Reports of Cases

JUDGMENT OF THE COURT (Second Chamber)

27 October 2022*

(Reference for a preliminary ruling – Food safety – Food – Regulation (EU) No 609/2013 – Article 2(2)(g) – Delegated Regulation (EU) 2016/128 – Food for special medical purposes – Other particular nutritional requirements – Food providing a general benefit for the patient – Distinction in relation to medicinal products)

In Case C-418/21,

REQUEST for a preliminary ruling under Article 267 TFEU from the Oberlandesgericht Düsseldorf (Higher Regional Court, Düsseldorf, Germany), made by decision of 28 June 2021, received at the Court on 9 July 2021, in the proceedings

Orthomol pharmazeutische Vertriebs GmbH

v

Verband Sozialer Wettbewerb eV,

THE COURT (Second Chamber),

composed of A. Prechal, President of the Chamber, M.L. Arastey Sahún, F. Biltgen, N. Wahl (Rapporteur) and J. Passer, Judges,

Advocate General: T. Ćapeta,

Registrar: A. Calot Escobar,

having regard to the written procedure,

after considering the observations submitted on behalf of:

– Orthomol pharmazeutische Vertriebs GmbH, by M. Hagenmeyer, Rechtsanwalt,

– Verband Sozialer Wettbewerb eV, by H. Reinhardt, Rechtsanwalt,

– the Greek Government, by V. Karra and A. Zacheilas, acting as Agents,

– the Italian Government, by G. Palmieri, acting as Agent, and by L. Vignato, avvocato dello Stato,

* Language of the case: German.

– the European Commission, by I. Galindo Martín and B.-R. Killmann, acting as Agents,

having decided, after hearing the Advocate General, to proceed to judgment without an Opinion,

gives the following

Judgment

1 This request for a preliminary ruling concerns the interpretation of Regulation (EU) No 609/2013 of the European Parliament and of the Council of 12 June 2013 on food intended for infants and young children, food for special medical purposes and total diet replacement for weight control and repealing Council Directive 92/52/EEC, Commission Directives 96/8/EC, 1999/21/EC, 2006/125/EC and 2006/141/EC, Directive 2009/39/EC of the European Parliament and of the Council and Commission Regulations (EC) No 41/2009 and (EC) No 953/2009 (OJ 2013 L 181, p. 35), as well as that of Commission Delegated Regulation (EU) 2016/128 of 25 September 2015 supplementing Regulation (EU) No 609/2013 of the European Parliament and of the Council as regards specific compositional and information requirements for food for special medical purposes (OJ 2016 L 25, p. 30).

2 The request has been made in the context of proceedings between Orthomol pharmazeutische Vertriebs GmbH ('Orthomol') and Verband Sozialer Wettbewerb eV ('VSW') concerning the marketing by Orthomol of products as food for special medical purposes.

Legal context

Regulation No 609/2013

3 Recitals 9, 10, 12, 13, 15 and 25 of Regulation No 609/2013 are worded as follows:

'(9) A report from the Commission of 27 June 2008 to the European Parliament and to the Council on the implementation of [the] notification procedure [provided for by Directive 2009/39/EC of the European Parliament and of the Council of 6 May 2009 on foodstuffs for particular nutritional uses (OJ 2009 L 124, p. 21)] showed that difficulties can arise from the definition of "foodstuffs for particular nutritional uses" which appeared to be open to differing interpretations by the national authorities. It therefore concluded that a revision of [Directive 2009/39] would be required to ensure a more effective and harmonised implementation of Union legal acts.

