

# Reports of Cases

# OPINION OF ADVOCATE GENERAL HOGAN delivered on 12 September 2019<sup>1</sup>

Case C-524/18

## Dr. Willmar Schwabe GmbH & Co. KG v Queisser Pharma GmbH & Co. KG

(Request for a preliminary ruling from the Bundesgerichtshof (Federal Court of Justice, Germany))

(Reference for a preliminary ruling — Public health — Information and consumer protection — Regulation (EC) No 1924/2006 — Health claims relating to food — Article 10(1) and (3) — Concept of 'accompanying' a specific health claim — Reference to general, non-specific beneficial effects — Obligation to produce scientific evidence — Scope)

- 1. Where the packaging of food supplements makes general health claims on the front of that package, can it be said that the manufacturer has complied with the requirement contained in Article 10(3) of Regulation No 1924/2006<sup>2</sup> that such claims "may only be made if accompanied by a specific health claim included in the lists provided for in Article 13 or 14" where such a specific health claim is depicted on the back of that package? That, in essence, is the principal question which this Court is now required to consider following a reference to this effect from the Bundesgerichtshof (Federal Court of Justice, Germany).
- 2. The question concerning scientific evidence has been addressed in the Opinion of Advocate General Bobek in *Nelsons* (C-177/15).<sup>3</sup> In the light of this, I accordingly propose in line with the Court's request to confine the present Opinion so as to address solely the issue concerning the interpretation of Article 10(3). Before doing so, it is necessary to set out the relevant legislative background.

## Legislative framework

## EU law

- 3. Regulation No 1924/2006 states in recital 1 that 'an increasing number of foods labelled and advertised in the Community bear nutrition and health claims. In order to ensure a high level of protection for consumers and to facilitate their choice, products put on the market ... must be safe and adequately labelled'.
- 1 Original language: English.
- 2 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), amended most recently by Commission Regulation (EU) 2019/343 of 28 February 2019. The facts of the present case are covered by the consolidated version of the regulation published on 13 December 2014 as Document 02006R1924-20141213.
- 3 EU:C:2016:474. The Court did not find occasion to address the issue in the judgment of 23 November 2016, Nelsons (C-177/15, EU:C:2016:888).



- 4. Recital 16 further states that 'it is important that claims on foods can be understood by the consumer and it is appropriate to protect all consumers from misleading claims. However, since the enactment of Council Directive 84/450/EEC of 10 September 1984 concerning misleading and comparative advertising, the Court of Justice of the European Union has found it necessary in adjudicating on advertising cases to examine the effect on a notional, typical consumer. In line with the principle of proportionality, and to enable the effective application of the protective measures contained in it, this Regulation takes as a benchmark the average consumer, who is reasonably well informed and reasonably observant and circumspect, taking into account social, cultural and linguistic factors, as interpreted by the Court of Justice, but makes provision to prevent the exploitation of consumers whose characteristics make them particularly vulnerable to misleading claims'.
- 5. Recital 23 provides that 'health claims should only be authorised for use in the Community after a scientific assessment of the highest possible standard. In order to ensure harmonised scientific assessment of these claims, the European Food Safety Authority should carry out such assessments'.
- 6. Article 2(2)(1) provides that a 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'.
- 7. Article 2(2)(5) further provides that a 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 5(1)(a) provides that 'the use of nutrition and health claims shall only be permitted if the following conditions are fulfilled: (a) the presence, absence or reduced content in a food or category of food of a nutrient or other substance in respect of which the claim is made has been shown to have a beneficial nutritional or physiological effect, as established by generally accepted scientific evidence'.
- 9. Article 6(1) provides that 'nutrition and health claims shall be based on and substantiated by generally accepted scientific evidence'.
- 10. Article 10(1) provides that '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'.
- 11. Article 10(3) provides that 'reference to general, non-specific benefits of the nutrient or food for overall good health or health-related well-being may only be made if accompanied by a specific health claim included in the lists provided for in Article 13 or 14'.
- 12. Article 13(1) provides that 'health claims describing or referring to: (a) the role of a nutrient or other substance in growth, development and the functions of the body; or (b) psychological and behavioural function ... which are indicated in the list provided for in paragraph 3 may be made without undergoing the procedures laid down in Articles 15 to 19, if they are: (i) based on generally accepted scientific evidence; and (ii) well understood by the average consumer'.
- 13. Article 13(3) provides that 'after consulting the [European Food Safety Authority], the Commission shall adopt, in accordance with the regulatory procedure with scrutiny referred to in Article 25(3), a Community list, designed to amend non-essential elements of this Regulation by supplementing it, of permitted claims as referred to in paragraph 1 and all necessary conditions for the use of these claims'.

