Reports of Cases

JUDGMENT OF THE COURT (Second Chamber)

2 March 2023 *

(Reference for a preliminary ruling – Food safety – Food – Regulation (EU) No 609/2013 – Article 2(2)(g) – Concept of 'food for special medical purposes' – Other particular nutritional requirements – Dietary management – Modification of the diet – Nutrients – Use under medical supervision – Ingredients not absorbed or metabolised in the alimentary canal – Distinction in relation to medicinal products – Distinction in relation to food supplements)

In Case C-760/21,

REQUEST for a preliminary ruling under Article 267 TFEU from the Verwaltungsgericht Wien (Administrative Court, Vienna, Austria), by decision of 26 November 2021, received at the Court on 10 December 2021, in the proceedings

Kwizda Pharma GmbH

v

Landeshauptmann von Wien,

THE COURT (Tenth 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:

– Kwizda Pharma GmbH, by J. Hütthaler-Brandauer, Rechtsanwalt,

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

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

* Language of the case: German.

gives the following

Judgment

1 This request for a preliminary ruling concerns the interpretation, first, of 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 (OJ 2013 L 181, p. 35), and Directive 2002/46/EC 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).

2 The request has been made in proceedings between Kwizda Pharma GmbH and the Landeshauptmann von Wien (Head of the Government of the Province of Vienna, Austria) concerning the latter's refusal to classify products marketed by Kwizda Pharma as food for special medical purposes.

The legal framework

Directive 2001/83/EC

3 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), 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'.

4 Article 2(2) of that directive provides:

'In cases of doubt, where, taking into account all its characteristics, a product may fall within the definition of a 'medicinal product' and within the definition of a product covered by other Community legislation the provisions of this Directive shall apply.'

Directive 2002/46

5 Article 2 of Directive 2002/46 is worded as follows:

‘For the purposes of this Directive:

(a) “food supplements” means foodstuffs the purpose of which is to supplement the normal diet and which are concentrated sources of nutrients or other substances with a nutritional or physiological effect, alone or in combination, marketed in dose form, namely forms such as capsules, pastilles, tablets, pills and other similar forms, sachets of powder, ampoules of liquids, drop dispensing bottles, and other similar forms of liquids and powders designed to be taken in measured small unit quantities;

(b) “nutrients” means the following substances:
(i) vitamins;
(ii) minerals.’

6 Article 5 of that directive provides:

‘(1) Maximum amounts of vitamins and minerals present in food supplements per daily portion of consumption as recommended by the manufacturer shall be set, taking the following into account:

(a) upper safe levels of vitamins and minerals established by scientific risk assessment based on generally accepted scientific data, taking into account, as appropriate, the varying degrees of sensitivity of different consumer groups;

(b) intake of vitamins and minerals from other dietary sources.

(2) When the maximum levels referred to in paragraph 1 are set, due account should also be taken of reference intakes of vitamins and minerals for the population.

(3) To ensure that significant amounts of vitamins and minerals are present in food supplements, minimum amounts per daily portion of consumption as recommended by the manufacturer shall be set, as appropriate.

…’

Regulation (EU) No 1169/2011

7 Article 2(2)(s) of Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) 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, and corrigendum OJ 2013 L 163, p. 32) provides:

'The following definitions shall also apply:

…

(s) "nutrient" means protein, carbohydrate, fat, fibre, sodium, vitamins and minerals listed in point 1 of Part A of Annex XIII to this Regulation, and substances which belong to or are components of one of those categories.'

Regulation No 609/2013

8 According to recital 24 of Regulation No 609/2013:

'Regulation … No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers lays down general labelling requirements. Those labelling requirements should, as a general rule, apply to the categories of food covered by this Regulation. However, this Regulation should also provide for additional requirements to, or derogations from, Regulation … No 1169/2011, where necessary, in order to meet the specific objectives of this Regulation.'

9 Article 2(2)(g) of that regulation states:

'The following definitions shall … apply:

…

(g) "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.'

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

'(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.

(6) Paragraph 5 shall not prevent the dissemination of any useful information or recommendations exclusively intended for persons having qualifications in medicine, nutrition, pharmacy, or for other healthcare professionals responsible for maternal care and childcare.'

Delegated Regulation (EU) 2016/128

11 Recitals 3 to 5, 13 and 15 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 foods for special medical purposes (OJ 2016 L 25, p. 30 and corrigendum OJ 2017 L 297, p. 28) 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.

…

(13) Food for special medical purposes has to comply with Regulation (EU) No 1169/2011 of the European Parliament and of the Council. In order to take account of the specific nature of food for special medical purposes, this Regulation should lay down additions and exceptions to those general rules, where appropriate.

