



HEALTHCARE, LIFE SCIENCES & PHARMACEUTICALS

Classification of products as “food for special medical purposes”

On 2 March 2023, in Case C-760/21, the **Court of Justice of the European Union** (“CJEU”) heard a request for a preliminary ruling from the Verwaltungsgericht Wien, the Administrative Court of Vienna, Austria. In the decision, the CJEU sets out **criteria for interpreting the definition of “food for special medical purposes”** in Regulation (EU) 609/2013 of the European Parliament and of the Council of 12 June 2013 on food intended for infants and young children and on total diet replacement for weight control. The CJEU also sets out the criteria for distinguishing this concept from the concepts of **“medicinal products”** and **“food supplements”**.

The Administrative Court of Vienna questioned the interpretation of some of the terms contained in the definition of **“food for special medical purposes”**.

The case concerned the marketing of four products recommended for use in cases of urinary tract infections and classified as *“food for special medical purposes”*. The German competent authority rejected this classification, taking the view that these products were not foodstuffs because the ingredients that produced the promised effect did not act by ingestion through the digestive tract but by acting on the target organs. The manufacturer of the products in question appealed against this decision to the Verwaltungsgericht Wien (Administrative Court of Vienna), which in turn questioned (i) the interpretation of some of the terms contained in the definition of *“food for special medical purposes”* and (ii) the criteria for distinguishing a food for special medical purposes from a medicinal product and a food supplement.

Regulation (EU) 609/2013 defines “food for special medical purposes” as *“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**”*.

Eduardo
Nogueira Pinto
Eliana Bernardo
Ricardo Rocha
Tiago Linhares
Carneiro
Rita Antunes
da Cunha

Healthcare,
Life Sciences &
Pharmaceuticals
team

The dietary management cannot depend on whether the effect of the product occurs only after or during digestion.

The CJEU has therefore clarified the concepts contained in the definition of “*food for special medical purposes*” as follows:

- i) **Dietary management** - for a foodstuff to be classified as a food for special medical purposes, there must be a suitability between the foodstuff and the nutritional requirements arising from a disease, disorder or state of health, when the **satisfaction of the requirement is indispensable for the patient**. It cannot therefore be limited to a purely advisory role. However, the dietary management **cannot depend on whether the effect of the product occurs only after or during digestion**, since the definition of foods for particular nutritional uses is not limited to foods intended to meet digestive difficulties but also includes foods intended for other stages of the nutritional process.
- ii) **Modification of the normal diet** - covers both situations in which a mere modification of the normal diet is impossible or dangerous for the patient and those in which the patient can only with great difficulty manage his or her diet by consuming ordinary food.
- iii) **Use under medical supervision** - the requirement that a food for special medical purposes be used under medical supervision is **not a necessary requirement for a product to be classified as a food for special medical purposes**. Nevertheless, this supervision is necessary in cases where the recommendation of the product and the subsequent evaluation of its effects by a health professional is necessary in view of the dietary management necessary as a result of a specific disease, disorder or medical condition, as well as the effects of the product on the nutritional requirements of the patient and the patient him or herself.
- iv) **Nutrient** - although not directly defined in Regulation 609/2013, given that a food for special medical purposes is a food and given the various interactions between Regulation 609/2013 and Regulation 1169/2011, the concept of nutrient must be defined in the context of the latter.

The requirement that a food for special medical purposes be used under medical supervision is not a necessary requirement for a product to be classified as a food for special medical purposes.

With regard to the **criteria** for distinguishing a **food for special medical purposes** from a **medicinal product** and a **food supplement**, the CJEU clarifies that:

- i) In the first case, the CJEU recalled, in line with previous case law¹, that these two categories of products are subject to different and exclusive definitions and legal frameworks and that, in case of doubt as to their classification, **priority** must be given to the **application of EU legislation on medicinal products** because of the stricter requirements which ensure a higher level of protection of human health. Accordingly, in case of doubt as to the classification of a product, the classification as a “*medicinal product*” must be given priority. *Products presented as having properties to cure a disease, but which are not intended to meet the nutritional needs of patients, cannot be marketed as “foods for special medical purposes”.*
- i) In the second case, the CJEU ruled that the concepts of “*food supplement*” and “*food for special medical purposes*” are mutually exclusive and that it is necessary to determine on a case-by-case basis, according to the characteristics and conditions of use, whether a product falls under one or the other of these concepts. The CJEU stressed that not only are the persons for whom these products are intended different, since food for special medical purposes is intended for patients, unlike food supplements, which are intended for all consumers, but only the former require medical supervision. On the other hand, classification as a “*food for special medical purposes*” depends on the fact that the nutritional requirements cannot be met by simply modifying the normal diet. In contrast, food supplements are an integral part of the normal diet because they supplement the normal diet. ■

In case of doubt as to their classification, priority must be given to the application of EU legislation on medicinal products.

1 Judgment of 27 October 2022, Orthomol, C-418/21.