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- 14. Commission Regulation No 432/2012<sup>4</sup> provides in Article 1(a) and (b) that 'the list of health claims which may be made on foods, as referred to in Article 13(3) of Regulation (EC) No 1924/2006, is set out in the Annex to this Regulation. Health claims referred to in paragraph 1 may be made on foods in compliance with the conditions set out in the Annex'.
- 15. The Annex includes Vitamin B in the forms B6 and B12, for both of which a claim may be made amongst other that it 'contributes to normal energy-yielding metabolism', as well as zinc, for which a claim may be made amongst other that it 'contributes to normal cognitive function'.
- 16. The Annex further specifies that the respective claims may be made only for food which is at least a source of Vitamin B6, B12 or zinc as listed in the Annex to Regulation No 1924/2006 under the heading entitled 'source of [name of vitamin/s] and/or [name of mineral/s]'.
- 17. Under that heading, the Annex of Regulation No 1924/2006 provides that 'a claim that a food is a source of vitamins and/or minerals, and any claim likely to have the same meaning for the consumer, may only be made where the product contains at least a significant amount as defined in the Annex to Directive 90/496/EEC or an amount provided for by derogations granted according to Article 6 of Regulation (EC) No 1925/2006 of the European Parliament and of the Council of 20 December 2006 on the addition of vitamins and minerals and of certain other substances to foods'.
- 18. Finally, by means of Commission Implementing Decision 2013/63<sup>5</sup> guidelines have been adopted for the implementation of specific conditions for health claims laid down in Article 10 of Regulation No 1924/2006 (the 'Guidelines').
- 19. Section 3(1) of the Guidelines states that 'Article 10(3) allows the use of easy, attractive statements which make reference to general, non-specific benefits of a food for overall good health or health-related well-being, without prior authorisation, subject to specific conditions. The use of such statements could be helpful to consumers as they would convey more consumer-friendly messages. However, they could be easily misunderstood and/or misinterpreted by consumers, possibly leading to imagine other/better health benefits of a food than those that actually exist. For this reason, when referring to general, non-specific health benefits, it is required to accompany such references by a specific health claim from the lists of permitted health claims in the Union Register. For the purposes of the Regulation, the specific authorised health claim accompanying the statement making reference to general non-specific health benefits, should be made 'next to' or 'following' such statement'.
- 20. Further, Section 3(2) states that 'the specific claims from the lists of permitted health claims should bear some relevance to the general reference. As this reference becomes broader, e.g. "for good health", more health claims from the permitted lists could be eligible to accompany it. Still, attention should be paid to the fact that Article 10 sets rules as regards the context in which health claims are used and given that Article 10 specifically refers to the rules of Chapters II and IV, those rules should also be taken into account if operators wish to comply with the requirement laid down in Article 10(3). Therefore, to avoid misleading consumers, food business operators have the responsibility to demonstrate the link between the reference to general, non-specific benefits of the food and the specific, accompanying, permitted health claim'.