…

(15) The nutrition declaration for food for special medical purposes is essential in order to guarantee its appropriate use, both for patients consuming that food and for health care professionals who recommend its consumption. For that reason and in order to provide more complete information to patients and healthcare professionals, the nutrition declaration should include more particulars than those required by Regulation … No 1169/2011. In addition, the exemption provided for in point 18 of Annex V to Regulation … No 1169/2011 should not apply and the nutrition declaration should be mandatory for all food for special medical purposes, irrespective of the package or container size.'

12 Article 2 of that 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.

…’

13 Article 5(1) and Article (2)(a), (d), (e) and (g) of that delegated regulation state:

‘(1) Unless otherwise provided in this Regulation, food for special medical purposes shall comply with Regulation … No 1169/2011.

(2) In addition to the mandatory particulars listed in Article 9(1) of Regulation … No 1169/2011, the following shall be additional mandatory particulars for food for special medical purposes:

(a) a statement that the product must be used under medical supervision;

…

(d) where appropriate, a statement that the product poses a health hazard when consumed by persons who do not have the disease, disorder or medical condition for which the product is intended;

(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.

…'

14 Article 6 of that delegated regulation provides:

'(1) In addition to the information referred to in Article 30(1) of Regulation … No 1169/2011, the mandatory nutrition declaration for food for special medical purposes shall include the following:

(a) the amount of each mineral substance and of each vitamin listed in Annex I to this Regulation and present in the product;

(b) the amount of components of protein, carbohydrate, fat and/or of other nutrients and their components, the declaration of which would be necessary for the appropriate intended use of the product;

(c) information on the osmolality or the osmolarity of the product where appropriate;

(d) information on the source and the nature of the protein and/or protein hydrolysates contained in the product.

(2) By way of derogation from Article 30(3) of Regulation … No 1169/2011, the information included in the mandatory nutrition declaration for food for special medical purposes shall not be repeated on the labelling.

(3) The nutrition declaration shall be mandatory for all food for special medical purposes, irrespective of the size of the largest surface of the packaging or container.

(4) Articles 31 to 35 of Regulation … No 1169/2011 shall apply to all the nutrients included in the nutrition declaration for food for special medical purposes.

(5) By way of derogation from Article 31(3) of Regulation … No 1169/2011, the energy value and the amounts of nutrients of food for special medical purposes shall be those of the food as sold and, where appropriate, those of the food ready for use after preparation in accordance with the manufacturer's instructions.

(6) By way of derogation from Article 32(3) and (4) of Regulation … No 1169/2011, the energy value and the amount of nutrients of food for special medical purposes shall not be expressed as a percentage of the reference intakes set out in Annex XIII to that Regulation.

(7) The particulars included in the nutrition declaration for food for special medical purposes that are not listed in Annex XV to Regulation … No 1169/2011 shall be presented after the most relevant entry of that Annex they belong to or are components of.

Particulars not listed in Annex XV to Regulation (EU) No 1169/2011 that do not belong to or are not components of any of the entries of that Annex shall be presented in the nutrition declaration after the last entry of that Annex.

The indication of the amount of sodium shall appear together with the other minerals and may be repeated next to the indication of the salt content as follows: "Salt: X g (of which sodium: Y mg)".'

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

15 Kwizda Pharma markets four products in respect of which it states that their ingredients prevent bacteria from adhering to the mucous membranes of the urinary tract, so that the consumption of those products is recommended in the event of urinary tract infections ('the products in question').

16 It notified the competent ministry of the placing on the market of those four products as food for special medical purposes within the meaning of Article 2(2)(g) of Regulation No 609/2013.

17 By two decisions dated 5 August 2021 and two decisions dated 6 August 2021, the Landeshauptmann von Wien (Head of the Government of the Province of Vienna) refused to classify those four products as 'food for special medical purposes'. Those decisions were based on the assessment of the administrative authority responsible for examining the samples of the products in question that the latter were not foodstuffs in so far as the ingredients which produced the claimed effect, namely D-mannose and cranberry, produced their effect not by being ingested in the digestive tract but as a result of their action on the renal excretory organs.

18 Kwizda Pharma challenged those four decisions before the referring court. The latter questions the concept of 'food for special medical purposes' and the distinction between that concept and those of 'medicinal product' and 'food supplement'.

19 First, the referring court seeks to identify the characteristics that a food must have in order to meet the dietary management needs of the persons for whom it is intended, within the meaning of Regulation No 609/2013.

20 That court considers that a product must be classified as a 'food for special medical purposes' if it produces the claimed medical effect exclusively in the context of its suitability to cover the medically intended nutritional needs of the person consuming it. It notes that Kwizda Pharma takes a different approach. According to Kwizda Pharma, the concept of 'dietary management' covers all cases in which, because of an illness or condition, the consumption of a certain nutrient is recommended. Therefore, in the present case, cranberry and D-mannose, which do not produce their effects as a result of a required change in diet and are neither absorbed nor metabolised during digestion, but whose consumption is recommended to promote renal excretion activity and thus the healing process of a urinary tract infection, meet such dietary management needs.

