Court of Justice EU, 23 November 2016, Nelsons v Ayonnax

ADVERTISING LAW

The transitional measure of article 28(2) of Regulation No 1924/2006 on food- and health claims for foodstuff is applicable to a foodstuff which was sold as a medicinal product before 2005 and was afterwards sold as a foodstuff under the same trademark or brand name.

- **Taking account of the foregoing considerations, the answer to the third question is that Article 28(2), first sentence, of Regulation No 1924/2006 must be interpreted as meaning that that provision applies in the situation in which a foodstuff bearing a trade mark or brand name was, before 1 January 2005, marketed as a medicinal product and then, while having the same physical characteristics and bearing the same trade mark or brand name, as a foodstuff prior to that date.**

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Court of Justice EU, 23 November 2016
(L. Bay Larsen, M. Vilaras, J. Malenovský, M. Safjan)
JUDGMENT OF THE COURT (Third Chamber)
23 November 2016 (*)
(Reference for a preliminary ruling — Consumer information and protection — Regulation (EC) No 1924/2006 — Nutrition and health claims made on foods — Transitional measures — Article 28(2) — Products bearing trade marks or brand names existing before 1 January 2005 — 'Bach flower' remedies — European Union mark RESCUE — Product marketed as medicinal products before January 2005 and as foodstuffs after that date)
In Case C-177/15,
REQUEST for a preliminary ruling under Article 267 TFEU, from the Bundesgerichtshof (Federal Court of Justice, Germany), made by decision of 12 March 2015, received at the Court on 21 April 2015, in the proceedings
Nelsons GmbH
v
Ayonnax Nutripharm GmbH,
Bachblütentreff Ltd,
THE COURT (Third Chamber),
composed of L. Bay Larsen, President of the Chamber, M. Vilaras, J. Malenovský, M. Safjan (Rapporteur) and D. Šváby, Judges,
Advocate General: M. Bobek,
Registrar: M. Aleksejev, Administrator,
having regard to the written procedure and further to the hearing on 6 April 2016, after considering the observations submitted on behalf of:
– Nelsons GmbH, by T. Salomon, B. Goebel and C. Alpers, Rechtsanwälte,
– Ayonnax Nutripharm GmbH and Bachblütentreff Ltd, by B. Ackermann, Rechtsanwältin,
– the Greek Government, by A. Dimitrakopoulou, K. Karavasili, P. Paraskevopoulou, K. Nassopoulou and S. Lekkou, acting as Agents,
– the European Commission, by S. Grünheid, acting as Agent,
after hearing **the Opinion of the Advocate General** at the sitting on 22 June 2016,
gives the following
Judgment
1. This request for a preliminary ruling concerns the interpretation of Article 4(3), Article 5(1)(a), Article 6(1), Article 10(3) and Article 28(2) 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').
2. The request has been made in proceedings between Nelsons GmbH and Ayonnax Nutripharm GmbH, a company incorporated in Germany, and Bachblütentreff Ltd, a company incorporated in the United Kingdom, concerning flower remedies marketed by Nelsons under the EU mark RESCUE.
Legal context
EU law
Regulation (EC) No 178/2002
3. Article 2 of Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ 2002 L 31, p. 1), entitled *'Definition of "food"', provides:*
'For the purposes of this Regulation, "food" (or "foodstuff") means any substance or product, whether processed, partially processed or unprocessed, intended to be, or reasonably expected to be ingested by humans.
"Food" includes drink, chewing gum and any substance, including water, intentionally incorporated

into the food during its manufacture, preparation or treatment. …
"Food" shall not include:
(d) medicinal products within the meaning of [Council Directive 65/65/EEC of 26 January 1965 on the approximation of provisions laid down by Law, Regulation or Administrative Action relating to proprietary medicinal products (English special edition: Series I Volume 1965-1966 p. 20 to 24)] and [Council Directive 92/73/EEC of 22 September 1992 widening the scope of Directives 65/65/EEC and 75/319/EEC on the approximation of provisions laid down by Law, Regulation or Administrative Action relating to medicinal products and laying down additional provisions on homeopathic medicinal products (OJ 1992 L 297, p. 8)];
…'

Regulation No 1924/2006

4. Recitals 1 and 4 of Regulation No 1924/2006 state:
'(1) An increasing number of foods labelled and advertised in the [Union] 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 must be safe and adequately labelled. A varied and balanced diet is a prerequisite for good health and single products have a relative importance in the context of the total diet.
…
(4) This Regulation should apply to all nutrition and health claims made in commercial communications, including inter alia generic advertising of food and promotional campaigns, such as those supported in whole or in part by public authorities. It should not apply to claims which are made in non-commercial communications, such as dietary guidelines or advice issued by public health authorities and bodies, or non-commercial communications and information in the press and in scientific publications. This Regulation should also apply to trade marks and other brand names
which may be construed as nutrition or health claims.'
5. Article 1 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.
…
3. A trade mark, brand name or fancy name appearing in the labelling, presentation or advertising of a food which may be construed as a nutrition or health claim may be used without undergoing the authorisation procedures provided for in this Regulation, provided that it is accompanied by a related nutrition or health claim in that labelling, presentation or advertising which complies with the provisions of this Regulation.
…'
6. Article 2 of the regulation, headed 'Definitions', provides:
'1. Within the meaning of this Regulation:
(a) the definitions of "food", "food business operator", "placing on the market", and "final consumer" set out in Articles 2, 3(3), 3(8) and 3(18) of [Regulation No 178/2002] of shall apply;
…
2. The following definitions shall also apply:
1. "claim" means any message or representation, which is not mandatory under [EU] or national legislation, including pictorial, graphic or symbolic representation, in any form, which states, suggests or implies that a food has particular characteristics;
…
5. "health claims" 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. Article 4 of that regulation, entitled *'Conditions for the use of nutrition and health claims'*, provides in paragraph 3:
'Beverages containing more than 1.2% by volume of alcohol shall not bear health claims.
…'
8. Article 5 of Regulation No 1924/2006, entitled *'General conditions'*, provides, in paragraph 1 thereof:
'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 data;
(b) the nutrient or other substance for which the claim is made:
(i) is contained in the final product in a significant quantity as defined in [EU] legislation or, where such rules do not exist, in a quantity that will produce the nutritional or physiological effect claimed as established by generally accepted scientific data …
…'
9. Article 6 of Regulation No 1924/2006, entitled *'Scientific substantiation for claims'*,
paragraph 1 provides:
'Nutrition and health claims shall be based on and substantiated by generally accepted scientific evidence.'
10. Article 10 of Regulation No 1924/2006, relating to health claims and entitled *'Specific conditions'*, provides in paragraphs 1 to 3:
'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.'

11. Article 28 of that regulation, entitled *'Transitional measures'*, provides in paragraph 2 thereof:

'Products bearing trade marks or brand names existing before 1 January 2005 which do not comply with this Regulation may continue to be marketed until 19 January 2022 after which time the provisions of this Regulation shall apply.'

German law

12. Under Paragraph 3(1) of the Gesetz gegen den unlauteren Wettbewerb (Law on Unfair Competition), in the version applicable to the dispute in the main proceedings (BGBl. 2010 I, p. 254, 'the UWG'):

'Unfair commercial practices shall be unlawful if they are likely to have a perceptible adverse effect on the interests of competitors, consumers or other market participants.'

13. Paragraph 4 of the UWG provides:

'Other unfair commercial practices A person shall be regarded as acting unfairly in particular where he

...

11. infringes a statutory provision that is also intended to regulate market behaviour in the interests of market participants'.

14. Paragraph 8(1), first part of sentence, of the UWG provides:

'Where a person engages in an unlawful commercial practice under Paragraphs 3 or 7, an action may be brought against that person to eliminate that practice and, where there is a risk of recurrence, for an injunction requiring him to desist.'

