulfilled.

21 In any event, Mezina considers that the requirement of 'the responsibility of food operators' as provided for in Article 28(5) of the regulation is fulfilled, since Mezina followed what must be regarded as good practice in the food supplement industry in terms of how the transitional provisions laid down in Article 28(5) are to be applied. The claims about botanicals for which authorisation is sought should be able to be used until the Commission adopts a decision thereon, irrespective of whether or not they have been assessed by EFSA and irrespective of what EFSA's assessment of a claim has been. That is particularly so given that these are botanicals that have been used for a very long time with good results, both for the individual substances in themselves and the products at issue in the present case. Mezina's burden of proof should accordingly be deemed to have been satisfied for the purposes of Article 28.

22 That follows from the Commission's having put on hold all applications relating to botanicals on the grounds that a discussion is ongoing between the Member States concerning whether EFSA's stringent assessment should actually be used for botanicals or whether they should instead be covered by separate legislation, as is the case for traditional plant-based medicines. Since EFSA's recommendation is not binding on the Commission and may be changed, no legal rules have been adopted for food business operators to work with until such time as the Commission adopts a final decision and a potential transitional period, which is determined by the Commission, has expired.

23 Mezina's position is not that it is sufficient merely to refer to EFSA in order to meet the responsibility of food operators requirement under Article 28(5) of the regulation. Instead, Mezina is of the view that it is inherent in that requirement that the claims in question must be drafted in accordance with the regulation, for example, in such a manner that the claims do not become medicinal or intensify the effects which form the basis of the application. Responsibility also encompasses an assessment of the evidence submitted as a basis for the application to EFSA in order to determine whether the evidence substantiates those claims for which the application for authorisation is being made. However, each individual food business operator cannot also be required to produce its own studies substantiating the health effects.

24 Mezina further considers that the claims about the products as such are non-specific. Those claims are accompanied by claims corresponding to health claims for which authorisation is sought in relation to the products' content of ginger, rose hip, boswellia, artichoke, dandelion and blueberries, respectively, for which transitional rules apply under Article 28(5) of the regulation. The marketing in question is therefore compatible with Article 10(3) of the regulation and is not contrary to good marketing practice under Paragraph 5 of the MFL.

25 Mezina considers that the target group for the marketing in question consists of health-conscious consumers who are interested in supplementing their usual diet with food supplements and are well informed about self-care. Since the marketing

occurs on Mezina's website it can be assumed, according to Mezina, that the target group is made up of accustomed internet users.

Brief presentation of the grounds for the request for a preliminary ruling

26 The case before the Patent- och marknadsdomstolen (Patent and Market Court) concerns the application of provisions of Regulation No 1924/2006 by a national court in a situation where national legislation transposing Directive 2005/29 is applied at the same time. The question is whether the burden of proof and evidentiary requirements in connection with the application of point (a) of the second paragraph of Article 3, and Articles 5(1)(a), 5(1)(b), 5(1)(d), 6, 10(1) and 28(5) of the regulation are to be determined according to national law or according to EU law in a situation such as the one in the present case. Should it be held that EU law prevails or has an influence on questions about the burden of proof and evidentiary requirements in connection with the application of those provisions before a national court, follow-up questions arise about the more detailed implications of EU law.

27 Under Article 13 of Regulation No 1924/2006, certain health claims made on foods may be made without a prior application procedure for authorisation. This is the case of health claims describing or referring to the role of a nutrient or other substance in growth, development and the functions of the body. In order to be covered by the provision, the claims must be included in a Community list adopted by the Commission. Further conditions are that the health claims must:

– be based on generally accepted scientific evidence, and

– be well understood by the average consumer.

28 Under the scheme for these types of health claims, the Member States were to provide the Commission with lists of health claims by 31 January 2008. The lists were to be accompanied by the conditions applying to them and by references to the relevant scientific justification. After consulting with EFSA, the Commission was to adopt a Community list by 31 January 2010.

29 Following the adoption of Regulation No 1924/2006, the Commission received a total of around 44 000 health claims from the Member States. The Commission requested a scientific opinion from EFSA. Given the high number of applications, the Commission requested EFSA to put on hold temporarily the assessment of the health claims about botanical substances and instead focus on the assessment of other claims referred, so that a list including those claims could be adopted as soon as possible.

30 On 16 May 2012, the Commission authorised a partial list of health claims. At the same time, the Commission compiled a list of over 2000 health claims for which EFSA's or the Commission's assessment had not yet been completed and published it on its website. According to the Commission, the assessment of those

claims, which inter alia referred to effects of botanical substances, was still on hold, which meant that they could still be used in accordance with the transitional provisions laid down in (in so far as is currently relevant) Article 28(5) of Regulation No 1924/2006.

31 The Court of Justice has stated, inter alia, the following concerning the transitional provisions of Regulation No 1924/2006 (judgment of 23 November 2017, *Bionorica and Diapharm* v *Commission* (C-596/15 P and C-597/15 P, EU:C:2017:886, paragraphs 87–89). Both permitted health claims and health claims the assessment of which is on hold may be used in connection with the marketing of food, but the requirements and the prerequisites are different for those two types of claims. Health claims the assessment of which is on hold are covered by the transitional provisions and, under Article 28(5) and 28(6) of the regulation, must be compatible, inter alia, with the regulation and with applicable national law provisions. Furthermore, health claims the assessment of which is on hold must also meet the requirements imposed under each Member State's national provisions.