(10) A study report of 29 April 2009 by Agra CEAS Consulting, concerning the revision of [Directive 2009/39], confirmed the findings of the Commission report of 27 June 2008 on the implementation of the notification procedure and indicated that an increasing number of foodstuffs are currently marketed and labelled as foodstuffs suitable for particular nutritional uses, due to the broad definition laid down in that Directive. The study report also pointed out that food regulated under that Directive differs significantly between Member States; similar food could at the same time be marketed in different Member States as food for particular nutritional uses and/or as food for normal consumption, including food supplements, addressed to the population in general or to certain subgroups thereof such as pregnant women, postmenopausal women, older adults, growing

children, adolescents, variably active individuals and others. This state of affairs undermines the functioning of the internal market, creates legal uncertainty for competent authorities, food business operators, in particular small and medium-sized enterprises (SMEs), and consumers, while the risks of marketing abuse and distortion of competition cannot be ruled out. There is therefore a need to eliminate differences in interpretation by simplifying the regulatory environment.

…

(12) Moreover, experience shows that certain rules included in, or adopted under, [Directive 2009/39] are no longer effective in ensuring the functioning of the internal market.

(13) Therefore, the concept of "foodstuffs for particular nutritional uses" should be abolished and [Directive 2009/39] should be replaced by this act. To simplify the application of this act and to ensure consistency of application throughout the Member States, this act should take the form of a Regulation.

…

(15) A limited number of categories of food constitute a partial or the sole source of nourishment for certain population groups. Such categories of food are vital for the management of certain conditions and/or are essential to satisfy the nutritional requirements of certain clearly identified vulnerable population groups. Those categories of food include infant formula and follow-on formula, processed cereal-based food and baby food, and food for special medical purposes. Experience has shown that the provisions laid down in [Commission] Directives 1999/21/EC [of 25 March 1999 on dietetic foodstuffs for special medical purposes (OJ 1999 L 91, p. 29)], 2006/125/EC [of 5 December 2006 on processed cereal-based foods and baby foods for infants and young children (OJ 2006 L 339, p. 16)] and 2006/141/EC [of 22 December 2006 on infant formulae and follow-on formulae and amending Directive 1999/21/EC (OJ 2006 L 401, p. 1)] ensure the free movement of those categories of food in a satisfactory manner, while ensuring a high level of protection of public health. It is therefore appropriate that this Regulation focuses on the general compositional and information requirements for those categories of food, taking into account Directives [1999/21, 2006/125 and 2006/141].

…

(25) The labelling, presentation or advertising of food covered by this Regulation should not attribute to such food the property of preventing, treating or curing a human disease nor should they imply such properties. Food for special medical purposes, however, is intended for the dietary management of patients with a limited, impaired or disturbed capacity, for example, to take ordinary food because of a specific disease, disorder or medical condition. Reference to the dietary management of diseases, disorders or medical conditions for which the food is intended should not be considered as attribution of the property of preventing, treating or curing a human disease.'

4 Article 1(1) of that regulation provides:

'This Regulation establishes compositional and information requirements for the following categories of food:

(a) infant formula and follow-on formula;

(a) processed cereal-based food and baby food;

(c) food for special medical purposes;

(d) total diet replacement for weight control.'

5 Article 2(2)(g) of that regulation sets out the following definition:

'"food for special medical purposes" means food specially processed or formulated and intended for the dietary management of patients, including infants, to be used under medical supervision; it is intended for the exclusive or partial feeding of patients with a limited, impaired or disturbed capacity to take, digest, absorb, metabolise or excrete ordinary food or certain nutrients contained therein, or metabolites, or with other medically determined nutrient requirements, whose dietary management cannot be achieved by modification of the normal diet alone'.

6 Article 9(1) and (5) of that regulation provides:

'1. The composition of food referred to in Article 1(1) shall be such that it is appropriate for satisfying the nutritional requirements of, and is suitable for, the persons for whom it is intended, in accordance with generally accepted scientific data.

…

5. The labelling, presentation and advertising of food referred to in Article 1(1) shall provide information for the appropriate use of such food, and shall not mislead, or attribute to such food the property of preventing, treating or curing a human disease, or imply such properties.'

