

**HEALTHCARE, LIFE SCIENCES & PHARMACEUTICALS**

CJEU clarifies the concept of food for special medical purposes

On 27 October 2022, the Court of Justice of the European Union (“CJEU”) published a judgment in which it clarified the concept of food for special medical purposes (Case C-418/21).

The judgment originated from an action brought by the German association Verband Sozialer Wettbewerb eV (“VSW”) – an association whose mission includes promoting fair competition – against the German company Orthomol Pharmazeutische Vertriebs GmbH (“Orthomol”) in connection with products marketed by Orthomol classified as food for special medical purposes. The action was brought before the Landgericht Düsseldorf (Regional Court of Düsseldorf) at first instance and was appealed to the Oberlandesgericht Düsseldorf (Regional Court of Appeal of Düsseldorf), which made a reference for a preliminary ruling to the CJEU.

VSW challenged Orthomol’s classification of products classed as food for special medical purposes under 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 integral diet replacement for weight control (“**Regulation 609/2013**”). Indeed, VSW challenged the classification of two products marketed by Orthomol as food for specific medical purposes. The first was challenged on the basis that the product was promoted as being intended for the medical-nutritional reinforcement of the immune system to satisfy nutritional needs in the event of nutrition-related immune deficiencies. The second was challenged on the basis that the product was promoted as being intended to meet the nutritional requirements in the case of age-related macular degeneration (“AMD”).

VSW based its argument on the fact that the products do not meet the requirements for this classification because Article 2(2)(g) of Regulation No 609/2013 defines foods for special medical purposes and provides for two cases which are inapplicable to the products at issue. Indeed, the diseases supposedly combated by these products – immune deficiencies of nutritional origin and AMD – are not diseases that cause a limitation, reduction or alteration in the ability of patients to take, digest, absorb, metabolise or excrete ordinary foodstuffs or some of the nutrients contained in them or metabolites.

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Moreover, the rule refers exclusively to diseases that are likely to cause a real and specific energy and nutritional need, and not to substances used to treat the disease itself.

Against this background, the referring court asked the CJEU whether Article 2(2)(g) of Regulation 609/2013, and, in particular, the concept of “particular nutritional requirements”, must be interpreted as meaning that, (i) to classify a product as a food for medicinal purposes, it is necessary for the disease to entail increased nutritional requirements, which the food must cover, or whether (ii) it is sufficient for the patient to derive a general benefit from the ingestion of that food because the substances it contains combat the disorder or alleviate its symptoms.

In that context, the CJEU clarified that Article 2(2)(g) of Regulation 609/2013, and, in particular, the concept of “particular nutritional requirements”, must be interpreted as meaning that a product constitutes a food for special medical purposes when the disease entails increased or specific nutritional requirements that the food must satisfy. Therefore, it is not sufficient, for the purposes of that classification, for the patient to derive a general benefit from the ingestion of that food because the substances contained in it combat the disorder or alleviate its symptoms.

It is now clear that to classify a product as food for special medical purposes under Regulation 609/2013, it is not sufficient for the intake of the product by the patient to have a general benefit for the patient's health. Instead, it must be specifically intended to make up, in full or in part, for the nutritional deficiencies caused to the patient by a specific disease.

The court also states that if the opposite were true - that is, in order for a food to qualify as a food for special medical purposes, it would be sufficient to obtain a generic benefit for the patient's health - the specific characteristics of food for special medical purposes would be ignored. This would even call into question the distinction between food for special medical purposes and medicinal products, which the legislator intended to establish.

Although there are still a number of vague concepts in this area that need to be clarified, the judgment has clarified the concept of food for special medical purposes and set the dividing line for products that are similar or whose function is likely to be confused. ■