<sup>4</sup> Commission Regulation (EU) No 432/2012 of 16 May 2012 establishing a list of permitted health claims made on foods other than those referring to the reduction of disease risk and to children's development and health (OJ 2012 L 136, p. 1), amended most recently by Commission Regulation (EU) 2017/1407. The facts of the present case are covered by the consolidated version of the Regulation published on 13 May 2014 as Document 02012R0432-20140513.

<sup>5</sup> 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 (EC) No 1924/2006 of the European Parliament and of the Council (OJ 2013 L 22, p. 25).

- 21. Finally, Section 3(3) states that 'some claims submitted for authorisation during their scientific assessment were judged to be too general or non-specific for evaluation. These claims could not be authorised and can therefore be found in the list of the non-authorised claims of the Union Register of nutrition and health claims. This does not exclude that those claims could benefit from the provisions laid down in Article 10(3) and can therefore be lawfully used when they are accompanied by a specific claim from the list of permitted health claims in accordance with that Article'.
- 22. The Union Register of nutrition and health claims is published by the European Commission. It contains 40 unauthorised claims concerning Vitamin B, including five concerning Vitamin B2 and six concerning Vitamin B12, as well as seven unauthorised claims concerning zinc. None of the unauthorised claims appears to correspond to those made in the present case.

#### National law

- 23. Article 3(1) of the Gesetz gegen den unlauteren Wettbewerb (UWG, Unfair Competition Law)<sup>7</sup> provides that 'unfair commercial practices are illegal when they are likely to significantly affect the interests of competitors, consumers or other market operators'.
- 24. Article 5(1)(1) of the UWG provides that 'any deceptive marketing practice constitutes an act of unfair competition. A business practice is misleading when it involves inaccurate claims, or other misleading claims, about one or more of the following (1) the essential characteristics of the good or service, such as its availability, nature, performance, advantages, risks, composition, accessories, method and date of manufacture, delivery or service, its usability, its possible uses, its quantity, its properties, the aftersales service and the processing of the claims, its geographical or commercial origin, the results expected from its use, as well as the results and the main characteristics tests carried out on the good or the service'.
- 25. Article 11(1) of the Lebensmittel, Bedarfsgegenstände und Futtermittelgesetzbuch (LFGB, Code on Foodstuffs, Consumer Staples and Animal Feed), provides that it is forbidden to market food under a misleading name or with a misleading representation or indication or to promote it in a general way or in a particular case by means of presentations or other misleading statements. There is deception in particular: (1) in the case of which foodstuffs, names, indications, presentations, descriptions or other statements which may be misleading as to its characteristics, in particular the type, quality, composition, quantity, shelf life, origin, provenance or method of manufacture or production'.

### Facts, procedure and questions referred

- 26. Dr. Willmar Schwabe GmbH & Co. KG, 'the Applicant', manufactures and sells plant-based medicinal products containing ginkgo leaf extract, which are authorised for the symptomatic treatment of mental impairment caused by organic brain syndrome, including memory and concentration disorders in particular.
- 27. Queisser Pharma GmbH & Co. KG, 'the Defendant', sells the food supplement 'Doppelherz aktiv Ginkgo + B-Vitamine + Cholin' (Doppelherz active ginkgo + B vitamins + choline), which consists of a total of eight ingredients, including choline, zinc, ginkgo leaf extract and the vitamins B1 (thiamine), B2, B5 (pantothenic acid) and B12.
- $\ 6\ See\ http://ec.europa.eu/food/safety/labelling\_nutrition/claims/register/public/.$
- 7 In the version applicable to the dispute in the main proceedings.
- 8 In the version applicable to the case in the main proceedings.

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- 28. The front of the outer packaging features the claim 'B-Vitamine und Zink für Gehirn, Nerven, Konzentration und Gedächtnis' (B vitamins and zinc for the brain, nerves, concentration and memory).
- 29. The back of the outer packaging features several claims, of which the following concern B vitamins and zinc in relation to the brain, nerves, concentration and memory:

'Vitamin B1 and vitamin B12 contribute to normal energy metabolism and normal function of the nervous system as well as supporting normal mental capacity.

