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Legislative and Jurisprudential Analysis Regarding the Circulation of Food Supplements at the Level of the European Union

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ABSTRACT: The Europe dietary supplements market exhibits a diverse end-user concentration, encompassing health-conscious individuals, fitness enthusiasts, and those seeking preventive healthcare solutions. With a growing awareness of holistic well-being, the market caters to a broad spectrum of consumers, ranging from aging populations seeking nutritional support to younger demographics embracing proactive health measures. In the context of an increasing number of products being introduced into the European Union market in the form of food products containing a concentrated source of nutrients and presented as supplementing the intake of these nutrients into the normal diet, this paper examines the regulation of the internal market of food supplements, as well as the obstacles arising to cross-border trade in dietary supplements containing substances other than vitamins and minerals. Given that European legislation does not include specific provisions on the use of substances other than vitamins or minerals in food supplements, the free movement of these products is governed by Articles 34 – 35 of TFEU/Treaty on the Functioning of the European Union and may thus be subject to national restrictions or prohibitions within the limits set out in Article 36. At the same time, the paper aims to present the relevant case-law of the Court of Justice of the European Union which restrictively interprets the list of derogations stipulated in Article 36 of TFEU, so that measures taken by Member States do not constitute a means of arbitrary discrimination or any restriction hid under the trade of food supplements containing *substances other than vitamins and minerals.*

KEYWORDS*:* European Union legislation, food supplements, internal market, free movement of goods, case-law of the Court of Justice of the European Union

Introduction

The Europe dietary supplements market size was valued at USD 40.73 billion in 2023 and is expected to grow at a compound annual growth rate (CAGR) of 7.0% from 2024 to 2030 (Grand View Research Report). The primary factors driving the market growth are increased awareness about healthcare, affordable/state-sponsored healthcare, a growing geriatric population (Rotaru 2016, 29-43), and a focus on preventive healthcare and personalized nutrition.

Consumers are shifting towards self-directed care driven by the growing personal health and well-being trend, and European Union residents are comparatively stricter and well-informed about nutrition and physical well-being. In addition, the ongoing COVID-19 pandemic (Rotaru 2020, 71-82) has furter hightened the focus on immunity-boosting product, leading to increased sales of vitamin C, zinc, and other immune-supporting supplements.

In this context, the development of a unanimous and viable legislation within the European Union has become a necessity.

Theory

The first specific legislative act on food supplements was Directive 2002/46/EC, on the approximation of the laws of the Member States relating to food supplements, a text relevant to the European Economic Area, in which the first definition of food supplements was given.

The adoption of EU Directive 2002/46/EC has been the starting point for many changes in the field of food supplements, both in EU Member States and in other European countries.

This Directive has also opened the possibility of discussions on a pan - European acceptance of the definition and requirements of health, of rules on labelling these products, and of the adoption of rules regarding the traditional medicinal plants.

Furthermore, all horizontal food laws also apply to food supplements, including the following regulations: food safety general requirements, responsibilities for producers and obligations regarding traceability, provision of information and recall of harmful products (Regulation (EC) No 178/2002); food preparation and hygiene based on the principles of hazard analysis and critical control points (HACCP) (Regulation (EC) No 852/2004); food labelling in order to adequately inform the consumer about the composition, properties and use of food products (Regulation (EU) No 1169/2011); the use of nutrition and health claims, which must be authorized before they can be used (Regulation (EC) No 1924/2006); conditions for the use of additives (Regulation (EC) No 1333/2008); maximum levels for residues and contaminants (Regulation (EC) NO 396/2005; Commission Regulation (EC) No 1881/2006); approval of novel foods (Regulation (EU) 2015/2283).

In some Member States, there is a well-established tradition of using certain substances, while these substances are practically absent in other Member States. As EU legislation does not include specific provisions on the use of substances other than vitamins or minerals in food supplements, the free movement of these products is governed by Articles 35 – 36 of the Treaty on the Functioning of the European Union (TFEU) and may thus be subject to national restrictions or prohibitions within the limits set out in Article 36 .

With regard to food supplements, in particular those containing substances other than vitamins or minerals, a number of borderline cases have arisen or could give rise to situations where a certain product is authorized for marketing as a food product in some Member States while the same product is classified as medicine in other Member States.

Results and discussions

The Food Supplements Directive has achieved two major objectives: firstly, the Directive provides a harmonized definition of a food supplement, which means that Member States must apply the same definition and must treat products in the same way.

Secondly, the Directive allows Member States to implement only a notification procedure whereby food supplements are reported to the authorities at the time of placing on the market. Most Member States have introduced such a notification requirement and some Member States apply it as a pre-marketing authorization procedure. However, some Member States have not considered it necessary to introduce a notification obligation.

The limited European harmonization of compositional requirements for food supplements has clearly led to a detailed legislation in some Member States. Such legislation differs considerably between Member States, not only in terms of design and implementation, but also in terms of content. There are positive and negative lists, with permitted or prohibited ingredients, maximum levels, specific labelling requirements and other conditions of use. Member States often prevent the legal access on the market of food supplements from another Member State, for not complying with their national requirements.

Despite several rulings by the Court of Justice of the European Union, the principle of free movement of goods is difficult to ensure. The principle originates in the famous *Cassis de Dijon* judgment of the Court of Justice of 20 February 1979 (Case C-120/78 *Rewe-Zentral AG v Bundesmonopolverwaltung für Branntwein*) and has formed the basis for a new development of the internal market for goods. Although not initially explicitly mentioned in the case-law of the Court of Justice, it is now fully recognized.