21 Secondly, the referring court questions the distinction between the concept of 'food for special medical purposes' and that of 'medicinal product' and 'food supplement'. It points out in that regard that, according to Kwizda Pharma, the composition of food supplements may mean that they can also be classified as 'food for special medical purposes' in so far as substances such as cranberry or D-mannose are considered to meet dietary management needs. It also notes that Kwizda Pharma maintains that a product may be classified as a 'food for special medical purposes' where it contains a substance, such as cranberry and D-mannose, which is capable of promoting the evolution of a disease or a cure. According to the referring court, such an argument blurs the distinction between food for special medical purposes and medicinal products.

22 Third, the referring court seeks to determine the scope of the requirement laid down in Article 2(2)(g) of Regulation No 609/2013 that the relevant ingredients for the purposes of classification as food for special medical purposes must produce their effect in the context of dietary management needs which cannot be met by altering the normal diet. It points out that Kwizda Pharma maintains that cranberry or D-mannose can only be ingested as part of the normal diet with significant effort, so that, as regards the products in question, that requirement is met.

23 Fourth, in order to assess Kwizda Pharma's argument based on the divergent definitions of the term 'nutrient' in EU law and according to which, in the context of Regulation No 609/2013, any food and any substance which may also form part of a food or food supplement must be considered to be a nutrient, within the meaning of Article 2(2)(g) of that regulation, the referring court asks the Court to define the term 'nutrient' within the meaning of that regulation.

24 Fifth, it observes that, according to Kwizda Pharma, the requirement that a food for special medical purposes is 'to be used under medical supervision', set out in Article 2(2)(g) of Regulation No 609/2013, is fulfilled once a health service provider, such as a pharmacist, hands over a food to the patient. However, that interpretation deviates significantly from the semantic content of the term 'medical supervision', so the referring court seeks to ascertain how that requirement is to be interpreted.

25 In those circumstances, the Verwaltungsgericht Wien (Administrative Court, Vienna, Austria) decided to stay the proceedings and to refer the following questions to the Court of Justice for a preliminary ruling:

'(1)(a) In order to be categorised as a "food for special medical purposes", must a product be demonstrably capable of achieving the claimed disease- or condition-specific results solely in the context of the dietary management indicated by that disease or condition with respect to the food-intake requirements of that condition or disease?

(1)(b) In that context, is dietary management to be assumed only in the case where a person changes his or her diet in such a way as to consume other or additional nutrients which are absorbed by the body by way of digestion?

(1)(c) For the purposes of categorisation as a food for special medical purposes, is it also necessary that the condition or disease for which the product is intended requires dietary management in order to ensure that the patient ingests the nutrients contained in the product which cannot be absorbed through the normal diet?

(1)(d) Must the food for special medical purposes achieve its medical effect solely by virtue of the fact that it contains some or all of those nutrients which cannot be absorbed through the normal diet but are absolutely necessary or required in order for the patient to maintain his or her vital functions?

If those questions are answered in the negative: What type of ingredients must a product contain in order to meet the requirements for a food for special medical purposes?

(2)(a) Does the categorisation of a product as a food supplement preclude the possibility of that product also being categorised as a food for special medical purposes?

(2)(b) If that question is answered in the negative: What criteria should be used to determine that a particular food supplement cannot be categorised as a food for special medical purposes?

(2)(c) Can the use of "food supplements" within the meaning of [Directive 2002/46] constitute, in itself, "dietary management" within the meaning of Article 2(2)(g) of [Regulation No 609/2013]?

(2)(d) Does a food already become a food for special medical purposes if it contains nutrients which can also be ingested by way of food supplements or other foods, but which are formulated specifically for a particular disease or condition?

(3) What criteria should be used as a basis for distinguishing a medicinal product from a food for special medical purposes or, alternatively, is it possible to draw a distinction between them?

(4) Is the requirement in Article 2(2)(g) of [Regulation No 609/2013], according to which the ingredients relevant to categorisation as food for special medical purposes must produce their effect in the context of dietary management which cannot be achieved by modification of the normal diet, to be interpreted as meaning that a patient in respect of whose disease or condition the food for special medical purposes is placed on the market is not able to meet his or her nutritional requirements adequately via the intake of generally available foods?

(5)(a) Is the phrase "whose dietary management cannot be achieved by modification of the normal diet alone" in Article 2(2)(g) of [Regulation No 609/2013] relative in nature in so far as fulfilment of that requirement is also to be assumed in the case where the nutrient intake required in the context of the disease or condition in question can be achieved by means of generally available foods (in particular, food supplements) only in a particularly burdensome manner?

(5)(b) If that question is answered in the affirmative, what criteria should be used to determine that the burden associated with the intake of generally available foods meets the requirement "whose dietary management cannot be achieved by modification of the normal diet alone" in Article 2(2)(g) of [Regulation No 609/2013]? In particular, is it to be assumed that that requirement is met in the case where a patient would be required to take several generally available food supplements separately?