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

15. Nelsons markets preparations made from flowers, known as 'Bach flower remedies', in pharmacies in Germany. They include products commonly called *'RESCUE'* remedies, which carry the designation 'Spirituose' ('spirit drink') and have an alcohol content of 27% by volume.

16 Those remedies are sold in dropper bottles, with a volume of either 10 ml or 20 ml, or as a spray *('the remedies at issue in the main proceedings'*). The product packaging contains the following dosage instructions:

'ORIGINAL RESCUE TROPFEN (ORIGINAL RESCUE DROPS) Add four drops to a glass of water and drink at intervals over the course of the day or take four drops undiluted as required'.

And *'RESCUE NIGHT SPRAY Apply two sprays directly on the tongue'*.

17. It is apparent from the order for reference that, before 1 January 2005, Nelsons also marketed the remedies at issue in the main proceedings in Germany as medicinal products, under the EU mark RESCUE, which was, at that time, registered for medicinal products. In 2007, Nelsons also obtained registration of the mark RESCUE as an EU mark for foodstuffs.

18. Furthermore, it is clear from the documents before the Court that, by a judgment of 21 February 2008, the Hanseatisches Oberlandesgericht Hamburg (Higher Regional Court, Hamburg, Germany) held that 'Bach flower' remedies are not medicinal products, but foodstuffs. Following that judgment, Nelsons, which was not a party to the dispute in that case, began marketing the remedies at issue in the main proceedings in Germany not as medicinal products, but as foodstuffs, without making any changes to them.

19. Ayonnax Nutripharm and Bachblütentreff, which also market 'Bach flower' remedies in Germany, brought an action before the Landgericht München I (Regional Court, Munich I, Germany) seeking, primarily, a general prohibition on marketing such flower remedies by Nelsons on the ground that it did not have authorisation to market them and that those remedies were not registered under the legislation on medicinal products.

20. In the alternative, Ayonnax Nutripharm and Bachblütentreff have challenged some of Nelson's advertising messages and the way in which it has presented the remedies at issue in the main proceedings on the German market. Those companies claim that Nelsons has advertised alcoholic beverages, by relying on effects that are beneficial, or in no way detrimental, to health, which constitute acts of unfair competition.

21. By judgment of 20 September 2011, the Landgericht München I (Regional Court, Munich I) ordered Nelsons to desist from using certain advertising messages containing the words 'Bach flowers', and dismissed the action for the remainder.

22. Aynonnax Nutripharm and Bachblütentreff brought an appeal against that judgment before the Oberlandesgericht München (Higher Regional Court, Munich, Germany). By judgment of 31 January 2013, that court held that those companies were entitled to an order prohibiting Nelsons commercial practices, pursuant to Paragraph 3(1), Article 4(11) and Article 8(1) of the UWG with regard to the remedies at issue in the main proceedings, on the ground that the advertising and distribution of those remedies infringed Article 4(3) of Regulation No 1924/2006.

23. Nelsons brought an appeal on point of law before the Bundesgerichtshof (Federal Court of Justice, Germany).

24. That court states, in particular, that, in its view, the words *'RESCUE TROPFEN'* and *'RESCUE NIGHT SPRAY'* are health claims within the meaning of Article 2(2)(5) of Regulation (EC) No 1924/2006. The target public, which is nowadays familiar with English, understands the meaning of *'RESCUE'*, which suggests to the consumers concerned that the use of the remedies at issue in the main proceedings is recommended so they can be 'rescued' when facing certain health problems. Thus, there is a connection between *'RESCUE TROPFEN'* and *'RESCUE NIGHT SPRAY'*,

on one hand, and an improvement in health, on the other.

25. In that connection, according to the referring court, *'RESCUE TROPFEN'* and *'RESCUE NIGHT SPRAY'* each contain a reference to general, non-specific benefits for overall good health and health-related well-being, within the meaning of Article 10(3) of Regulation (EC) No 1924/2006. Therefore, the question arises whether the requirements laid down in Article 5(1)(a) and Article 6(1) thereof must be observed for a health claim such as that at issue in the main proceedings.

26. Finally, the referring court asks whether Article 28(2) of Regulation No 1924/2006 applies where a product was marketed before 1 January 2005, not as a foodstuff, but as a medicinal product, so that the provisions of that regulation are not applicable to the remedies at issue in the main proceedings during the transitional period laid down in that provision.

27. In those circumstances the Bundesgerichtshof (Federal Court of Justice) decided to stay the proceedings before it and to refer the following questions to the Court for a preliminary ruling:

'1. Are liquids with an alcohol content of 27% by volume, which are described as spirit drinks and are sold through pharmacies in 10 ml or 20 ml dropper bottles or as sprays, beverages containing more than 1.2% by volume of alcohol within the meaning of Article 4(3) of Regulation No 1924/2006, where, according to the dosage instructions given on the packaging,

(a) four drops of the liquid are to be added to a glass of water and drunk at intervals over the course of the day or four drops are to be taken undiluted, as required,

(b) two sprays of the liquid sold in spray form are to be applied to the tongue?

2. If Questions 1(a) and 1(b) are to be answered in the negative:

Must evidence within the meaning of Article 5(1)(a) and Article 6(1) of Regulation No 1924/2006 be present also in the case of references to general, non-specific benefits within the meaning of Article 10(3) of that regulation?

3. Does the provision set out in the first half of the sentence contained in Article 28(2) of Regulation No 1924/2006 apply in the case where, prior to 1 January 2005, the product concerned was marketed under its brand name not as a foodstuff but as a medicinal product?'

Consideration of the questions referred for a preliminary ruling

The third question

28. By its third question, which it is appropriate to answer first, the referring court asks essentially whether the first sentence of Article 28(2) of Regulation No 1924/2006 must be interpreted as meaning that that provision applies in the situation in which a product bearing a trade mark or brand name was marketed as a medicinal product before 1 January 2005 and subsequently, although having the same characteristics and bearing the same trade mark or brand name, is marketed as a food stuff after that date.

29. According to Article 28(2) of Regulation No 1924/2006, products bearing trade marks or brand names existing before 1 January 2005 which do not comply with that regulation may continue to be marketed until 19 January 2022, after which time the provisions of that regulation will apply.

30. That provision is thus a transitional measure derogating from Article 1(3) of Regulation 1924/2006, according to which a trade mark, brand name or fancy name appearing in the labelling, presentation or advertising of a food which may be construed as a nutrition or health claim may be used without undergoing the authorisation procedures provided for in this regulation, provided that it is accompanied by a related nutrition or health claim in that labelling, presentation or advertising which complies with the provisions of the regulation.

31. In that connection, it must be recalled that Article 28(2) of Regulation No 1924/2006 refers to products bearing a trade mark or brand name which must be regarded as nutrition or health claims within the meaning of that regulation (see, to that effect, **judgment of 18 July 2013, Green — Swan Pharmaceuticals CR, C-299/12, EU:C:2013:501, paragraph 36**).

32. In the present case, it is clear from the order for reference that, before 1 January 2005, Nelsons were already selling the remedies at issue in the main proceedings as medicinal products using the European Union mark RESCUE, which was then registered for medicinal products. In 2007, Nelsons also registered RESCUE as a European Union mark for foodstuffs.

33. By a judgment delivered in 2008, as mentioned in paragraph 18 of this judgment, a German court held that Bach flower remedies are not medicinal products but are foodstuffs.

34. As a result of that judgment, Nelsons began marketing the remedies at issue in the main proceedings in Germany as foodstuffs, although that was not accompanied by any change to them. Consequently, as the referring court observed, as compared with the situation existing on the day taken into consideration in Article 28(2) of Regulation No 1924/2006, that is the day before 1 January 2005, only the legal classification of the remedies at issue in the main proceedings had changed.