Delegated Regulation 2016/128

7 Recitals 3 to 5 of Delegated Regulation 2016/128 are worded as follows:

'(3) Food for special medical purposes is developed in close cooperation with health care professionals to feed patients affected by or malnourished because of a specific diagnosed disease, disorder or medical condition that makes it impossible or very difficult for those patients to satisfy their nutritional needs through the consumption of other foods. For that reason, food for special medical purposes is to be used under medical supervision, which may be applied with the assistance of other competent health professionals.

(4) The composition of food for special medical purposes may differ substantially depending, among others, on the specific disease, disorder or medical condition for the dietary management of which the product is intended, on the age of the patients and the place in which they receive health care support, and the product's intended use. In particular, food for special medical purposes can be classified in different categories depending on whether

its composition is standard or specifically nutrient-adapted for a disease, disorder or medical condition and on whether or not it constitutes the sole source of nourishment for the persons for whom it is intended.

(5) Because of the wide diversity of food for special medical purposes, the rapidly evolving scientific knowledge on which it is based, and the need to ensure adequate flexibility to develop innovative products, it is not appropriate to lay down detailed compositional rules for such food products. It is, however, important to set principles and requirements specific to them in order to ensure that they are safe, beneficial and effective for the persons for whom they are intended on the basis of generally accepted scientific data.'

8 Article 2 of this delegated regulation states:

'1. Food for special medical purposes is classified in the following three categories:

(a) nutritionally complete food with a standard nutrient formulation which, used in accordance with the manufacturer's instructions, may constitute the sole source of nourishment for the persons for whom it is intended;

(b) nutritionally complete food with a nutrient-adapted formulation specific for a disease, disorder or medical condition which, used in accordance with the manufacturer's instructions, may constitute the sole source of nourishment for the persons for whom it is intended;

(c) nutritionally incomplete food with a standard formulation or a nutrient-adapted formulation specific for a disease, disorder or medical condition which is not suitable to be used as the sole source of nourishment.

The food referred to in points (a) and (b) of the first subparagraph may also be used as a partial replacement or as a supplement to the patient's diet.

2. The formulation of food for special medical purposes shall be based on sound medical and nutritional principles. Its use, in accordance with the manufacturer's instructions, shall be safe, beneficial and effective in meeting the specific nutritional requirements of the persons for whom it is intended, as demonstrated by generally accepted scientific data.

3. Food for special medical purposes developed to satisfy the nutritional requirements of infants shall comply with the compositional requirements set out in Part A of Annex I.

Food for special medical purposes other than that developed to satisfy the nutritional requirements of infants shall comply with the compositional requirements set out in Part B of Annex I.

4. The compositional requirements set out in Annex I shall apply to the food for special medical purposes ready for use, marketed as such or after preparation in accordance with the manufacturer's instructions.'

9 Article 5(2)(e) and (g) of that delegated regulation provides:

‘2. … the following shall be additional mandatory particulars for food for special medical purposes:

(e) the statement “For the dietary management of …” where the blank shall be filled in with the disease, disorder or medical condition for which the product is intended;

…

(g) a description of the properties and/or characteristics that make the product useful in relation to the disease, disorder or medical condition for the dietary management of which the product is intended, in particular, as the case may be, relating to the special processing and formulation, the nutrients which have been increased, reduced, eliminated or otherwise modified and the rationale of the use of the product’.

10 Article 9 of Delegated Regulation 2016/128 provides:

‘When food for special medical purposes is placed on the market, the food business operator shall notify the competent authority of each Member State where the product concerned is being marketed of the information appearing on the label, by sending to it a model of the label used for the product, and of any other information the competent authority may reasonably request to establish compliance with this Regulation, unless a Member State exempts the food business operator from that obligation under a national system that guarantees an efficient official monitoring of the product concerned.’

Directive 2001/83/EC

11 Article 1.2 of Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ 2001 L 311, p. 67), as amended by Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004 (OJ 2004 L 136, p. 34) (‘Directive 2001/83’), provides:

‘For the purposes of this Directive, the following terms shall bear the following meanings:

2. *Medicinal product:*
   (a) Any substance or combination of substances presented as having properties for treating or preventing disease in human beings; or
   (b) Any substance or combination of substances which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis’.