(6)(a) What is to be understood by a "nutrient" [Nährstoff] within the meaning of Article 2(2)(g) of [Regulation No 609/2013]?

6(b) What criteria should be used to determine whether a certain ingredient of a product is to be categorised as a nutrient [Nährstoff] within the meaning of Article 2(2)(g) of [Regulation No 609/2013]?

(7)(a) Is the requirement "to be used under medical supervision" in Article 2(2)(g) of [Regulation No 609/2013] already met in the case where that product is supplied in a pharmacy without the need to obtain beforehand a doctor's prescription?

(7)(b) What criteria should be used to determine whether the requirement of use under medical supervision within the meaning of Article 2(2)(g) of [Regulation No 609/2013] is met with regard to a certain product?

(7)(c) What is the consequence of the eventuality that that requirement of use under medical supervision within the meaning of Article 2(2)(g) of [Regulation No 609/2013] is not met in a specific case, or in general?

(8)(a) Is the existence of a food for special medical purposes to be assumed only in the case where it is not possible to use that food without medical supervision?

(8)(b) If that question is answered in the affirmative, what criteria should be used in order to determine whether a food can also be used without medical supervision?'

The questions referred for a preliminary ruling

The third question

26 By its third question, which should be dealt with first, the referring court asks, in essence, what criteria are used to distinguish between the concepts of 'medicinal product', within the meaning of Article 1(2) of Directive 2001/83, and 'food for special medical purposes', within the meaning of Article 2(2)(g) of Regulation No 609/2013.

27 In that regard, it should be noted that the Court has already emphasised that food for special medical purposes is distinct from medicinal products and that those two categories of products are, in view of their specific characteristics, subject to separate and exclusive definitions and legal regimes (see, to that effect, judgment of 27 October 2022, *Orthomol*, C-418/21, EU:C:2022:831, paragraph 37).

28 The characteristics and functions of food for special medical purposes are distinct from those of medicinal products, which are defined in Article 1(2) of Directive 2001/83, and 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 (judgment of 27 October 2022, *Orthomol*, C-418/21, EU:C:2022:831, paragraph 38).

29 Food for special medical purposes are foodstuffs which are intended to meet the nutritional needs of patients and not to prevent or cure human disease, to restore, correct or modify physiological functions by exerting a pharmacological, immunological or metabolic action, or to make a medical diagnosis (see, to that effect, judgment 27 October 2022, *Orthomol*, C-418/21, EU:C:2022:831, paragraphs 26 and 39).

30 Thus, food for special medical purposes does not as such make it possible to combat a disease, disorder or health condition, but is characterised by its nutritional function (judgment of 27 October 2022, *Orthomol*, C-418/21, EU:C:2022:831, paragraph 40).

31 Consequently, as the Court has already held, 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, then that product is intended not to feed that patient but to treat him, to prevent a disease or to restore, correct or modify physiological functions by exerting a pharmacological, immunological or metabolic action which militates in favour of classifying that product as something other than 'food for special medical purposes' (judgment of 27 October 2022, *Orthomol*, C-418/21, EU:C:2022:831, paragraph 41).

32 In the present case, it is apparent from the information provided by the referring court that Kwizda Pharma markets the products in question by claiming that the consumption of those products promotes the elimination of the pathogens concerned in the event of urinary tract infection.

33 While it is for the competent national authorities to determine, on a case-by-case basis and taking into account all the characteristics of those products, whether those products may be marketed as food for special medical purposes (see, to that effect, judgment of 9 June 2005, *HLH Warenvertrieb and Orthica*, C-211/03, C-299/03 and C-316/03 to C-318/03, EU:C:2005:370, paragraph 30), the fact remains that products which are presented as having curative properties in respect of a disease but which are not intended to meet the nutritional needs of patients cannot be marketed as food for special medical purposes.

34 In that regard, it should also be pointed out that, in the event of doubt as to the correct classification of the products in question, Article 2(2) of Directive 2001/83 gives priority to the application of EU law relating to medicinal products, which, by reason of the higher requirements deriving from the law relating to medicinal products for the placing of products on the market, is also consistent with the objective of a high level of protection of human health pursued by Article 168 TFEU.

35 As the Court has held, that provision applies both to the classification of 'medicinal product by function', referred to in Article 1(2)(b) of that directive, and to that of 'medicinal product by presentation', referred to in Article 1(2)(a) of that directive (judgment of 19 January 2023, *Bundesrepublik Deutschland (Nasal Drops)*, C-495/21 and C-496/21, (EU:C:2023:34, paragraph 35)).