35. Furthermore, in its decision, the referring court states that it considers that *'RESCUE TROPFEN'* and *'RESCUE NIGHT SPRAY'* are health claims, within the meaning of Article 2(2)(5) of Regulation No 1924/2006, and that RESCUE constitutes a trade mark or brand name within the meaning of Article 28(2) thereof.

36. Therefore, the question which arises is whether remedies such as those at issue in the main proceedings, which were marketed before 1 January 2005 as medicinal products and, subsequent to that date, as foodstuffs are 'products' within the meaning of Article 28(2) of that regulation.

37. In that connection, it must be observed that 'products', within the meaning of that provision, must be understood as referring to 'foodstuffs' for the purposes of Regulation No 1924/2006.
38. First, that regulation, as its title states, concerns nutritional and health claims made on foods. Second, it is clear, in particular, from recital 1 and Article 5(1)(b)(i) of that regulation, that the latter does not expressly distinguish between 'foodstuffs' and 'products',
the two words being used interchangeably.
39. In those circumstances, Article 28(2) of Regulation No 1924/2006 must be understood as referring only to foodstuffs bearing a trade mark or brand name which must be considered a nutrition or health claim within the meaning of that regulation (see, to that effect, **judgment of 18 July 2013, Green — Swan Pharmaceuticals CR, C-299/12, EU:C:2013:501, paragraph 37**).
40. In the present case, according to Ayonnax and Bachblütentreff, the Greek Government and the European Commission, since the remedies at issue in the main proceedings were marketed as medicinal products before 1 January 2005, and not as food, they cannot fall within the scope of Article 28(2) of Regulation No 1924/2006.
41. In that connection, it must be observed that, according to Article 2 of Regulation No 178/2002, to which Article 2(1)(a) of Regulation No 1924/2006 refers for the definition of 'food', that definition does not cover 'medicinal products'.
42. Thus, the remedies at issue in the main proceedings, the composition of which has not been changed, cannot be or have been, both, 'foodstuffs' and 'medicinal products'.
43. Therefore, as the Advocate General noted in **point 87 of his Opinion**, if the remedies at issue in the main proceedings were 'medicinal products', they could not fall within the scope of Regulation No 1924/2006.
44. However, it is clear from the order for reference that the Court is asked about a different situation, in which those remedies are presented as having been objectively 'foodstuffs' within the meaning of that regulation, both during the relevant period with regard to Article 28(2) of that regulation, that is before 1 January 2005, and now.
45. In that case, as is clear from paragraph 39 of the present judgment, the remedies at issue in the main proceedings must be classified as 'products' within the meaning of Article 28(2) of Regulation No 1924/2006.
46. That provision is applicable only to products bearing a trade mark or brand name 'existing' before 1 January 2005.
47. Having regard to the wording of that provision, 'existing' must be understood as meaning that those products had, already before that date, to have the same substantive characteristics and bear the same trade mark or brand name. It is clear from the order for reference that such is the case in the main proceedings.
48. Taking account of the foregoing considerations, the answer to the third question is that Article 28(2), first sentence, of Regulation No 1924/2006 must be interpreted as meaning that that provision applies in the situation in which a foodstuff bearing a trade mark or brand name was, before 1 January 2005, marketed as a medicinal product and then, while having the same physical characteristics and bearing the same trade mark or brand name, as a foodstuff prior to that date.

The first and second questions

49. Having regard to the answer to the third question, and given the nature of the main proceedings, which seek to immediately put an end to Nelsons' commercial practices as far as concerns the remedies at issue in the main proceedings, there is no need to answer the first and second questions.

Costs

50. Since these proceedings are, for the parties to the main proceedings, a step in the action pending before the national 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 (Third Chamber) hereby rules:

Article 28(2), first sentence, 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 that provision applies in the situation in which a foodstuff bearing a trade mark or brand name was, before 1 January 2005, marketed as a medicinal product and then, although having the same physical characteristics and bearing the same trade mark or brand name, as a foodstuff after that date.

OPINION OF ADVOCATE GENERAL BOBEK
delivered on 22 June 2016 (1)
Case C‑177/15
Nelsons GmbH
v
Ayonnax Nutripharm GmbH
Bachblütentreff Ltd
(Request for a preliminary ruling from the Bundesgerichtshof (Federal Court of Justice, Germany))
(Public health — Health claims made on foods — Notion of 'beverages containing more than 1.2% by volume of alcohol' — Inclusion of liquid in the form of a spray or drops containing more than 27% alcohol by volume — Requirement to provide scientific evidence — Transitional regime for existing trade marks)

I – Introduction

1. Nelsons GmbH ('Nelsons' or the appellant) markets Bach flower remedies in Germany. These include 'RESCUE' products sold in 10 ml and 20 ml dropper bottles and sprays ('RESCUE products'). The RESCUE products have an alcohol content of 27% by volume.

2. Regulation EC No 1924/2006 (2) lays down certain rules on nutrition and health claims made about foods. Those rules include a general prohibition on making health claims in relation to 'beverages' containing more than 1.2% alcohol by volume.
3. Are Nelsons' RESCUE products 'beverages' within the meaning of Regulation No 1924/2006? If they are, RESCUE products' high alcohol content would, in principle, exclude any health claims being made about them. If they are not, what (if any) evidence must be provided to back up such health claims? Finally, can RESCUE products benefit from an exemption to the normal rules applying under Regulation No 1924/2006 as a result of their having been marketed for a long time in Germany? Those are the questions raised by the national court in this case.

II – Legal framework

A – EU law

1. Regulation No 1924/2006

4. Regulation No 1924/2006 lays down the conditions under which 'food' (3) sold in the EU can be the subject of nutrition and health claims.
5. Regulation No 1924/2006 states that health claims should generally only be authorised after scientific assessment (recital 23).
6. Article 1(3) of Regulation No 1924/2006 provides that:
'A trade mark, brand name or fancy name appearing in the labelling, presentation or advertising of a food which may be construed as a nutrition or health claim may be used without undergoing the authorisation procedures provided for in this Regulation, provided that it is accompanied by a related nutrition or health claim in that labelling, presentation or advertising which complies with the provisions of this Regulation.'
7. Article 2(2) of Regulation No 1924/2006 defines 'claim' and 'health claim' as follows:
'1) "claim" means any message or representation, which is not mandatory under Community or national legislation, including pictorial, graphic or symbolic representation, in any form, which states, suggests or implies that a food has particular characteristics;
...
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.'
8. Article 4(3) of that regulation provides that:
'Beverages containing more than 1.2% by volume of alcohol shall not bear health claims.'
9. Regulation No 1924/2006 does not contain any definition of 'beverage'. However, recital 13 provides that 'food supplements', as defined in Directive 2002/46/EC, (4) should not be considered as 'beverages' when they are presented in liquid form and contain over 1.2% alcohol by volume.
10. Article 5(1)(a)provides that health claims shall only be permitted if:
'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.'
11. Article 5(1)(b) to (d) also provides that the relevant 'nutrient or other substance' in relation to which the claim is made is actually contained in the food in sufficient quantities and in a form that can be used by the body.
12. Article 6(1) further provides that:
'Nutrition and health claims shall be based on and substantiated by generally accepted scientific evidence.'
13. Article 10, lays down, in the following terms, the specific conditions with which health claims must also comply:
'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.'
14. Article 13 provides that the Commission shall adopt lists of permitted health claims. (5) The list of permitted claims under Article 13 was first adopted as an annex to Regulation No 432/2012/EU (6) and has been updated several times since.
15. Article 14 applies to certain specific types of claim. (7) It provides for the creation of a list of claims following an application under the procedures set out in Articles 15 to 17 and 19. The list of permitted claims under Article 14 was first adopted as an annex to Regulation (EC) No 983/2009 (8) and has been updated several times since.
16. Article 28(2) provides for the following transitional measures:
'Products bearing trade marks or brand names existing before 1 January 2005 which do not comply with this Regulation may continue to be marketed until 19 January 2022 after which time the provisions of this Regulation shall apply.'