Regulation (EC) No 178/2002

12 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"', is worded as follows:

'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" shall not include:

…

(d) medicinal products within the meaning of Council Directives 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 (OJ, English Special Edition 1965-1966, p. 20)] and 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)]'.

13 Directives 65/65 and 92/73, referred to in the preceding paragraph, were codified by Directive 2001/83.

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

14 Orthomol is a pharmaceutical company which markets the products 'Orthomol Immun' and 'Orthomol AMD extra' as food intended for special medical purposes. It promotes those products by stating that the first is used to 'support the immune system using nutritional science' for 'the dietary management of nutrition-related immune deficiencies' (for example, recurrent respiratory infections')' and that the second is used for the 'dietary management of advanced age-related macular degeneration' ('AMD').

15 VSW, an association one of whose statutory objects is to ensure compliance with the rules on fair competition, brought an action against Orthomol by which it sought a prohibition of the marketing of the products in question as foods for special medical purposes.

16 In that regard, VSW submitted that those products do not meet the conditions necessary for such a classification. It pointed out that Article 2(2)(g) of Regulation No 609/2013 defines food intended for special medical purposes by contemplating two situations which are not applicable to the products in question. Thus, the illnesses which those products are supposed to combat, namely nutrition-related immune deficiency and AMD, are not illnesses which lead to a limited, impaired or disturbed capacity to take, digest, absorb, metabolise or excrete ordinary foods or certain nutrients contained therein, or metabolites, within the meaning of the first situation envisaged under that provision. Furthermore, it was argued, the second situation contemplated in

Article 2(2)(g) of Regulation No 609/2013 concerns exclusively diseases giving rise to a particular energy and nutritional need, such as cystic fibrosis, cancerous cachexia, serious wounds/burns/pressure ulcers, and not the substances used to treat the disease itself.

17 The court of first instance, the Landgericht Düsseldorf (Regional Court, Düsseldorf, Germany), delivered a judgment upholding the action on the ground that, in order for a product to be classified as a food intended for special medical purposes, it is not sufficient that the nutrients have positive effects on the occurrence or course of a disease in that they contribute to preventing, mitigating or curing it.

18 Orthomol brought an appeal against that judgment before the Oberlandesgericht Düsseldorf (Higher Regional Court, Düsseldorf, Germany), which is the referring court.

19 That court must determine whether the products 'Orthomol Immun' and 'Orthomol AMD extra' can be classified as food for special medical purposes and it expresses uncertainty, in that context, as to the interpretation of that concept. In that regard, it states that the Bundesgerichtshof (Federal Court of Justice, Germany) has interpreted the legislation prior to Regulation No 609/2013, namely Directive 1999/21 and Directive 2009/39, as meaning that a particular nutritional purpose exists not only where there is a medically determined nutritional deficiency, but also where the nutrient intake is intended to counteract illnesses in another way and the consumer can derive a particular benefit from the controlled intake of certain nutrients. Commentary on that case-law expresses the view that such foodstuffs have thereby been categorised as 'small medicinal products'.

20 However, the referring court is uncertain whether that interpretation can be maintained in the context of Regulation No 609/2013. In its view, it follows from the history and the wording of that regulation that food for special medical purposes must be developed, intended and suitable for patients whose nutritional needs cannot be met by the consumption of ordinary food because of certain diseases, disorders or a particular state of health.

21 In the present case, since the immune deficiency of nutritional origin and AMD are illnesses, it seeks to ascertain whether classification as a food for special medical purposes, under Article 2(2)(g) of Regulation No 609/2013, presupposes that the product is designed to meet a particular nutritional need or whether it is sufficient that the product procures a general benefit for the patient in so far as the substances of which it is composed contribute to preventing, alleviating or curing a disease.