36 In the light of all the foregoing considerations, the answer to the third question is that Article 1(2) of Directive 2001/83 and Article 2(2)(g) of Regulation No 609/2013 must be interpreted as meaning that, for the purposes of distinguishing between the concepts of 'medicinal product' and 'food for special medical purposes', which are defined in those provisions respectively, it must be assessed in the light of the nature and characteristics of the product concerned, whether it is food intended to meet particular nutritional requirements or a product intended to prevent or cure

human disease, to restore, correct or modify physiological functions by exerting a pharmacological, immunological or metabolic action, or to make a medical diagnosis, or where appropriate, presented as such.

The first, fourth and fifth questions

37 By its first, fourth and fifth questions, which should be considered together, the referring court asks the Court, in essence, to interpret the concepts of 'dietary management' and 'modification of the normal diet alone' within the meaning of Article 2(2)(g) of Regulation No 609/2013.

38 As regards, in the first place, the concept of 'dietary management', it follows from the wording of that provision that food for special medical purposes has two characteristics which distinguish it from other categories of products. First, it is food intended to constitute the exclusive or partial diet of patients suffering from a specific disease, disorder or state of health. Secondly, it is specially processed or formulated to meet the particular nutritional requirements resulting from such a disease, disorder or medical condition (judgment of 27 October 2022, *Orthomol*, C-418/21, EU:C:2022:831, paragraph 25).

39 Thus, food for special medical purposes is food with a particular nutritional function in that it is 'specially processed or formulated' to meet the particular nutritional requirements of patients.

40 It follows that the classification of a food as a food for special medical purposes requires a match between the food, in its composition, consistency or form, and the nutritional requirements, caused by a disease, disorder or health condition, which that food is intended to meet.

41 That suitability is all the more necessary when a food for special medical purposes meets 'nutritional requirements', caused by a disease, disorder or health condition, the satisfaction of which is essential for the patient.

42 Consequently, the use of the concept of 'dietary management' by the EU legislature is clear evidence that the use of food for special medical purposes cannot, contrary to Kwizda Pharma's argument, be merely advisory.

43 However, given the variety of 'dietary management' needs which food for special medical purposes may have to meet, the classification of a product as such cannot be made conditional on the satisfaction of the 'dietary management' needs caused by a disease, disorder or health condition and, consequently, the effect of that product taking place during or following digestion.

44 Thus, according to the very letter of Article 2(2)(g) of Regulation No 609/2013, foods for special medical purposes are, inter alia, 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'.

45 In so doing, the EU legislature did not limit the definition of food for special medical purposes to food which is difficult to digest, but, by also including absorption, assimilation, metabolisation and excretion, it covered all stages of the nutritional process.

46 Since a food for special medical purposes may, for example, be designed to respond to mechanical or neurological deficiencies that prevent patients from ingesting sufficient food or to the inability of certain patients to excrete certain nutrients, the concept of 'dietary management' cannot be limited to the satisfaction, through digestion, of nutrient requirements.

47 As regards, in the second place, the concept of 'modification of the normal diet alone', it should be noted that recital 3 of Delegated Regulation 2016/128 states that foods for special medical purposes are designed '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'.

48 Thus, a food intended for special medical purposes is intended for patients whose state of health determines other particular nutritional requirements which cannot be met by 'a modification of the normal diet alone', within the meaning of Article 2(2)(g) of Regulation No 609/2013, since those nutritional requirements cannot be met through the consumption of ordinary food alone.

49 Furthermore, the concept of 'modification of the normal diet alone' within the meaning of that provision should cover not only situations in which a modification of the diet is impossible or dangerous for the patient, but also situations in which the patient can only 'with great difficulty' meet his or her nutritional requirements with ordinary food.

50 Therefore, it is necessary to assess on a case-by-case basis whether, and to what extent, a patient can meet his or her nutritional requirements caused by a specific disease, disorder or health condition through modification of the normal diet alone.

51 To that end, the characteristics of the disease or disorder in question, the difficulties involved in altering the normal diet alone, and in particular the practical possibility of access to the necessary foods, the ways in which those foods are consumed and their practicality, must be taken into consideration in order to determine whether the use of food for special medical purposes enables the patient to meet his or her nutritional requirements more easily or more safely.

52 In the light of those considerations, the answer to the first, fourth and fifth questions is that that Article 2(2)(g) of Regulation No 609/2013 must be interpreted as meaning that, first, the concept of 'dietary management' covers requirements caused by a disease, disorder or health condition, the satisfaction of which is indispensable to the patient from a nutritional point of view, condition, the satisfaction of which is indispensable to the patient from a nutritional point of view, secondly, the classification as a 'food for special medical purposes' cannot be made subject to the condition that the satisfaction of 'nutritional needs' caused by a disease, disorder or health condition secondly, the qualification of 'food for special medical purposes' cannot be made conditional on the satisfaction of 'dietary management' needs caused by a disease, disorder or health condition, and therefore the effect of the product, necessarily taking place during or following digestion and, thirdly, the concept of 'modification of the normal diet alone' includes both situations in which a modification of the diet is impossible or dangerous for the patient and situations in which the patient can only with great difficulty satisfy his or her nutritional requirements with ordinary food.