Vitamin B2, like vitamin B1, plays a role in normal energy metabolism and the normal function of the nervous system. It furthermore contributes to protecting cells against oxidative stress.

The trace element zinc contributes to normal cognitive function and helps to protect cells against oxidative stress.'

- 30. The back of the package also features additional claims concerning B vitamins in other relations than the brain, nerves, concentration and memory, as well as additional claims concerning other ingredients.
- 31. The Applicant initiated proceedings before the Landgericht Düsseldorf (Regional Court, Düsseldorf, Germany) with a plea that the claim on the front of the outer packaging violates Article 5(1)(a), 6(1) and 10(1) of Regulation No 1924/2006, as well as Article 5(1) UWG and Article 11(1) LFGB. The Landgericht Düsseldorf (Regional Court, Düsseldorf) dismissed the case by judgment of 28 August 2014.
- 32. In a judgment delivered on 30 June 2016 by Oberlandesgericht Düsseldorf (Regional High Court, Düsseldorf, Germany), the applicant's appeal was dismissed on the ground that the claim on the front of the outer packaging violates neither Article 10(1) nor Article 10(3) of the regulation.
- 33. The Oberlandesgericht Düsseldorf (Regional High Court, Düsseldorf) found that the claim was a general, non-specific health claim that was accompanied by specific health claims on the back of the outer packaging, including claims concerning Vitamins B1, B5 and B12, as well as zinc. Furthermore, the Oberlandesgericht Düsseldorf (Regional High Court, Düsseldorf) found that Article 10(3) of the Regulation did not set specific requirements for the manner in which specific claims were to accompany a general claim.
- 34. Furthermore, the Oberlandesgericht Düsseldorf (Regional High Court, Düsseldorf) found that if the claim on the front of the outer packaging were to be considered a specific health claim, it would satisfy the requirements of Article 10(1) as evidence would have been provided for the individual specific claims on the back of the outer packaging. However, the Oberlandesgericht Düsseldorf (Regional High Court, Düsseldorf) found that only a claim concerning specific functions of the organism could be regarded as a specific health claim, which was not the case here.
- 35. As for the plea in relation to Article 5(1) UWG and Article 11(1) LFGB, the Oberlandesgericht Düsseldorf (Regional High Court, Düsseldorf) found that, given its finding concerning the regulation, there was no need to address these provisions.
- 36. The Applicant further appealed to the referring court, the Bundesgerichtshof (Federal Court, Germany), under a special procedure limited to questions of law. The referring court in general confirmed the interpretation established by the Oberlandesgericht Düsseldorf (Regional High Court, Düsseldorf) of Article 10(3) of the regulation, but held that the alternative consideration of Article 10(1) was not required.

- 37. However, the referring court did find that the manner in which specific claims were to accompany a general claim did raise issues of interpretation of the regulation, especially as different language versions, as well as previous case-law of the referring court, would seem to require a direct link between the general and specific claims, such as, for example, by an asterisk to refer the reader from one to the other.
- 38. Furthermore, the referring court found that the present case would also depend on whether a general health claim, in addition to being accompanied by specific health claims, would also itself need to be based on scientific evidence, although such general health claims under Article 10(3) are exempted from the authorisation procedures of the Regulation.
- 39. Against this background, the referring court submitted the following questions:
- '(1) Is a reference to general, non-specific health-related benefits 'accompanied' within the meaning of Article 10(3) of Regulation (EC) No 1924/2006 by specific health claims in accordance with one of the lists provided for in Article 13 or 14 of that regulation, even if that reference is situated on the front and the authorised claims are situated on the back of an outer packaging and, in the perception of the public, although the claims are clearly related to the reference in terms of content, the reference does not contain a clear indication, marked with an asterisk, for example, to the claims on the back?
- (2) Does evidence within the meaning of Article 5(1)(a) and Article 6(1) of Regulation (EC) No 1924/2006 also need to be provided in the case of reference being made to general, non-specific benefits within the meaning of Article 10(3) of that regulation?'
- 40. Written observations have been submitted by the Applicant, the Defendant and the Commission, who also made submissions during the oral hearing.

