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CASE NOTES

European Court of Justice Provides Guidance on Classification Issues

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In cases of doubt as to the correct classification of the products in question, the application of Union law on medicinal products takes precedence, which, because of the stricter requirements arising from the law on medicinal products for the marketing of products, is also consistent with the objective of a high level of human health protection pursued by Article 168 TFEU.

Legislation

Article 2(2)(g) of Regulation (EU) 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, as amended, OJ L - 181 of 29.06.2013 pp 35–56.

Facts

This contribution[1] concerns a judgment of the Court of Justice of the European Union ("EU") ("CJEU") of 2 March 2023 in a reference for a preliminary ruling submitted by the Verwaltungsgericht Wien in Austria ("Referring Judge") in the case between Kwizda Pharma GmbH ("Kwizda Pharma") and the Landeshauptmann von Wien ("Competent Authority"). A company wanted to market a number of products – with D-mannose and cranberry as the main ingredients – as "food for special medical purposes" within the meaning of Article 2(2)(g) of Regulation (EU) 609/2013. However, this was refused by the competent authority because the competent authority considered it a medicinal product.

In food law, classification issues – or delimitation issues – are a familiar problem. Is the cheerful plastic packaging of a children's sweet a food contact material or a toy? Is snus tobacco or a food? Is something an animal by-product or a medicine? Particularly with fast evolving innovative products or production processes, where the European legislator logically did not consider all the relevant innovations when drafting the definitions in the various Regulations and Directives, such questions often arise. In this judgment, the CJEU provided an answer in relation to four concrete classification questions.

[1] This contribution has also been contributed to a jubilee booklet of the Dutch Society of Food Law (NVLR) in honour of their twenty year existence: B.M.J. van der Meulen e.a. (red), *20 jaar Nederlandse Vereniging voor Levensmiddelenrecht*, Ars Aequi: Nijmegen 2023.

But the judgment is also of greater importance, as the way in which the CJEU answers these preliminary questions may also guide other classification issues.

Kwizda Pharma markets four products whose ingredients it claims prevent bacteria from adhering to the mucous membrane of the urinary tract, so their use is recommended in cases of urinary tract infections ("Concerned Products").

The company notified the Competent Authority that it would market these four products as "food for special medical purposes" within the meaning of Article 2(2)(g) of Regulation (EU) 609/2013.

In four separation decisions, the Competent Authority refused to classify these four products as "food for special medical purposes". These decisions were based on the assessment of the government agency responsible for examining the samples of the Concerned Products Involved, according to which these products are not foodstuffs as the ingredients producing the claimed effect, namely D-mannose and cranberry, do not achieve their effect through absorption through digestion, but through their action on the excretory functions of the kidneys.

Kwizda Pharma is challenging these four decisions before the Referring Judge.

Judgement

The Referring Judge questioned what exactly the concept of "food for special medical purposes" means and what distinction should be made between this concept and the concepts of "medicinal product" and "food supplement". He also requests more guidance on the concept of "nutrient" and whether it still matters whether a product is available from a pharmacy or not. In that context, in summary, the referring Judge makes the following observations and asks the following questions.

The Referring Judge questioned what exactly the concept of "food for special medical purposes" means and what distinction should be made between this concept and the concepts of "medicinal product" and "food supplement". He also requests more guidance on the concept of "nutrient" and whether it still matters whether a product is available from a pharmacy or not. In that context, in summary, the Referring Judge makes the following observations and asks the following questions.

First, the Referring Judge expresses a desire to learn what characteristics a food must have in order to satisfy the particular nutritional requirements of the persons for whom it is intended ("dietary management") within the meaning of Regulation (EU) 609/2013. Indeed, the Referring Judge considers that a product must be classified as "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. According to the Referring Judge, Kwizda Pharma advocates 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, 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.

Second, the Referring Judge wonders what distinction should be made between the concept of "food for special medical purposes" on the one hand and the concepts of "medicinal product" and "food supplement" on the other. According to Kwizda Pharma, the composition of food supplements can lead to them also being classified as "food for special medical purposes" because certain substances, such as cranberry or D-mannose, are deemed to meet nutritional needs. Moreover, Kwizda Pharma argues that a product may be classified as a "food for special medical purposes" where it contains a

substance which is capable of promoting the evolution of a disease or a cure. According to the Referring Judge, such an argument blurs the distinction between "food for special medical purposes" and "medicinal products", but requests clarification of the CJEU.

Thirdly, the Referring Judge wishes to know the scope of the requirement of Article 2(2)(g) of Regulation (EU) 609/2013, which states that, for classification as a "food for special medical purposes", determining ingredients must produce their effects in the context of nutritional needs that cannot be met by modification of the normal diet. It notes that, according to Kwizda Pharma, cranberry or D-mannose can only be taken as part of the normal diet with great difficulty, so this requirement is met for the Products in question.

Finally, for the purposes of assessing the argument put forward by Kwizda Pharma concerning the divergent definitions of the term "nutrient" in EU law – according to which, for the purposes of Regulation (EU) 609/2013, any food and any substance that may also be contained in a food or food supplement must be regarded as a "nutrient" within the meaning of Article 2(2)(g) of that regulation – the Referring Judge wishes to know from the CJEU what is to be understood by the term "nutrient" within the meaning of that regulation.