The sixth question

53 By its sixth question, the referring court asks about the interpretation of the concept of 'nutrient' within the meaning of Article 2(2)(g) of Regulation No 609/2013 and, in particular, about the criteria for determining whether a substance is to be classified as a 'nutrient' within the meaning of that provision.

54 At the outset, it should be pointed out that the term 'nutrient' does not appear in the French version of Article 2(2)(g) of Regulation No 609/2013.

55 However, that term appears, instead of the term 'ingredient' used in the French version of that provision, in the other language versions of that provision, as evidenced, inter alia, by the Dutch ('nutriënten'), Spanish ('nutrientes'), German ('Nährstoffe'), Czech ('živiny'), Swedish ('näringsämnen') and English ('nutrients') language versions.

56 In that regard, it is sufficient to note that, according to settled case-law, the wording used in one of the language versions of a provision of EU law cannot serve as the sole basis for the interpretation of that provision or be given priority over the other language versions (judgment of 15 April 2021, *The North of England P & I Association*, C-786/19, EU:C:2021:276, paragraph 54).

57 As indicated in paragraph 23 of the present judgment, Kwizda Pharma maintains before the referring court that, under that regulation, any foodstuff and any substance which may also form part of a foodstuff or food supplement must themselves be regarded as a nutrient. On the contrary, the administrative authority responsible for examining the samples of the products in question took the much more restrictive view that the classification of a substance as a 'nutrient' is subject to the fact that it is metabolised during digestion and is of significant importance for maintaining or ensuring bodily functions.

58 First, it cannot be inferred from the absence of a definition of the term 'nutrient' in Regulation No 609/2013 or from the absence of a reference to the definition laid down in another piece of EU law that the EU legislature intended, without making it explicit, to have recourse, in the context of that regulation, to a specific definition laid down in that regulation.

59 Secondly, since food for special medical purposes is, first and foremost and despite its specificities, food, Regulation No 609/2013 and Delegated Regulation 2016/128 must be understood in the light of other legislation applicable to foodstuffs.

60 It should be noted, to that end, that, according to recital 24 of Regulation No 609/2013, the labelling requirements laid down in Regulation No 1169/2011 apply, as a general rule, to the categories of foodstuffs covered by the former regulation.

61 In addition, and more specifically, Delegated Regulation 2016/128 refers explicitly and on numerous occasions to Regulation No 1169/2011. In particular, it follows from Article 5(1) of that delegated regulation that, in principle, food for special medical purposes must comply with Regulation No 1169/2011 as regards food information. Furthermore, as regards the specific requirements for the nutrition declaration, Article 6 of that delegated regulation relies heavily on the requirements of that regulation and explicitly indicates the cases in which it is appropriate to deviate from its provisions.

62 Since the latter requirements include, inter alia, information on nutrients, the concept of 'nutrient' must, in the context of Regulation No 609/2013 and Delegated Regulation 2016/128, be defined in accordance with Regulation No 1169/2011. It would be inconsistent to apply such requirements to food for special medical purposes while retaining another, non-explicit, definition of the concept of 'nutrient'.

63 Consequently, in the context of Regulation No 609/2013 and Delegated Regulation 2016/128, the concept of 'nutrient' should be defined in the same way as in the context of Regulation No 1169/2011, taking into account the interactions between those texts.

64 In that regard, it should, finally, be pointed out that, according to Article 2(2)(s) of Regulation No 1169/2011, the term 'nutrient' means proteins, carbohydrates, fats, dietary fibres, sodium, vitamins and minerals referred to in the Annex to that regulation, as well as substances which belong to or are components of one of those categories of substances.

65 Such a definition, which is based on the nature of the substances, and not on the metabolism and effects of the substances as the administrative authority alleged in the present case, is, contrary to the interpretation proposed by Kwizda Pharma, consistent with the particular nutritional function of food for special medical purposes.

66 In the light of all the foregoing considerations, the answer to the sixth question is that Article 2(2)(g) of Regulation No 609/2013 must be interpreted as meaning that, for the purposes of the application of that regulation, which does not define the concept of 'nutrient', reference must be made to the definition of that concept in Article 2(2)(s) of Regulation No 1169/2011.

The seventh and eighth questions

67 By its seventh and eighth questions, which should be considered together, the referring court, first, is unsure as to the criteria for determining that a product is 'to be used under medical supervision' within the meaning of Article 2(2)(g) of Regulation No 609/2013 and, second, asks, in substance whether that provision is to be interpreted as meaning that the requirement that a food for special medical purposes is 'to be used under medical supervision' is necessary for a product to be classified as a food for special medical purposes and, where appropriate, what consequences attach to failure to comply with that requirement.