2. Regulation (EC) No 110/2008 (9)

17. Article 2(1) of Regulation No 110/2008 defines 'spirit drink' as an 'alcoholic beverage' with certain characteristics. Article 9 provides that spirit drinks not having a particular designation (brandy, whisky etc.) must be labelled as 'spirit drinks'.

III – Facts, procedure and questions referred

A – The appellant's RESCUE products

18. Through pharmacies in Germany, Nelsons markets Bach flower remedies. They include RESCUE products which come in dropper bottles or as a spray with a volume of either 10 ml or 20 ml. Those products carry the designation 'Spirituose' ('spirit drink') and have an alcohol content of 27% by volume. The dosing instructions advise four drops or two sprays per day.

19. Nelsons has been selling RESCUE products in Germany since before 1 January 2005. (10) During that period, the composition of the products has not changed and they have, since prior to 1 January 2005, been sold using the Community trade mark 'RESCUE'.
20. Initially Nelsons' RESCUE products were sold as medicines and the RESCUE trade mark was registered for medicines (not for foods). In 2007 Nelsons also registered 'RESCUE' as a Community trade mark for food. In February 2008, following proceedings to which Nelsons was not a party, a judgment by the Oberlandesgericht Hamburg (Higher Regional Court, Hamburg) concluded that similar Bach flower remedies sold by Nelsons' competitors were not medicines but foods. (11) Following this decision by the Oberlandesgericht Hamburg (Higher Regional Court, Hamburg), Nelsons began to market its RESCUE products in Germany as foods.

B – Case giving rise to the present request for a preliminary ruling

21. The respondents in the main case — Ayonnax Nutripharma GmbH and Bachblütentreff Ltd (the respondents) — sell their own Bach flower remedies in Germany which compete with Nelsons' RESCUE products.
22. The respondents brought an action against Nelsons before the German courts. To the extent relevant here, they accused Nelsons of unfair competition, basically consisting of selling alcoholic beverages accompanied by health claims. The alleged health claim is the word 'RESCUE', which is said to imply that the user of Nelsons' products will somehow be 'rescued' from poor health.
23. In their action, the respondents sought an injunction preventing Nelsons from selling its products using the name 'RESCUE'.
24. The respondents' action was mostly rejected at first instance. However, on appeal, the requested injunction was granted on the basis that the RESCUE products were 'beverages' within the meaning of Article 4(3) of Regulation No 1924/2006. Consequently, they were prohibited from bearing any health claims.
25. The appeal decision granting the injunction was in turn challenged before the Bundesgerichtshof (Federal Court of Justice). The Bundesgerichtshof (Federal Court of Justice) began from the premiss that the term 'RESCUE' used for RESCUE products constitutes a health claim. However, it expressed doubts about RESCUE products' qualification as 'beverages'. In the event that those products were not considered to be 'beverages', the Bundesgerichtshof (Federal Court of Justice) also questioned how the various requirements on scientific support for health claims, as contained in Articles 5 and 6 of Regulation No 1924/2006, should apply in this case. Finally, the Bundesgerichtshof (Federal Court of Justice) expressed doubts in relation to the transitional provisions in Article 28 of Regulation No 1924/2006 and their application to a trade mark which predated 1 January 2005, but where the relevant product was, at that time, being sold as a medicine.
26. In the light of the above, the national court stayed the proceedings and referred the following questions to the Court:

'(1) Are liquids with an alcohol content of 27% by volume, which are described as spirit drinks and are sold through pharmacies in 10 ml or 20 ml dropper bottles or as sprays, beverages containing more than 1.2% by volume of alcohol within the meaning of Article 4(3) of Regulation (EC) No 1924/2006, where, according to the dosage instructions given on the packaging,

(a) four drops of the liquid are to be added to a glass of water and drunk at intervals over the course of the day or four drops are to be taken undiluted, as required,

(b) two sprays of the liquid sold in spray form are to be applied to the tongue?

(2) If Questions 1 (a) and 1 (b) are to be answered in the negative:

Must evidence within the meaning of Article 5(1)(a) and Article 6(1) of Regulation No 1924/2006 be present also in the case of references to general, non-specific benefits within the meaning of Article 10(3) of that regulation?

(3) Does the provision set out in the first half of the sentence contained in Article 28(2) of Regulation No 1924/2006 apply in the case where, prior to 1 January 2005, the product concerned was marketed under its brand name not as a foodstuff but as a medicinal product?'

27. Written observations were submitted by the parties to the main proceedings as well as by Greece and the Commission. With the exception of Greece, all parties presented oral arguments at the hearing on 6 April 2016.

IV – Assessment

A – Are the RESCUE products 'beverages'?

28. By its first question the national court seeks clarification on whether products with characteristics similar to the RESCUE products fall within the notion of 'beverage' under Regulation No 1924/2006.
29. I consider that they do not.
30. Regulation No 1924/2006 does not contain any positive definition of 'beverage'. However, recital 13 of that regulation clarifies that food supplements in liquid form containing more than 1.2% by volume of alcohol are not considered to be 'beverages'. (12)
31. According to the Court's case-law, (13) the meaning and scope of a term for which EU law provides no definition (14) must be determined by considering its usual meaning in everyday language, while also taking into account the context in which it occurs and the purpose of the rules of which it forms part.
32. Dictionary definitions of 'beverage' are generally very broad, encompassing anything that could theoretically be ingested and which is not technically a solid or a gas. (15) However, 'beverage' is clearly not used so broadly in everyday speech: for example, vinegar is a liquid that is ingested, but it is unlikely to be referred to as a 'beverage' or 'drink' in common parlance. Similarly, a fine throat spray may condense

into drops of liquid on the tongue or roof of the mouth and be ingested, but again one would not be 'drinking' it in any normal conversation.

33. There are, moreover, various elements of context and purpose that would tend to confirm that the word 'beverage' in Article 4(3) does not mean all liquids, but only those liquids intended to be ingested in material quantities (that is, more than a few drops or a couple of sprays).

34. First, the prohibition contained in Article 4(3) of Regulation No 1924/2006 is intended to guard against the particular negative effects of alcohol on health. (16) However, in order for such effects to manifest themselves, the alcohol has to be consumed in a non-negligible quantity. In the present case, the very small quantities of liquid involved, combined with the method of consumption (dripping into the mouth, mixing with other liquids, or spraying) in my view generally mean that the health concerns addressed in Article 4(3) of Regulation No 1924/2006 would not normally arise in relation to Nelsons' RESCUE products. (17)

35. Second, recital 13 of Regulation No 1924/2006 clarifies that liquid food supplements containing over 1.2% alcohol by volume are not considered to be 'beverages'. The Commission communication responding to the Council's Common Position and agreeing to the clarification contained in recital 13 explicitly states that the raison d'être of recital 13 is that 'the alcohol quantity provided by the consumption of such foodstuffs is negligible'. (18) This could be taken to imply that the health concerns about alcohol addressed in Article 4(3) of Regulation No 1924/2006 do not arise in relation to liquids ingested in extremely small quantities, and so health claims can be tolerated in such cases.