#### Assessment

### Introductory remarks

- 41. The Applicant has noted that the questions from the referring court are concentrated on the interpretation of Article 10(3) of the regulation, whereas the Applicant contends that the Court should also address the interpretation of Article 10(1).
- 42. The Commission has also suggested that the Court should take a position on whether general health claims that refer to the combined effect of several ingredients will require authorisation under the Regulation.
- 43. As a point of departure, it follows from well-established case-law that since under Article 267 TFEU 'the power to formulate the questions to be referred is vested in the national court or tribunal alone, the parties cannot alter the wording of those questions'.
- 44. It also follows, however, from well-established case-law that the Court may address additional issues when it finds that this may be useful for the referring court. 10

<sup>9</sup> Judgment of 6 March 2003, Kaba (C-466/00, EU:C:2003:127, paragraph 40 and the case-law cited).

<sup>10</sup> See judgment of 17 December 2015, Neptune Distribution (C-157/14, EU:C:2015:823, paragraph 33 and the case-law cited), as well as judgment of 7 August 2018, Smith (C-122/17, EU:C:2018:631, paragraph 34).

- 45. In the present case, I consider that in order to reply to the first question from the referring court, it will be necessary first to address the distinction between general and specific claims, although this issue has not explicitly been raised by the national court.
- 46. As for the issue of the combined effect of general health claims covering several ingredients, this would relate to the second question from the referring court. As I have already observed, the Court has requested that the present Opinion should be limited to concern the first question.

## Question 1

47. The first question essentially concerns the manner in which general health claims must be accompanied by specific health claims, but as set out above, I consider that it is necessary first to establish the criteria for distinction between general and specific health claims.

### Specific and general health claims

- 48. Article 2(2)(5) of Regulation No 1924/2006, which defines health claims, does not provide any distinction between specific and general claims. Likewise, no distinction is made in Article 5(1), which requires scientific evidence for health claims, or Article 10(1), which requires use of an authorised wording for health claims, as set out in the Annex to Commission Regulation No 432/2012.
- 49. The use of general health claims is, however, expressly provided for in Article 10(3), which furthermore refers to them as 'non-specific' and requires that they must be accompanied by 'specific' health claims. On this background, it seems clear that specific and general claims form complementary parts of health claims, so that any claim must be either specific or general.
- 50. This is supported by the position taken by Advocate General Bobek in *Nelsons*, where he stated that Article 10(3) does not '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'. 11
- 51. This understanding is further confirmed by the Guidelines established by Commission Implementing Decision 2013/63 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, which state in Section 3(3) that 'some claims submitted for authorisation during their scientific assessment were judged to be too general or non-specific for evaluation'. For such claims, the Section further states that this 'does not exclude that those claims could benefit from the provisions laid down in Article 10(3) and can therefore be lawfully used when they are accompanied by a specific claim from the list of permitted health claims in accordance with that Article'.
- 52. This raises the question of whether it would serve any useful purpose to set definitional criteria for distinguishing between specific and general health claims. In order to be 'lawful', specific health claims must be 'authorised' and their wording must be included on a published list. A health claim that is found to be too general will be refused authorisation, but it may nonetheless be used as a general health claim if it is accompanied by a lawful specific claim.

<sup>11</sup> Opinion of Advocate General Bobek in Nelsons GmbH v Ayonnax Nutripharm GmbH and Bachblütentreff Ltd (C-177/15, EU:C:2016:474, point 56).