32 The Patent- och marknadsdomstolen (Patent and Market Court) takes the view that the wording of Article 6 of Regulation No 1924/2006 clearly suggests that it is the food business operators or the party placing a product on the market who have the burden of proving that a health claim is based on scientific evidence ('shall be based on and substantiated by', 'a food business operator making a nutrition or health claim shall justify the use of the claim', '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'). This does, in any event, seem to be implied (see, by analogy, judgment of 15 October 2015, *Nike European Operations Netherlands* (C-310/14, EU:C:2015:690), paragraph 25).

33 The wording of Article 5(1)(a) of Regulation No 1924/2006 also suggests that EU law regulates the burden of proof ('has been shown to'), even though the provision does not state clearly who has the burden of proof.

34 Several references are made in Articles 5, 6 and 13 of Regulation No 1924/2006 to 'generally accepted scientific evidence'. The expression can be construed as meaning that the legislation regulates the evidentiary requirements.

35 On the one hand, there are passages that can give the impression that EU law regulates the burden of proof and the evidentiary requirements.

36 On the other hand, Regulation No 1924/2006 does not contain specific provisions about the regulation's application before national courts, such as provisions on, inter alia, the taking of evidence, what evidence is admissible before national courts, or which principles are to be applied in connection with the national court's examination of the probative value of the evidence submitted. According to the Patent- och marknadsdomstolen (Patent and Market Court), that indicates

that the issues of burden of proof and evidentiary requirements fall to be determined according to national law.

37 In the absence of harmonisation of such rules under EU law, it is for the national legal order of each Member State to establish them in accordance with the principle of procedural autonomy. Those rules must not, however, be less favourable than those governing similar domestic situations (principle of equivalence) and must not make it excessively difficult or impossible in practice to exercise the rights conferred by EU law (principle of effectiveness) (see judgment of 15 October 2015, *Nike European Operations Netherlands* (C-310/14, EU:C:2015:690, paragraph 28).

38 The principle of effectiveness precludes, first, the application of national rules of procedure which would make reliance on EU law impossible or excessively difficult by providing for rules which are too onerous, especially in connection with proof of the negative, namely that certain circumstances do not exist. Second, that principle precludes national rules of evidence which are not sufficiently rigorous, the application of which would, in practice, have the effect of shifting the burden of proof laid down in EU law (see judgment of 15 oktober 2015, *Nike European Operations Netherlands* (C-310/14, EU:C:2015:690, paragraph 29); for similar reasoning, see also the judgment of 21 January 2016, *Eturas and Others* (C-74/14, EU:C:2016:42).

39 Directive 2005/29 does not contain any rules on evidentiary requirements, which thus fall to be provided for under national law.

40 The Patent- och marknadsdomstolen (Patent and Market Court) is of the view that there is a need for clarification of the interpretation of Articles 5 and 6 of Regulation No 1924/2006, read in conjunction with Articles 10(1) and 28(5) of the regulation. The need for interpretation concerns where the burden of proof lies and whether the regulation regulates the evidentiary requirements in a situation such as that in the case before the Patent- och marknadsdomstolen (Patent and Market Court).

41 There is also a need for interpretation in relation to the interaction between Regulation No 1924/2006 and Directive 2005/29 with regard to the burden of proof and evidentiary requirements. The Patent- och marknadsdomstolen (Patent and Market Court) takes the view that, since Regulation No 1924/2006 contains specific provisions on nutrition and health claims made on foods, it 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 provided for in Directive 2005/29. That, in turn, could lead to the conclusion that, in the event of conflict between the provisions of Directive 2005/29 and those of Regulation No 1924/2006, the regulation's provisions take precedence and apply to those specific aspects of unfair commercial practices (judgment of 16 July 2015, *Abcur* (C-544/13 and C-545/13, EU:C:2015:481, paragraphs 80 and 81)).

42 In the case before it, the Patent- och marknadsdomstolen (Patent and Market Court) must apply the provisions of Regulation No 1924/2006 and, at the same time, provisions of national legislation (the MFL) transposing Directive 2005/29.

43 According to consistent national practice, the trader has the burden of proving the veracity of marketing-related claims. In national practice, evidentiary requirements have been set relatively high in relation to nutritional and health claims. The Patent- och marknadsdomstolen (Patent and Market Court) seeks to know whether the application of Regulation No 1924/2006, particularly point (a) of the second paragraph of Article 3, means that there are grounds to contemplate approaches in considering the burden of proof and evidentiary requirements other than those resulting from national practice.

44 The Patent- och marknadsdomstolen (Patent and Market Court) has also noted that a health claim that is based on and can be substantiated by generally accepted scientific evidence can also give rise to a conflicting and confusing message and therefore not be permitted (judgment of 16 March 2016, *Dextro Energy* v *Commission*, T-100/15, EU:T:2016:150 and, on appeal, judgment of 8 June 2017, *Dextro Energy* v *Commission* C-296/16 P, EU:C:2017:437). Against that background, and in the light of the 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), it seems that the Patent- och marknadsdomstolen (Patent and Market Court) cannot assume that health claims covered by the transitional rule in Article 28(5) of Regulation No 1924/2006 are compatible with the regulation's provisions and with those of Directive 2005/29. Instead, a determination must be made as to whether the health claims are compatible with the regulation and with applicable national provisions, and whether the health claim fulfils the requirements laid down in national provisions. The issues of burden of proof and evidentiary requirements are of great importance to that assessment.