36. Third, Annex XIII of Regulation (EU) No 1169/2011 (19) (the general regulation on labelling) states that lower concentrations of vitamins and minerals are acceptable in beverages than are acceptable in non-beverages. As pointed out by the Commission in its written submissions, this could be taken to indicate that 'beverages' are generally expected to be ingested in greater quantities than other food. (20)

37. For the reasons set out above, I consider that the term 'beverage' does not cover products with the characteristics highlighted by the national court in its question. In view of the purpose of Article 4(3) of Regulation No 1924/2006 and a contextual and systemic reading, a teleological reduction of the broad dictionary meaning of beverage is thus called for. The term should properly encompass only liquids with an alcohol content exceeding 1.2% by volume that, if used in a normal and standard way, are liable to cause negative effects on human health.

38. It ought to be underlined, as follows already from the preceding arguments, that the same answer should be given both to parts (a) and (b) of the first question posed by the national court, relating respectively to the same liquid sold in drop or spray form. Indeed, as the question posed by the national court already suggests, the substance of the product remains the same (liquid), it is just the form of delivery that changes.

39. By way of final observation on the meaning of 'beverage', a number of parties have referred to the fact that the RESCUE products are labelled as 'spirit drinks'.

40. It is possible that this labelling was intended to implement Regulation No 110/2008 (which requires 'alcoholic beverages' to be labelled as 'spirit drinks').

41. However, this does not change my conclusion. Even if RESCUE products were technically considered to be 'alcoholic beverages' within the meaning of Regulation No 110/2008, that would certainly not automatically entail their classification as 'beverages' under Regulation No 1924/2006. Indeed, there are no particular rules on coordination or use of common definitions between the two regulations. (21)

42. In the light of the foregoing, I recommend that the Court replies to the first question asked by the national court that liquids with characteristics similar to those of the products in the main proceedings having an alcohol content of 27% by volume, which are described as spirit drinks and are sold through pharmacies in 10 ml or 20 ml dropper bottles or as sprays, and which, according to the accompanying instructions, are intended to be taken in very small quantities in drop or spray form, do not constitute 'beverages' within the meaning of Article 4(3) of Regulation No 1924/2006.

B – Must references to general, non-specific benefits be supported by scientific evidence?

1. Introduction

43. By its second question, the national court asks whether references to general, non-specific benefits within the meaning of Article 10(3) of Regulation No 1924/2006 must be supported by scientific evidence within the meaning of Article 5(1)(a) and Article 6(1) of that regulation.

44. For the reasons set out below, I consider that such references do not need to be accompanied by direct scientific evidence. However, according to the clear wording of Article 10(3), such references must be accompanied by 'specific' health claims. Those specific health claims must themselves be supported by scientific evidence within the meaning of Article 5(1)(a) and Article 6(1). As a result, references to general, non-specific benefits must always be supported, at least indirectly, by scientific evidence.

2. Scope of Article 10(3) of Regulation No 1924/2006

45. Article 10(3) of Regulation No 1924/2006 refers to two types of statement (a) 'references to general, non-specific benefits' and (b) 'specific health claims'. Before replying to the national court's question on evidential requirements, it is necessary to consider the meaning and scope of these two concepts, neither of which is defined in Regulation No 1924/2006.

46. Given the qualifier 'specific', the natural meaning of the term 'specific health claim' is narrower than the notion of 'health claim' (defined in the regulation). It refers to more precise claims about the effects a given product will have on one's health. In other words,

'specific health claims' are a logical subset of 'health claims'.
47. By contrast, 'references to general, non-specific benefits …' are vaguer statements about the positive effects of a product on 'health' or 'health-related well-being'. The suggestion that such 'references to general, non-specific benefits' are types of 'health claims' as defined in Article 2(2)(5) of the regulation, is not entirely obvious.
48. One possible reading of Article 10(3) might nevertheless be that that provision sets down rules relating to 'health claims' and it has the same scope as Article 2(2)(5) of Regulation No 1924/2006. However, in contrast to Article 2(2)(5), Article 10(3) distinguishes between two different types of 'health claim', namely 'general health claims' (referred to in the regulation as 'references to general, non-specific benefits …') and 'specific health claims'.
49. The precise meaning of the concepts employed in Article 10(3) thus remains ambiguous. It is therefore necessary to examine the context and purpose of that provision.
50. The legislative history of Regulation No 1924/2006 is instructive. Article 10 of the Commission's initial proposal (22) laid down the specific conditions under which health claims would be permitted. In contrast, Article 11 listed a number of health claims that were to be prohibited. In particular, Article 11(1)(a) provided that '[t]he following implied health claims shall not be allowed: (a) claims which make reference to general, non-specific benefits of the nutrient or food for overall good health, well-being …'.
51. After the first reading, the European Parliament rejected such a total prohibition contained in Article 11(1)(a) and deleted it. (23) This deletion was accepted by the Council in its Common Position. (24) A new Article 10(3) was inserted with the wording that appears in the final text. In its Explanatory Memorandum, (25) the Council stated that it agreed with the Commission's proposed prohibition of certain claims, but chose to allow others under certain conditions, explicitly referring in this regard to what is now Article 10(3).
52. The Commission accepted this amendment (26) as did the European Parliament after its second reading. (27)
53. I consider that these aspects of the legislative history corroborate the interpretation outlined above. Thus, although not stated explicitly, Article 10(3) appears to refer to health claims within the meaning of Article 2(2)(5) of Regulation No 1924/2006. Article 10(3) should therefore be read as distinguishing between (a) 'general health claims' (which are called 'reference(s) to general, non-specific benefits …' in the regulation) and (b) 'specific health claims'.
54. A more contextual and systemic reading of Article 10(3) also tends to confirm — or at least does not contradict — the same understanding.

55. In this respect, there is a clear parallel between Article 10(3) and Article 1(3) of the regulation. Article 1(3) states that a trade mark that can be construed as a health claim (which does not require authorisation) must be accompanied by a related health claim (which must comply with Regulation No 1924/2006).
56. Both Article 10(3) and Article 1(3) appear to address potential concerns that certain kinds of health claims take a form which may make full compliance with Regulation No 1924/2006 more difficult, warranting exemption from (some of) the requirements of the regulation. Article 10(3) and Article 1(3) do not, in my view, seek to identify a new different category of statement appearing on products, but rather to recognise two particular types of health claims — general and specific — that merit different treatment.
57. Thus, it is my understanding of Article 10(3) that 'reference(s) to general, non-specific benefits …' mean 'general health claims', which are distinct from 'specific health claims'. In my subsequent analysis relating to evidential obligations, I shall therefore use this terminology in preference to the more clunky 'references to general, non-specific benefits …'.

3. Evidential obligations in relation to references to general, non-specific benefits under Article 10(3)

58. Article 10(3) of Regulation No 1924/2006 imposes the requirement that general health claims be accompanied by a specific health claim included in the lists referred to in Article 13 or 14 of that regulation.
59. It clearly follows that general health claims are not subject to the requirement of inclusion in the Article 13 or 14 lists. This does not, however, lead to the automatic conclusion that general health claims are exempt from any other requirements of the regulation (including the requirements under Article 5(1)(a) or Article 6(1)). Indeed, there are good arguments to the contrary, based on Article 10 itself.
60. Article 10(1) of Regulation No 1924/2006 lays down the rule that health claims must comply with the general requirements in Chapter II (which includes Articles 5 and 6). Article 10(3) creates an exemption to the Article 10(1) rule and should therefore be construed narrowly. Extending Article 10(3) beyond an exemption from the Article 13 and 14 listing requirements would need strong justification. (28)
61. In order to understand the exact scope of the evidential requirements imposed by Article 5(1)(a) and Article 6(1), a closer examination of those provisions is called for.
62. What does the natural meaning of Article 5(1)(a) and Article 6(1) tell us about their applicability to general health claims?
63. Neither Article 5(1)(a) nor Article 6(1) makes any explicit distinction between the scientific evidence required for general health claims, on the one hand, and specific health claims, on the other.
64. Article 5(1)(a) of Regulation No 1924/2006 requires generally accepted scientific evidence of the beneficial effects of 'a nutrient or other substance in respect of which the claim is made'. (29) In my view, the natural meaning of these words is that scientific evidence is required at least in relation to claims relating to 'nutrients or other substances'. It is not

clear, however, whether such a requirement applies (or can apply) in exactly the same way to health claims that relate to the product more generally and that cannot be tied back to specific 'nutrients or other substances'.