- 53. Accordingly, the practical administration of Regulation No 1924/2006 in this regard would seem to require that only two issues should be considered. The first is whether the health claim is a lawful specific claim found on the list of authorised claims, and if that is not the case, the second is whether the health claim is accompanied and supported by lawful specific claims.
- 54. The question of whether, in a given case, a health claim constitutes a lawful specific claim or a supported general claim is for the national court to assess in the light of the facts of the case. The assessment of specific claims is less complex, as it is based on a comparison with the list of authorised claims. The assessment of general claims is in turn a somewhat more complex exercise, as it requires comparison of the general claims with the specific claims that allegedly support it.
- 55. Neither the regulation nor the additional measures adopted by the Commission provide any indication of the level of support that must be established, although the Guidelines do state in Section 3(2) that 'food business operators have the responsibility to demonstrate the link between the reference to general, non-specific benefits of the food and the specific, accompanying, permitted health claim'.
- 56. In the present case, the general claim would seem to be supported in part by an authorised specific claim concerning zinc, whereas the extent to which it is supported by authorised specific claims concerning B vitamins is a rather more complex exercise. As, however, I have just indicated, this is a matter for the national court to assess in the light of the facts of the case and any relevant scientific or other evidence, which the parties may choose to address.

### Accompanied claims

- 57. The Defendant argues for a wide interpretation of the term 'accompanying', as a consumer must be assumed to read also the back side of a package, whereas the Applicant and the Commission argue for a restrictive interpretation of the term 'accompanying', as Article 10(3) forms an exception to the main rule in Article 10(1), which requires authorisation of health claims. They also argue that in the present case, the allegedly supportive specific health claims are mixed into a longer list of various claims, thus making it difficult to ascertain which claims are meant to support the general health claim.
- 58. The Guidelines state in Section 3(1) that 'for the purposes of Regulation No 1924/2006, the specific authorised health claim accompanying the statement making reference to general non-specific health benefits, should be made 'next to' or 'following' such statement'. 12
- 59. If the wording in the Guidelines ("next to" or "following") were to be taken at face value, then it suggests that the specific health claim must be immediately adjacent to the general health claim in order to comply with the "accompanied" requirement contained in Article 10(3) of the regulation. While it is true that Article 10(4) envisages that Guidelines may be adopted, which in line with Recital 2 of Commission Implementing Decision 2013/63 may have the purpose of ensuring "consistency in the application of these provisions" and to "ensure greater clarity and certainty for economic operators", it is axiomatic that in a Union founded on respect for the rule of law, the actual wording of Article 10(3) of the regulation cannot be changed or amended or otherwise enlarged by reason of Guidelines such as these.

<sup>12</sup> The same follows from the German version of the Guidelines, which state that 'für die Zwecke der Verordnung sollte die dem Verweis auf allgemeine, nichtspezifische Vorteile für die Gesundheit beigefügte zugelassene spezielle gesundheitsbezogene Angabe neben oder unter diesem Verweis angebracht werden'.