22 In those circumstances, the Oberlandesgericht Düsseldorf (Higher Regional Court, Düsseldorf) decided to stay the proceedings and to refer the following questions to the Court of Justice for a preliminary ruling:

'(1) Under what circumstances are there other medical nutrient requirements pursuant to the second alternative in Article 2(2)(g) of Regulation No 609/2013?

Namely: do they require – in addition to the limited, impaired or disturbed capacity to take, digest, absorb, metabolise or excrete ordinary food, as referred to in the first alternative – that there is an increased nutrient requirement brought about by illness, which is to be covered by the food, or is it sufficient that the patient … benefits generally from the intake of that food because substances contained therein counteract the disorder or alleviate its symptoms?

(2) In the event that the first question is answered in accordance with the latter alternative: do "generally accepted scientific data" within the meaning of Article 2(2) of the Delegated Regulation [2016/128] always require a randomised, placebo-controlled double-blind study which, although not related to the product in question itself, at least provides starting points for the claimed effects?'

Consideration of the questions referred

The first question

23 By its first question, the referring court asks, in essence, whether Article 2(2)(g) of Regulation No 609/2013 and, in particular, the concept of 'other medically determined nutrient requirements', must be interpreted as meaning that, for the purposes of classifying a product as a food intended for special medical purposes, the disease must give rise to increased nutritional requirements, which are to be covered by the food, or whether it is sufficient that the patient benefits generally from the intake of that food because substances contained therein counteract the disorder or alleviate its symptoms.

24 As regards the interpretation of that provision and, in particular, of the concept of 'other medically determined nutrient requirements', in order to determine the meaning and scope of that provision, account must be taken, in accordance with settled case-law, not only of its wording but also of its context and the objectives pursued by the rules of which it is part (judgment of 17 December 2020, *A.M. (Labelling of cosmetic products)*, C-667/19, EU:C:2020:1039, paragraph 22 and the case-law cited).

25 In the first place, it follows from the wording of Article 2(2)(g) of Regulation No 609/2013 that foodstuffs intended for special medical purposes have two characteristics which distinguishes them from other categories of products. First, they are foodstuffs intended for the exclusive or partial feeding of patients with a specific disease, disorder or medical condition. Second, they are specially processed or formulated to meet the particular nutritional needs resulting from such a disease, disorder or medical condition.

26 Thus, it should be noted at the outset that, according to their actual description, foods intended for special medical purposes are foodstuffs which, by their nature, are intended to be ingested and used for human consumption.

27 That nutritional function of food for special medical purposes is confirmed by the fact that, in accordance with Article 2(2)(g) of Regulation No 609/2013, it is intended for 'the exclusive or partial feeding' of certain patients, in particular those who, because of their medical condition, have 'medically determined nutrient requirements'.

28 However, foods for special medical purposes are not ordinary foodstuffs. As their name indicates, they are intended 'for special medical purposes'.

29 It thus follows, in particular, from Article 2(2)(g) of Regulation No 609/2013 that a food for special medical purposes is a food which is 'specially processed or formulated' to meet the particular nutritional needs of patients and which may be used only under medical supervision.

30 Furthermore, the EU legislature has defined the concept of 'food for special medical purposes' by envisaging two types of special medical purposes for which those foods may be intended.

31 On the one hand, they are intended for patients whose capacity to take, digest, absorb, metabolise, or excrete ordinary food or some of its ingredients or metabolites is limited, impaired or disturbed.

32 Alternatively, they are intended for patients whose medical condition gives rise to other medically determined nutrient requirements which cannot be satisfied by a modification of the normal diet alone.

33 Thus, the first situation envisaged in Article 2(2)(g) of Regulation No 609/2013 concerns those categories of patients whose intake, absorption or metabolism is disrupted. The second situation referred to in that provision relates to patients who have particular physiological conditions and who therefore have specific needs in terms of the composition, consistency or form of foodstuffs.