68 In that regard, it should be noted that, although it follows from the actual wording of Article 2(2)(g) of Regulation No 609/2013 that food for special medical purposes may be used 'under medical supervision', it cannot be inferred from that that it concerns a necessary condition for the classification of a product as a food for special medical purposes.

69 Since the fulfilment of such a qualification condition depends on random circumstances independent of the producer of the product in question and materialising, downstream of such a qualification, through the use of that product, it is inoperative by nature.

70 However, it should be noted that the fulfilment of such a requirement is one of the parameters which the competent national authorities must take into account if, as in the present case, after placing a product on the market as a food for special medical purposes, they are required to verify, first, that such a qualification is appropriate and, secondly, that the product complies with the obligations set out in Regulation No 609/2013 and in Delegated Regulation 2016/128.

71 It follows from those two texts that medical examination is integral to the concept of 'food for special medical purposes'.

72 That concept implies, by definition, that the food is intended for a special 'medical purpose' and that it is designed for the dietary management of a particular disease, disorder or health condition.

73 In those circumstances, the fact that a food is supplied in a pharmacy is not sufficient to consider that it must, given its very nature and characteristics, be used under medical supervision.

74 'Use under medical supervision', referred to in Article 2(2)(g) of Regulation No 609/2013, implies that, in view of the product in question, medical supervision is necessary prior to sale. Thus, the use of a food for special medical purposes, which is special because it is adapted to the patient's dietary management needs, must be recommended, without necessarily being the subject of a prescription, to the patient by a health professional in the light of the patient's dietary management needs. In that context, 'medical supervision' implies that a health professional, as referred to in recitals 3 and 15 of the Delegated Regulation 2016/128, ensures that the use of a food for special medical purposes is in line with the patient's specific dietary management needs.

75 Moreover, 'use under medical supervision' also implies that the medical supervision must extend beyond the delivery of the product and continue for the duration of its consumption so that the health professional concerned can assess the effects of the product on the patient's nutritional needs and on the patient.

76 In that regard, it should be added that, by providing in Article 9(6) of Regulation No 609/2013 for the possibility of communicating any useful information or recommendations intended exclusively for persons with qualifications in medicine, nutrition, pharmacy or any other healthcare professional responsible for maternal and child care, the EU legislature has recognised the particular responsibility incumbent on those persons in relation to food for special medical purposes.

77 In addition, the recommendation by a health professional is all the more necessary for food for special medical purposes since, as set out in recital 4 of the Delegated Regulation 2016/128, the composition of such food may differ significantly depending on, inter alia, the particular disease, disorder or health condition giving rise to the nutritional requirements that the food meets, the age of the patients and the place where they receive health care, as well as the intended use of the food.

78 Such a recommendation ensures that, in accordance with Article 2(2) of that delegated regulation, the use of food for special medical purposes is, in accordance with the manufacturers' instructions, suitable and effective to meet the particular nutritional requirements of the persons for whom they are intended.

79 More specifically, since food for special medical purposes are designed for the dietary management of a particular disease, disorder or health condition, the use of such a food that is inadequate in the sense that it does not correspond to a patient's disease, disorder or health condition could be ineffective for the patient or have negative effects.

80 Moreover, that risk must be indicated to patients and, in accordance with Article 5(2)(d) of the Delegated Regulation 2016/128, must be indicated on food for special medical purposes.

81 Having regard to all of the foregoing considerations, the answer to the seventh and eighth questions is that Article 2(2)(g) of Regulation No 609/2013 must be interpreted as meaning that, first, a product must be used under medical supervision if the recommendation and subsequent assessment of a health professional are necessary in the light of the dietary management needs arising from a particular disease, disorder or health condition and the effects of the product on the patient's dietary management and on the patient, and, secondly, that the requirement that a food for special medical purposes is 'to be used under medical supervision' is not a condition for qualification of a product as such.

The second question

82 By its second question, the referring court asks, in essence, what criteria are used to distinguish between the concepts of 'food for special medical purposes' within the meaning of Article 2(2)(g) of Regulation No 609/2013 and 'food supplement' within the meaning of Article 2 of Directive 2002/46, and whether each of those concepts is exclusive.

83 In that regard, it must be noted that, having regard to the respective characteristics of food for special medical purposes and food supplements, it cannot be ruled out that their uses may overlap. However, those two concepts, and the legal qualifications which follow from them, are necessarily exclusive, so that it is necessary to determine on a case-by-case basis whether a product should be classified as a 'food for special medical purposes' or as a 'food supplement'.

84 Thus, although food supplements are, according to Article 2(a) of Directive 2002/46, intended solely to supplement 'the normal diet', whereas, according to Article 2(2)(g) of Regulation No 609/2013 and Article 2(1) and (2) of Delegated Regulation 2016/128, food intended for special medical purposes is a substitute for the diet in whole or in part, food supplements are a concentrated source of nutrients or other substances with a nutritional or physiological effect which may, like certain food for special medical purposes, meet specified nutritional requirements.