- 60. It follows, therefore, that the issue must be determined exclusively by reference to the actual words of Article 10(3). Narrow and fine though the distinction might be, the word 'accompany' is nonetheless somewhat broader and more expansive than the words 'next to' or 'following' as used in the Guidelines. One could thus in everyday conversation speak, for example, of a letter 'accompanying' a gift, even though the letter might be in a sealed envelope and the gift itself separately wrapped.
- 61. To my mind, therefore, the use of the word "accompany" in this context suggests that it is sufficient that the specific health claims required by Article 10(3) are prominently displayed elsewhere on the packaging. It is not necessary that the specific health claims are placed next to, or follow, or are otherwise immediately adjacent to the general health claims made in the present case on the front of the package. Nor does Article 10(3) contain any requirement that the general and the specific health claims be linked in some way, such as by an asterisk. It is instead sufficient that the specific health claims are given sufficient prominence such that they are accessible and can be read by the consumer.
- 62. If it is considered that, as so judicially interpreted, Article 10(3) is deficient or does not adequately protect the consumer interests, then, of course, it is open to the Union legislature to remedy that deficiency. As the law stands, however, it must be admitted that, as a matter of ordinary speech, a statement on the back of consumer packaging can be said to "accompany" a statement on the front of that packaging.
- 63. This view is supported by *Neptune* (C-157/14), <sup>13</sup> in which the Court confirmed that 'by adopting the provisions of Regulation No 1924/2006 and Directive 2009/54, the EU legislature deemed it necessary to ensure that the consumer receives appropriate and transparent information'.
- 64. Furthermore, it follows from *Teekanne* (C-195/14), <sup>14</sup> that 'it is apparent from the case-law that the Court has acknowledged that consumers whose purchasing decisions depend on the composition of the products in question will first read the list of ingredients'.
- 65. In my opinion, the criteria considered in this case-law may be applied by analogy to the present case, so that it may be expected that a consumer reading a general health statement on the front of the packaging of a food product will also consult the further information provided on the back of the packaging, which in addition to a list of ingredients may also include a set of specific health claims that are meant to support the general health claim.
- 66. Thus, in my opinion, it cannot be a general requirement that a specific linking tool, such as the use of an asterisk, be deployed in order to guide the consumer from the front to the back of the packaging. However, the situation becomes more complex where the information on the back of the packaging contains a mix of statements, of which only some serve to support the general health claim on the front of the package, as referred to by the Applicant and the Commission.
- 67. The question of whether a general health claim is, in fact, supported by specific health claims in a manner that is sufficiently clear for the consumer to assess, is for the national court to consider in the light of the facts of the case.
- 68. In this connection, it should be noted that the Court in *Teekanne* (C-195/14), <sup>15</sup> underlined that 'the national court must in essence take account of the presumed expectations, in light of that labelling, which an average consumer who is reasonably well informed, and reasonably observant and circumspect has'.

<sup>13</sup> Judgment of 17 December 2015 (EU:C:2015:823, paragraph 51).

<sup>14</sup> Judgment of 4 June 2015, Teekanne (C-195/14, EU:C:2015:361, paragraph 37).

<sup>15</sup> Judgment of 4 June 2015 (EU:C:2015:361, paragraph 36).

69. Furthermore, it may be noted that in the present case there might be an additional problem, as several of the statements on the back of the packaging concerning Vitamin B would seem not to correspond to the list of authorised specific health statements. This, however, is again a matter for the national court to assess.

### **Question 2**

- 70. As set out above, this Opinion is limited to addressing the first question.
- 71. In *Nelsons* (C-177/15), <sup>16</sup> Advocate General Bobek gave the opinion 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. I would agree with this opinion.

#### Conclusion

- 73. I propose that the Court should give the following answer to the first question referred for a preliminary ruling by the Bundesgerichtshof (Federal Court of Justice, Germany):
- (1) Article 10(1) and (3) of Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods, is to be interpreted so that the term 'specific health claims' refers to claims that have been authorised under the Regulation, whereas the term 'general health claims' refers to claims that may be accompanied by specific health claims.
- (2) Article 10(3) of Regulation No 1924/2006 is to be interpreted so that when assessing whether general health claims are accompanied by specific health claims, it must be assessed, firstly, whether the specific health claims have been authorised, secondly, whether the specific health claims support the general health claims, and thirdly, whether the relationship between the general and specific claims may be discerned by an average consumer who is reasonably well informed, and reasonably observant and circumspect.
- (3) As a point of departure, the placing of general health claims on the front of packaging and the placing of specific health claims on the back of packaging will be sufficient to establish a relationship between the claims so that the general health claim may be said to be 'accompanied' by the specific health claim within the meaning of Article 10(3). However, the national court must assess whether the placing of other information on the packaging may cause the relationship to become insufficiently clear for an average consumer who is reasonably well informed, and reasonably observant and circumspect.

<sup>16</sup> Opinion of Advocate General Bobek in Nelsons GmbH v Ayonnax Nutripharm GmbH and Bachblütentreff Ltd (C-177/15, EU:C:2016:474, point 71).