34 The suitability required between the foodstuff, in its composition, consistency or form, and the nutritional needs, caused by a disease, disorder or medical condition, which the foodstuff seeks to address, precludes a product from being classified as a food for special medical purposes solely on the ground that the nutrients of which it is composed have positive effects in the sense that they bring general benefit to the patient and contribute to preventing, alleviating or curing that patient's illness, disorder or medical condition.

35 On the one hand, although food for special medical purposes must be designed to meet specific nutritional requirements arising from a specific disease, disorder or medical condition, it does not at all follow from Article 2(2)(g) of Regulation No 609/2013, that, in order to be classified as a food for special medical purposes, it is sufficient that a product has such effects and provides a general benefit to the patient.

36 On the other hand, such a requirement for suitability illustrates the specific nature of the nutritional function of food for special medical purposes. Thus, a product which, although beneficial to the patient or, as claimed by Orthomol in respect of the products in question, otherwise combating a disease, disorder or medical condition by means of nutritional intake, but which lacks such a nutritional function, cannot be classified as a food for special medical purposes.

37 In that context, it must be pointed out that food for special medical purposes differs both from ordinary food, coming under Regulation No 178/2002, and from medicinal products and that those three categories of products are, in view of their specific characteristics, the subject of separate and exclusive definitions and legal regimes.

38 In that regard, the characteristics and functions of food intended for special medical purposes differ from those of medicinal products which, under Article 1.2 of Directive 2001/83, are to be understood as any substance or combination of substances presented for treating or preventing disease in human beings or any substance or combination of substances which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis.

39 It cannot be inferred from Article 2(2)(g) of Regulation No 609/2013 that food for special medical purposes is intended to prevent or cure human diseases, to restore, correct or modify physiological functions by exerting a pharmacological, immunological or metabolic action, or to make a medical diagnosis, since they are intended to meet patients' nutritional needs.

40 Thus, foods for special medical purposes do not, as such, make it possible for a disease, disorder or medical condition to be counteracted, but rather their specific nutritional function makes it possible to characterise them in such a way that a product which is not intended to perform such a function cannot be classified as such.

41 However, if a patient derives a general benefit from the intake of a product in so far as the substances of which it is composed contribute to preventing, alleviating or curing a disease, at that time that product is intended not to feed that patient but to treat him or her, prevent a disease or restore, correct or modify physiological functions by exerting a pharmacological, immunological or metabolic action militating in favour of a classification of that product as other than a food for special medical purposes.

42 In the second place, the context of Article 2(2)(g) of Regulation No 609/2013 confirms such an interpretation of that provision.

43 Thus, recital 15 of that regulation states that foods for special medical purposes 'constitute a partial or the sole source of nourishment' for certain population groups and are 'vital for the management of certain conditions and/or are essential to satisfy the nutritional requirements' of those population groups.

44 Furthermore, the necessary suitability between a food intended for special medical purposes and the nutritional needs caused by the disease, disorder or medical condition which it is designed to address is confirmed by the provisions of Regulation No 609/2013 and of Delegated Regulation 2016/128 on the composition and labelling of foods for special medical purposes.

45 In that regard, it should be noted that, in accordance with Article 9(1) of Regulation No 609/2013, the composition of food intended for special medical purposes must be appropriate for satisfying nutritional requirements and must be suitable for the patients for whom it is intended.

46 Article 9(5) of that regulation thus states that the labelling, presentation and advertising of food for special medical purposes must not attribute to such food the properties of preventing, treating or curing a human disease.

47 It would, however, be inconsistent to classify a product as a food intended for special medical purposes on the ground that the patient derives a general benefit from the intake of that product because the substances that it contains counteract the disorder or alleviate its symptoms while prohibiting mention of that fact on the labelling of such a product.

48 The requirement of suitability between a product classified as a food for special medical purposes and the nutritional needs caused by the disease, disorder or medical condition which it is intended to address also follows from the provisions of Delegated Regulation 2016/128.

49 Thus, in defining, in Article 2(1) of that delegated regulation, the three categories of food for special medical purposes, that provision requires that their respective compositions be adapted to meet the nutritional needs relating to a disease, disorder or medical condition. Similarly, Article 2(2) of that regulation states that the use of such foods must be adapted in particular to meet the specific nutritional requirements of the persons for whom they are intended.