65. Article 6(1) of the regulation more generally requires health claims to be 'based on and substantiated by' generally accepted scientific evidence. The natural meaning of that provision is that it applies both to general and specific health claims. That said, it is not crystal clear whether the requirement for evidence must (or even can) be fulfilled in exactly the same way for general and specific health claims.

66. In the light of the above, the natural wording of Article 5(1)(a), Article 6(1) and Article 10(3) of Regulation No 1924/2006 does not lead us to a firm conclusion on the scope of the evidential requirement applying to general health claims. However, it is my view that those provisions do not create a complete and generally applicable exemption from the obligation to provide some form of scientific evidence to support general health claims.

67. A systemic and purposive analysis provides assistance in clarifying this issue. First, the clear message that comes through in multiple provisions of Regulation No 1924/2006 is that health claims create a risk of misleading consumers and must therefore be backed up by science (see, for example, recitals 9, 14, 16, 17 and 23). Again, no distinction is made here between general and specific health claims. However, this point of principle does not prevent the requirement for scientific evidence from being fulfilled in different ways for general and specific health claims.

68. Second, it has been stated both by the referring court and in the written observations of Nelsons and the Commission that there are general health claims, which are in practice too general for evaluation, and therefore inherently incapable of being established by scientific evidence. (30) As a result, it could be argued that imposing a requirement of demonstration by generally accepted scientific evidence, in relation to general health claims, would amount to a de facto prohibition on making such claims. That would be contrary to the European Parliament and Council's explicit rejection of a total prohibition on making general health claims (see point 51 above).

69. Nonetheless, it is equally the case that a complete and generally applicable exemption from the obligation to supply scientific evidence for general health claims is problematic. It would go, not only against the natural meaning of the text, but also against the regulation's objective of consumer protection, and more specifically, the avoidance of misleading claims, which include those having no basis in science.

70. In the light of the foregoing, I consider that Article 10(3) simply cannot be read as providing a general exemption to the evidentiary requirements in Articles 5(1)(a) and 6(1) of the regulation.

71. However, I agree with the Commission that it is not necessary to provide direct scientific evidence of general health claims. Instead such claims must be accompanied by specific health claims that are supported by such evidence. This results in indirect evidence being provided for the general claim.

72. This interpretation is in line with a systemic reading of the regulation, whilst respecting the clear legislative intent not to impose a total prohibition on general health claims but still to require their scientific justification, albeit indirectly.

73. Finally, I note that the above reading of Article 10(3) requires that there must be a link between the general claim and the accompanying specific claim. A detailed discussion on the precise nature of that link is beyond the scope of the national court's questions and will not be addressed in detail here. However, in the light of the above reasoning, the relationship between the general and specific claims must be such that the evidence supporting the specific claim is relevant to the general claim and capable of providing indirect support for it. (31)

4. Conclusion

74. In the light of the foregoing, I propose to reply to the national court's second question in the sense that references to general, non-specific benefits within the meaning of Article 10(3) of Regulation No 1924/2006, do not require direct scientific evidence within the meaning of Article 5(1)(a) and Article 6(1) of that regulation. They do require, however, indirect evidence in the form of generally accepted scientific evidence supporting the specific claim which must accompany the references to general, non-specific benefits.

75. By way of final remark, although not explicitly raised as part of the national court's questions, I observe that the request for preliminary ruling takes the position that the requirement that general health claims be accompanied by specific health claims will only come into force once the Article 13 or 14 lists have been finalised.

76. I do not consider that to be a correct reading of Article 10(3). No such limitation on the temporal application of that provision is foreseen. Nor can it be deduced from a more systemic or purposive interpretation. In particular, Article 28 of Regulation No 1924/2006 explicitly foresees a number of transitional measures. (32) These do not include any suspension of the Article 10(3) requirements. More generally, by their very nature, the Article 13 or 14 lists are capable of constant evolution and will never become immutable. (33) Consequently, I consider that the Article 10(3) requirements are already fully applicable.

C – Is the Article 28(2) exception relevant if the product was marketed as a medicine?

1. Introduction

77. By its third question, the national court asks in substance whether the Article 28(2) exception requires that the relevant product was marketed as a food before 1 January 2005.

78. By way of introduction to this question, I consider it useful to recall certain very peculiar aspects of this case.

79. The RESCUE products have existed with exactly the same physical form and with the same trade mark

since before 1 January 2005. What has changed is the way in which the RESCUE products are marketed and the categories of product for which the trade mark is registered.

80. Until 2007, the RESCUE products were marketed as medicines and the trade mark was registered for medicines (among other things). Since 2007/2008, the RESCUE products have been marketed as foods and the trade mark has been registered for foods. However, the change in approach to marketing did not come about as a result of a unilateral decision by the appellant. Instead, it followed a judgment by a court, the Oberlandesgericht Hamburg (Upper Regional Court, Hamburg), which implied that the approach to marketing previously taken by the appellant was wrong. The relevant products should not have been marketed as medicines but rather as foods.

81. These factual elements highlight the issue underlying the national court's third question, namely: what pre-2005 factors are relevant to the application of the Article 28(2) exception (physical characteristics of the product; legal classification (by the seller or the competent authorities); marketing, etc.).

2. Analysis

82. According to its text, Article 28(2) applies to 'products' which bear trade marks (or brand names) (34) that 'existed' prior to 1 January 2005, and that are not in compliance with Regulation No 1924/2006.

83. It is not clear from the text of Article 28(2) exactly what needed to 'exist' prior to 1 January 2005 (the product, the relevant trade mark or the products bearing the relevant trade mark). The word 'exist' is itself also vague. It does not seem to imply any particular form of commercialisation of the product (or any commercialisation at all).

84. However, it is clear that, on a purely textual interpretation, medicines marketed before 2005 using a trade mark also predating 2005 do fall within the notion of 'products bearing trade marks or brand names existing before 1 January 2005'.

85. Article 28(2) goes on to require that products bearing trade marks 'do not comply with this Regulation'. The verb 'comply' is in the present tense. Textually, therefore, it does not require that the 'products bearing the trade marks' were in violation of the regulation on 1 January 2005, but that they are in a state of non-compliance at the moment the transitional exception is invoked. On that basis, again Article 28(2) may apply to the type of situation described in the national court's question, which refers to products that were marketed as medicines but are now marketed and legally classified as foods.

86. In their observations, the respondents and the Commission consider that Article 28(2) cannot apply. Their main line of argument is in substance that Article 28(2) concerns foods. Only foods can bear health claims and, as a result, not comply with the regulation. Article 28(2) cannot, therefore, apply to medicines.

87. The problem with this line of argument is that it does not address the specific problem in this case, which is that the relevant products have changed their legal category. If the RESCUE products had continued to be marketed and legally categorised as medicines, the Article 28(2) exception could not apply. However, in that case the entire regulation would also, in principle, be irrelevant.