With this in mind, the Referring Judge asked a large number of preliminary questions. The CJEU deals with the questions clustered into a number of topics and thus answers several issues of classification.

I only highlight one of those answers in this note, which is the difference between a foodstuff ("food for special medical purposes") and medicinal product.

Food and medicine

The CJEU first addressed the third – and in my view most important – question of this judgment. This question was: "*What criteria should be used to distinguish a medicinal product from food for special medical purposes?*" Answering this question involves 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 1(EU) 609/2013.

In answering this question, the CJEU first refers to the judgment of 27 October 2022, Orthomol, C 418/21, EU:C:2022:831, paragraph 37, in which it has already been emphasised that food for special medical purposes is distinct from medicines, and that the two categories of products, in view of their specific characteristics, are subject to different definitions and regulations that are mutually exclusive.

The CJEU continues that the characteristics and functions of food for special medical purposes are different from those of medicines, meaning that they are products that purport to have therapeutic or prophylactic properties in relation to human diseases either to restore, improve or modify physiological functions by exerting a pharmacological, immunological or metabolic effect or to make a medical diagnosis.

However, food for special medical purposes is different, the CJEU stresses. Indeed, it concerns food intended to meet the nutritional needs of patients and not to prevent or cure diseases in humans, or to restore, improve or modify physiological functions by exerting a pharmacological, immunological or metabolic effect, or to make a medical diagnosis. Therefore, food for special medical purposes cannot, as such, combat diseases, disorders or ailments, but is characterised by its nutritional function.

Consequently, if a patient generally benefits from the ingestion of a product to the extent that the substances it contains help to prevent, alleviate or cure a disease, the purpose of that product is not to nourish that patient, but to care for him, prevent a disease or restore, improve or modify physiological functions by producing a

pharmacological, immunological or metabolic effect, which argues in favour of classifying that product as other than "food for special medical purposes".

This assessment of the legislation includes very much the actual text of the rules and therefore not surprising. But then the CJEU applies it to the case before it, ruling that in the present case, it is clear from the information provided by the Referring Judge that Kwizda Pharma *markets* the products in question and indicates that the consumption of these products in cases of urinary tract infection is conducive to the elimination of the pathogens in question.

Even if it is for the competent national public authorities to determine, on the basis of a case-by-case assessment and taking into account all the characteristics of those products, whether those products can be marketed as food for special medical purposes, the fact remains, that products presented as having therapeutic properties in relation to a disease, but which are not intended to meet particular nutritional needs of patients, cannot be marketed as food for special medical purposes, but as medicinal products. Kwizda Pharma's argument therefore fails.

This is because, according to the CJEU, the following consideration also comes into play. Article 2(2) of Directive 2001/83 states that, in case of doubt as to the correct classification of the products concerned, priority shall be given to the application of EU legislation on medicinal products, which, because of the stricter requirements resulting from pharmaceutical law for the marketing of products, is also consistent with the objective of a high level of human health protection pursued by Article 168 TFEU.

The CJEU therefore answers the third question that the distinction between concepts of "medicinal product" and "food for special medical purposes" must be assessed – in the light of the nature and characteristics of the product in question – whether it is a foodstuff intended to satisfy particular nutritional needs or a product intended to prevent or cure diseases in human beings, to restore, improve or modify physiological functions by exerting a pharmacological, immunological or metabolic effect, or to make a medical diagnosis, or possibly presented as such. The destination is thus of decisive importance.

Comment: Classification – A Common Problem

In food law, classification issues – or delimitation issues – are a familiar problem. Is the cheerful plastic packaging of a children's sweet a food contact material or a toy? Is snus tobacco or a foodstuff? Is something an animal by-product or a medicine? Particularly with innovative products or production processes, where the European legislator did not consider the definitions in the various Regulations and Directives, such questions often arise. In this judgment, the CJEU answered two concrete classification questions. However, in my opinion the judgment is also of greater importance as the way in which the CJEU answers these questions may also guide other classification issues. In it, the CJEU gives the following principles which I summarise as follows:

- As a first step, it is necessary to check carefully which definitions – and thus within the scope of which Regulation and Directive – a particular product falls under. Here, overlapping definitions cannot be ruled out.
- It is then necessary to see whether the two European regulations have a provision determining the rules of precedence.
- If this is not the case, the concepts will have to be compared and an assessment must be made of where the concepts and the resulting qualifications are necessarily mutually exclusive.
- On that basis, it can then be determined on a case-by-case basis under which concept a product falls. Whereby, on the one hand, reference can therefore be made to the

> CJEU judgment of 19 January 2023 (C-495/21 and C-496/21 - ECLI:EU:C:2023:143) indicating that if a product clearly meets the conditions set out in another definition, then the Medicines Directive *does not apply*, but that in case of doubt as to the correct classification of the products in question, the Medicines Directive should take precedence, as this legal framework imposes stricter requirements which, in view of the objective of a high level of protection of human health pursued by Article 168 TFEU, is deemed appropriate.

It will still often be a grey area and in special cases – as in this case – a national court might still be forced to ask preliminary questions. Nevertheless, in my view, the roadmap suggested by the CJEU in this judgment is often sufficient to answer most questions on classification.

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