50 Furthermore, it follows from Article 5(2)(e) and (g) of that delegated regulation that each food intended for special medical purposes is to include, first, the indication of the nutritional requirements and the disease, disorder or medical condition for which it is intended and, second, a description of the properties and characteristics that make the product useful in relation to the nutritional requirements in the case of the disease, disorder or medical condition which it is intended to manage.

51 Such a reference presupposes that the nutritional needs caused by the disease, disorder or medical condition which the food for special medical purposes is supposed to meet are identified.

52 The requirement of that indication demonstrates unequivocally that a food for special medical purposes must meet nutritional needs defined by a particular disease, disorder or medical condition and that a product which provides a general benefit to the patient does not, in principle, have such properties and characteristics in so far as it does not have the function of meeting such particular nutritional needs. It follows that such a product cannot, for that reason, be classified as a food for special medical purposes.

53 Third, that interpretation of Article 2(2)(g) of Regulation No 609/2013 is supported by the objectives of that regulation.

54 As is apparent from recitals 9 and 10 of Regulation No 609/2013, the purpose of the latter is, inter alia, to clarify the concept of 'foodstuffs for particular nutritional uses' referred to in Directive 2009/39 and to ensure uniform and appropriate interpretation and application within the European Union of the various categories of food coming within the scope of that regulation.

55 Such an objective presupposes, in particular, that the concept of 'food for special medical purposes' is not interpreted, in respect of certain products, so broadly as to encroach on other categories of products which are the subject of specific rules under EU law.

56 The interpretation to the effect that it is sufficient, in order to be classified as a food for special medical purposes, for the patient to benefit generally from the intake of a product because the substances which it contains counteract a disorder or alleviate its symptoms disregards the specific characteristics of foodstuffs intended for special medical purposes and calls into question, in particular, the distinction between such foodstuffs and medicinal products.

57 Classification as a food for special medical purposes could thus be acquired if the product counteracts a disease or disorder from which the patient is suffering even though it does not meet the nutritional needs arising from that disease or that disorder, but comes under the legislation on medicinal products which makes the placing on the market of such products subject to the grant of authorisation.

58 It follows that the fact that a product makes it possible to control in some other way, by means of nutritional intake, a disease, disorder or medical condition is not sufficient for such a product to be classified as a food for special medical purposes if that product is not intended to meet the particular nutritional needs caused by a disease, disorder or medical condition.

59 In the light of all the foregoing considerations, Article 2(2)(g) of Regulation No 609/2013 and, in particular, the concept of 'other medically determined nutrient requirements', must be interpreted as meaning that a product constitutes a food for special medical purposes if the disease results in increased or specific nutritional requirements which the food is intended to cover, such that it is not sufficient, for the purposes of such a qualification, that the patient derives a general benefit from the intake of that food because the substances that it contains counteract the disorder or alleviate its symptoms.

The second question

60 In view of the answer to the first question referred, there is no need to answer the second question.

Costs

61 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 (Second Chamber) hereby rules:

Article 2(2)(g) of Regulation (EU) No 609/2013 of the European Parliament and of the Council of 12 June 2013 on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control and repealing Council Directive 92/52/EEC, Commission Directives 96/8/EC, 1999/21/EC, 2006/125/EC and 2006/141/EC, Directive 2009/39/EC of the European Parliament and of the Council and Commission Regulations (EC) No 41/2009 and (EC) No 953/2009 and, in particular, the concept of 'other medically determined nutrient requirements',

must be interpreted as meaning that a product constitutes a food for special medical purposes if the disease results in increased or specific nutritional requirements which the food is intended to cover, such that it is not sufficient, for the purposes of such a qualification, that the patient derives a general benefit from the intake of that food because the substances that it contains counteract the disorder or alleviate its symptoms.

[Signatures]