88. For the reasons set out above, I consider that the text of Article 28(2) is clearly capable of covering this type of (very peculiar) situation. Nonetheless, the word 'products' in Article 28(2) has been considered in a different light in the Court's judgment in Green-Swan, (35) which has been cited by all parties.

a) Green-Swan case and the meaning of 'products' under Article 28(2)

89. In its judgment in Green-Swan, the Court held that Article 28(2) of Regulation No 1924/2006 'must be interpreted as referring only to foods bearing a trade mark or brand name which must be considered a nutrition or health claim within the meaning of that regulation and which, in that form, existed before 1 January 2005'. (36)

90. In Green-Swan the Court could therefore be understood as having read 'products' as 'foods' in Article 28(2). Relying on that judgment, the respondents and the Commission basically argue that a product formerly marketed as a medicine can never fall within the scope of the Article 28(2) exemption.

91. I disagree. The conclusion that 'products' should be read as 'foods' is not so obvious, and in my view was actually not explicitly ruled upon by the Court in Green-Swan.

92. Individual statements made by the Court in a reply to a request for a preliminary ruling should be read in their context and interpreted against the factual scope of the case. The statement taken from the Green-Swan judgment and invoked by the respondents and the Commission is merely a passing statement, formulated in a specific way in order to reply to the particular question posed by the national court. It reproduces the exact wording of the national court's question, which itself referred to foods rather than products. However, the question of whether 'products' should be read as 'foods' was not material to the Green-Swan case. It was not discussed in any detail.

93. For these reasons, relying on the Green-Swan judgment may provide only limited guidance in the present case.

94. In general, the natural meaning of 'products' is clearly different from and broader than 'foods'. Systemically, the term 'foods' is used over 70 times in the regulation including in Article 28 itself. 'Products' appears twice — in recital 1 and Article 28(2). It might thus be assumed that the legislator was aware of the terminological distinction it wished to implement in the wording of the provision, which appears to be the same in all the official languages. Indeed, against such a background, considerably more detailed and focused judicial reasoning would be necessary for substituting 'products' with 'foods'.

95. However, and in addition, I consider that even reading the word 'products' as 'foods' in Article 28(2)

does not exclude application of that provision to cases like the one at hand.
96. In that regard I underline that this case concerns a very particular situation. The relevant products are in fact foods, but they were marketed as medicines until their correct legal classification was clarified by a national court judgment. This happened not long after the 1 January 2005 cut-off date appearing in the Article 28(2) exemption.
97. These factual circumstances highlight specific characteristics of the applicable regulatory regime. Under EU law, the classification of a product as a medicine or a food has very significant regulatory consequences. However, in practice the borderline between medicines and foods is not necessarily always clear and may vary over time or between Member States. (37) As a result, in the present case simply observing that in Article 28(2) 'products' should be read as 'foods' does not provide a complete solution. It begs the question: foods at what point in time and according to whom?
98. This is a conundrum which arises only because of very particular circumstances. Products can shift between the legal categories of medicines and foods, but that should be the exception rather than the rule. In other words, the question 'foods at what point in time and according to whom' is one that should only arise in marginal cases.
99. I shall return to this issue further below. In conclusion to this section, suffice it to say that even reading 'products' as 'foods' does not ipso facto exclude the application of Article 28(2) to products that were marketed as medicines before 2005 but are now classified and marketed as foods (and have the same physical form with the same trade mark as before).

b) Broader contextual, systemic and purposive interpretation

100. Recital 4 of Regulation No 1924/2006 confirms that the regulation applies to trade marks that can be construed as health claims. (38) The regulation contains two other provisions dealing with trade marks. First, Article 1(3), which essentially exempts from the regulation's authorisation requirements any trade mark that can be construed as a health claim, provided it is accompanied by a related, authorised health claim. Second, there is the Article 28(2) exemption.
101. Article 1(3) and Article 28(2) taken together clarify the way in which Regulation No 1924/2006 is to apply to trade marks. These provisions were not in the initial Commission proposal for the regulation, which foresaw no special treatment for trade marks. (39) The European Parliament proposed to remove trade marks from the regulation entirely in its first and second reading. It considered that applying the regulation to trade marks would cause legal uncertainty and 'disadvantage existing brand-mark owners who partly strongly depend on the brand recognition'. (40) This total removal was ultimately rejected and the compromise found translated into Article 1(3) and Article 28(2) was the final result.
102. From these observations, I would draw the following general conclusions for the interpretation of Article 28(2).
103. First, trade marks that may be construed as health claims are explicitly recognised as presenting specific issues under Regulation No 1924/2006, such that the normal regime cannot apply in exactly the same way.
104. Second, I consider that the above observations confirm that Article 28(2) requires both the product and trade mark concerned to have existed prior to 1 January 2005 (as opposed to just the product or just the trade mark).
105. It appears from the legislative history that Article 28(2) aims at giving some transitional protection to established trade marks. Companies that have invested in a brand and rely on that accumulated investment and resulting brand recognition to sell their products would face disproportionate consequences if the regulation were to introduce an overnight ban on the relevant trade mark.
106. This, in my view, strongly indicates that Article 28(2) cannot be read as offering a general exemption to trade marks that can be construed as a health claim and predate 1 January 2005, independently of the products they are used on. Instead, Article 28(2) offers protection where a particular product combined with a relevant trade mark ('relevant product/trade mark combination') existed before 1 January 2005. Otherwise, a trade mark existing before 1 January 2005 could be used on entirely new products after that date and still benefit from the exemption, even though no obvious disproportionate and unfair disadvantage would be suffered in such cases.
107. This approach is also in line with the Green-Swan judgment, which states that foods bearing relevant trade marks must have existed 'in that form' on 1 January 2005. It is clear from the national court's question in Green-Swan and the reply of this Court that 'in that form' refers to the foods bearing relevant trade marks (as opposed to just the food (41) or just the trade mark).
108. Third, Article 28(2) requires that the relevant product/trade mark combination 'existed' before 1 January 2005. In my opinion, the natural meaning of 'exist' in this context is that the relevant product/trade mark combination existed in the same physical form at that date. I see nothing in the context, system or purpose of Regulation No 1924/2006 that justifies a different reading.
109. In particular, I do not see any justification for changing the way in which Article 28(2) is applied depending on the way the product has been marketed in the past or on the basis of an apparently incorrect legal classification by the seller.
110. Fourth, Article 28(2) lays down a condition that the relevant product/trade mark combination 'do[es] not comply' with the regulation. Again, referring to the purpose of that provision, it aims at preventing a disproportionate impact on the holder of a trade mark as a result of overnight withdrawal of the right to use that trade mark because it does not comply with the regulation. In the present case, it is indeed a situation of

alleged non-compliance with the regulation (I understand that that is the basis of the appellant's case). Whether that state of non-compliance has arisen as a result of a change in marketing or a legal reclassification of a product is, to my mind, irrelevant. This is not a case where a new product/trade mark combination is being put on the market in a state of non-compliance. The relevant product/trade mark combination was on the market for years before 1 January 2005 in exactly the same physical form. That seems to me to be precisely the type of product the Article 28(2) transitional exemption is aiming at.

111. Finally, when interpreting, in general, the scope of the transitional exemption in Article 28(2), one has to take into account not only the fact that exceptions are to be interpreted strictly, but also the fact that trade marks are a type of property. (42) As already apparent from the legislative process outlined above in point 101, not providing for any reasonable transitional provisions could, in extreme cases, be seen as a form of expropriation.

3. Conclusion

112. In the light of the foregoing, I propose to answer the national court's third question that the provision set out in the first half of the sentence contained in Article 28(2) of Regulation No 1924/2006 can apply in the case where, prior to 1 January 2005, the product concerned was marketed under its brand name not as a foodstuff but as a medicinal product. In such cases, Article 28(2) requires that the relevant product existed at that date (a) in the same physical form and (b) with the same trade mark.