85 However, as noted in paragraph 39 of the present judgment, foods for special medical purposes are distinguished by the medical purposes for which those foods may be intended.

86 In that context, it should be noted that food for special medical purposes and food supplements are food intended for different recipients. It does not follow from Article 2(a) of Directive 2002/46 that food supplements are, like food for special medical purposes, intended solely for patients.

87 In that regard, it is important to emphasise that, in accordance with Article 2(2)(g) of Regulation No 609/2013, food intended for special medical purposes is intended for dietary management in such a way that qualification as a 'food for special medical purposes' is conditional on the fact that such dietary management cannot be effected solely by means of a modification of the normal diet, whereas food supplements, as long as they supplement the normal diet, form an integral part thereof.

88 The rules on the composition of those two categories of food also reflect those differences and particularities.

89 Thus, Article 5 of Directive 2002/46 provides that the maximum level of vitamins and minerals in food supplements is to be determined taking into account the upper safe levels of vitamins and minerals established by scientific risk assessment based on generally accepted scientific data, taking into account, where appropriate, the different sensitivities of different groups of consumers, the intakes of vitamins and minerals from other dietary sources and the reference intakes of vitamins and minerals for the population.

90 Such data refer to the needs and intakes of the general population and not of patients with nutritional needs caused by a disease, disorder or health condition.

91 By contrast, the minimum and maximum levels of vitamins and minerals in food for special medical purposes other than those formulated to meet the nutritional requirements of infants are set out in Table 2 of Part B of Annex I of the Delegated Regulation 2016/128 and are expressed, not in terms of reference intakes, but as minimum and maximum amounts per 100 kilojoules (kj) or 100 kilocalories (kcal) of product. In addition, the particular intended use of certain foods for special medical purposes allows for derogations.

92 As regards their use, unlike food supplements, food for special medical purposes is intended for patients and must therefore be used under medical supervision.

93 In the light of all the foregoing considerations, the answer to the second question is that Article 2 of Directive 2002/46 and Article 2(2)(g) of Regulation No 609/2013 must be interpreted as meaning that the concepts of 'food supplement' and 'food for special medical purposes', which are defined in those provisions respectively, are mutually exclusive and that it is necessary to determine on a case-by-case basis and according to the characteristics and conditions of use whether a product falls within one or other of those concepts.

Costs

94 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:

1. **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, as amended by Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004, and 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,**

   must be interpreted as meaning that for the purposes of distinguishing between the concepts of 'medicinal product' and 'food for special medical purposes', which are defined in those provisions respectively, it must be assessed in the light of the nature

and characteristics of the product concerned, whether it is food intended to meet particular nutritional requirements or a product intended to prevent or cure human disease, to restore, correct or modify physiological functions by exerting a pharmacological, immunological or metabolic action, or to make a medical diagnosis, or where appropriate, presented as such.

2. Article 2(2)(g) of Regulation No 609/2013

must be interpreted as meaning that first, the concept of 'dietary management' covers requirements caused by a disease, disorder or health condition, the satisfaction of which is indispensable to the patient from a nutritional point of view, secondly, the classification as a 'food for special medical purposes' cannot be made subject to the condition that the satisfaction of 'nutritional needs' caused by a disease, disorder or health condition secondly, the qualification of 'food for special medical purposes' cannot be made conditional on the satisfaction of 'dietary management' needs caused by a disease, disorder or health condition, and therefore the effect of the product, necessarily taking place during or following digestion and, thirdly, the concept of 'modification of the normal diet alone' includes both situations in which a modification of the diet is impossible or dangerous for the patient and situations in which the patient can only with great difficulty satisfy his or her nutritional requirements with ordinary food.

3. Article 2(2)(g) of Regulation No 609/2013

must be interpreted as meaning that for the purposes of the application of that regulation, which does not define the concept of 'nutrient', reference must be made to the definition of that concept in Article 2(2)(s) of Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) 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.

4. Article 2(2)(g) of Regulation No 609/2013

must be interpreted as meaning that first, a product must be used under medical supervision if the recommendation and subsequent assessment of a health professional are necessary in the light of the dietary management needs arising from a particular disease, disorder or health condition and the effects of the product on the patient's dietary management and on the patient, and, secondly, that the requirement that a food for special medical purposes is 'to be used under medical supervision' is not a condition for qualification of a product as such.

5. Article 2 of Directive 2002/46 and Article 2(2)(g) of Regulation No 609/2013

must be interpreted as meaning that the concepts of 'food supplement' and 'food for special medical purposes', which are defined in those provisions respectively, are mutually exclusive and that it is necessary to determine on a case-by-case basis and

according to the characteristics and conditions of use whether a product falls within one or other of those concepts.

[Signatures]