V – Conclusion

113. I recommend to the Court that it answers the questions referred to it by the Bundesgerichtshof (Federal Court of Justice) as follows:

Question 1

Liquids with characteristics similar to those of the products in the main proceedings, having an alcohol content of 27% by volume, which are described as spirit drinks and are sold through pharmacies in 10 ml or 20 ml dropper bottles or as sprays, and which, according to the accompanying instructions, are intended to be taken in very small quantities in drop or spray form, do not constitute 'beverages' within the meaning of Article 4(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.

Question 2

References to general, non-specific benefits within the meaning of Article 10(3) of Regulation No 1924/2006, do not require direct scientific evidence within the meaning of Article 5(1)(a) and Article 6(1) of that Regulation. They do require, however, indirect evidence in the form of generally accepted scientific evidence supporting the specific claim which must accompany the references to general, non-specific benefits.

Question 3

The provision set out in the first half of the sentence contained in Article 28(2) of Regulation No 1924/2006 can apply in the case where, prior to 1 January 2005, the product concerned was marketed under its brand name not as a foodstuff but as a medicinal product. In such cases, Article 28(2) requires that the relevant product existed at that date (a) in the same physical form and (b) with the same trade mark.

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1 – Original language: English.

2 – Regulation 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).

3 – As defined in Article 2 of Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ 2002 L 31, p. 1).

4 – Article 2(a) of Directive 2002/46 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).

5 – Article 13 applies to health claims except those referring to the reduction of disease risk and to children's development and health. These are dealt with under Article 14.

6 – Commission Regulation 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).

7 – Reduction of disease risk claims and claims referring to children's development and health.

8 – Commission Regulation of 21 October 2009 on the authorisation and refusal of authorisation of certain health claims made on food and referring to the reduction of disease risk and to children's development and health (OJ 2009 L 277, p. 3).

9 – Regulation of the European Parliament and of the Council of 15 January 2008 on the definition, description, presentation, labelling and the protection of geographical indications of spirit drinks and repealing Council Regulation (EEC) No 1576/89 (OJ 2008 L 39, p. 16).

10 – A potentially relevant date in the light of Article 28(2) of Regulation No 1924/2006 (see point 16 above).

11 – Judgment of the Oberlandesgericht Hamburg (Higher Regional Court, Hamburg) (21 February 2008 — 3 U 235/06).

12 – According to the referring court Bach flower remedies are not food supplements as defined in Article 2(a) of Directive 2002/46.

13 – See, for example, judgment of 3 September 2014 in Deckmyn and Vrijheidsfonds, C‑201/13, EU:C:2014:2132, paragraph 19.

14 – Judgments 3 April 2008 in Endendijk, C‑187/07, EU:C:2008:197, paragraph 15; 27 January 2000 in DIR International Film and Others v Commission, C‑164/98

P, EU:C:2000:48, paragraph 26; and 27 January 1988 in Denmark v Commission, 349/85, EU:C:1988:34, paragraph 9.

15 – English 'a drink of any type' (Cambridge dictionary); German 'zum Trinken zubereitete Flüssigkeit' (Duden); French: 'tout liquid qui peut être bu' (Académie française); Czech: 'tekutina určená k pití, k ukojení žízně' (Slovník spisovného jazyka českého).

16 – See in this regard, for example, judgment of 6 September 2012 in Deutsches Weintor, C‑544/10, EU:C:2012:526, paragraph 48 et seq.

17 – This conclusion is, moreover, reinforced by the fact that they are sold through pharmacies.

18 – COM(2006) 2 final.

19 – Regulation of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, amending Regulations No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004 (OJ 2011 L 304, p. 18).

20 – Moreover, Annex XIII refers explicitly to products other than beverages that are measured in millilitres, making it plain that not all liquids are 'beverages'.

21 – Cf. Directive 2002/46: Regulation No 1924/2006 applies 'without prejudice' to that directive (Article 1(5)(d) of Regulation No 1924/2006); cf. also Regulation No 178/2002 in particular whose definition of 'food' is imported into Regulation No 1924/2006 (Article 2(1)(a) of Regulation No 1924//2006).

22 – Proposal for a regulation of the European Parliament and of the Council on nutrition and health claims made on foods, COM(2003) 424 final (OJ 2004 C 96, p. 8), amendment 42.

23 – Report on the proposal for a regulation of the European Parliament and of the Council on nutrition and health claims made on foods, A6-0128/2005.

24 – Common Position (EC) 3/2006 adopted by the Council on 8 December 2005 (OJ 2006 C 80 E/43), see in particular pp. 3 and 7.

25 – Exposé des motifs du Conseil, 8 December 2005, 2003/0165 (COD), p. 7.

26 – Communication from the Commission to the European Parliament, COM(2006) 2 final, p. 4.

27 – Recommendation for second reading on the Council Common Position for adopting a regulation of the European Parliament and of the Council on nutrition and health claims made on foods, A6-0122/2006.

28 – This is particularly obvious when one considers the rather fundamental nature of some of the other Chapter II requirements from which exemption is being asked (for example, claims must not be false, ambiguous or misleading or encourage excess consumption of a food). See Article 3(a) and (c) of Regulation No 1924/2006.

29 – Emphasis added. These words also appear in Article 5(1)(b), (c) and (d).

30 – See also Commission Implementing Decision 2013/63/EU of 24 January 2013 adopting guidelines for the implementation of specific conditions for health claims laid down in Article 10 of Regulation (No 1924/2006 of the European Parliament and of the Council (OJ 2013 L 22, p. 25), at p. 28, final paragraph.

31 – See also Commission Implementing Decision 2013/63, which requires that a specific health claim 'should bear some relevance to' the general claim; Article 1(3) of Regulation No 1924/2006, which is analogous to Article 10(3) (see point 55 above), states that the authorised health claim must be 'related' to the claim contained in the trade mark.

32 – This includes Article 28(5), which foresees transitional measures pending the adoption of the list pursuant to Article 13(3).

33 – See also on this point the Opinion of Advocate General Wathelet in Ehrmann, C‑609/12, EU:C:2013:746, point 97.

34 – For simplicity of presentation, I refer hereafter to trade marks only.

35 – Judgment of 18 July 2013 in Green — Swan Pharmaceuticals CR, C‑299/12, EU:C:2013:501.

36 – At paragraph 37.

37 – The present case is an example of such a situation. See, for example, judgments of 21 March 1991 in Delattre, C‑369/88, EU:C:1991:137, paragraphs 27 and 29; 9 June 2005 in HLH Warenvertrieb and Orthica, C‑211/03, C‑299/03 and C‑316/03 to C‑318/03, EU:C:2005:370, paragraph 56; 5 March 2009 in Commission v Spain, C‑88/07, EU:C:2009:123, paragraph 69.

38 – Recital 4: 'This Regulation should also apply to trade marks and other brand names which may be construed as nutrition or health claims.'

39 – COM(2003) 424 final (OJ 2004 C 96, p. 8).

40 – Report on the proposal for a regulation of the European Parliament and of the Council on nutrition and health claims made on foods, A6-0128/2005, amendment 19.

41 – The national court in Green — Swan basically asked if the Article 28(2) exception applied to (a) foods 'in that form' or (b) foods bearing a trade mark 'in that form'.

42 – Article 17(2) of the Charter of Fundamental Rights; see, in general, judgment of 16 July 2015 in Coty Germany, C‑580/13, EU:C:2015:485, paragraph 29; see also judgment of the Grand Chamber of the European Court of Human Rights of 11 January 2007 in Anheuser-Busch Inc. v. Portugal, (ECLI:CE:ECHR:2007:0111JUD007304901), paragraphs 66 to 78 (extending Article 1 of Protocol No 1 protection even to mere applications for the registration of a trade mark).