Technical barriers to the free movement of goods in the European Union remain widespread. They occur when national authorities apply national rules setting out the requirements that products must meet (in terms of name, shape, size, weight, composition, presentation, labelling and packaging) for the products from other Member States, in which

they are produced and legally marketed. If these rules do not implement the secondary legislation of the European Union, they constitute technical barriers to which Articles 34 and 36 of TFEU/Treaty on the Functioning of the European Union apply. This applies even when those rules apply to all products, without distinction.

A ban on the marketing of a particular product or substance is the most restrictive measure a Member State can adopt with regard to the free movement of goods. Most goods subject to national bans are food products (see: Case 174/82 Sandoz; Case C-24/00 Commission v France; Case C-420/01 Commission v Italy; Case C-192/01 Commission v Denmark; Case C-41/02 Commission v Netherlands; Case C-319/05 Commission v Germany), including vitamins, food supplements and chemicals.

In most cases, the justifications provided by Member States for these severe measures relate to the protection of the health and life of humans, animals and plants, in accordance with Article 36 of TFEU, as well as to the imperative requirements stipulated in the case-law of the Court of Justice of the European Union, such as those on environmental protection. These justifications are often combined. The Member State imposing a national ban on a product / substance must demonstrate that the measure is necessary and, where appropriate, that the sale of the products in question poses a serious risk to public health and that the respective rules comply with the principle of proportionality. This includes providing relevant evidence, such as technical, scientific, statistical, and nutritional information, as well as all other relevant information.

In order to facilitate the application of the principle of mutual recognition, by laying down procedures to minimize the possibility of creating illegal obstacles to the free movement of goods which have already been lawfully marketed in another Member State, the European Union has adopted Regulation (EC) no. 764/2008. Moreover, the burden of proving that the stated purpose cannot be achieved by other means with a less restrictive effect on trade between the Member States within the EU falls on the Member State (Case 104/75 De Peijper). For example, with regard to a ban in France against the addition of caffeine to beverages above a certain level, the Court stated that "*appropriate labelling and informing consumers about the nature, ingredients and characteristics of energy products may allow users whose health may be affected by the excessive consumption of a nutrient added to these products to decide for themselves whether to consume them*" (Case C-24/00 Commission v France, paragraph 75). The Court, therefore, considered that the ban on the addition of caffeine above a certain level was not necessary in order to protect consumers.

The *Danish vitamins* case (Case C-192/01 Commission v Denmark) referred to the Danish administrative practice of banning the enrichment of food products with vitamins and minerals if it could not be proved that such an enrichment was necessary for the Danish population. The Court initially agreed that the task of determining the level of protection of human health and life rested with Denmark, taking into account the principle of proportionality. However, the Court noted, in paragraph 46, that the Danish authorities had the responsibility to "*demonstrate in each case, in light of national food habits and in light of the results of international scientific research, that the proposed rules are necessary to effectively protect the interests endorsed in the respective provision and, in particular, that the marketing of the respective products results in a real risk to public health*". After examining the Danish administrative practice in question, the Court concluded, in paragraph 56, that the measure "*does not allow the compliance with the EU law regarding the identification and assessment of a real risk to public health, which requires careful examination, on a case-by-case basis, of the effects that enrichment with minerals and vitamins may entail*".

The European Commission has repeatedly taken administrative measures against certain Member States and, finally, brought them to court. In each of these cases, the Court ruled that the actions taken by the Member States were not in accordance with Article 34 of TFEU (see: Case 387/99: 29/04/2004. Commission of the European Communities v. Federal Republic of

Germany; Case 24/00: 05/02/2004. Commission of the European Communities v. French Republic; Case 150/00: 29/04/2004. Commission of the European Communities v. Republic of Austria; Case 192/01: Commission of the European Communities v. Kingdom of Denmark; Case 41/02: 02/12/2004. Commission of the European Communities v. Kingdom of The Netherlands) and that the Member States had failed to fulfill their obligations under the Treaty. In addition, the Court has also ruled that Articles 34 and 36 must be interpreted as not precluding a Member State from prohibiting the marketing without prior authorization of food lawfully manufactured and marketed in another Member State, provided that certain conditions are met.

Since many problems have been found to continue to exist with regard to the implementation of the principle of mutual recognition, Regulation (EC) no. 764/2008, which had several shortcomings, was replaced by Regulation (EU) 2019/515. This Regulation, adopted to ensure that existing rights and obligations arising from the principle of mutual recognition are respected by both economic operators and national authorities, should not affect the further harmonization of conditions for the marketing of goods in order to improve the functioning of the internal market.

Conclusions

As a general rule, despite the existence of national technical rules in the Member State of destination, according to the principle of mutual recognition in the non-harmonized field, food supplements lawfully manufactured or marketed in another Member State enjoy a fundamental right to free movement guaranteed by the TFEU. As an exception to this principle, products lawfully manufactured or marketed in another Member State shall not enjoy this right if the Member State of destination can demonstrate that it is essential to impose its own technical rules with respect to the products in question, on the grounds stipulated in Article 36 of TFEU or in the imperative requirements of the case-law of the Court and provided that the principle of proportionality is respected.

National authorities invoking the exception to the rule on the free movement of goods within the EU must demonstrate, in light of national food habits and taking into account the results of international scientific research, that the regulation of exceptional measures is necessary to effectively protect the interests of protecting public health, for which the marketing of the respective product presents a real risk (Case C-319/05 Commission v Federal Republic of Germany, paragraphs 86-88).

Romania, being a EU Member State, can prohibit the marketing, without prior authorization, of food products lawfully manufactured and marketed in another Member State, taking into account that:

- ✓ there is no unitary European regulation on food supplements containing substances other than vitamins or minerals;
- ✓ the approximation of the laws, enshrined in Directive 2002/46/EC, concerns only food supplements containing vitamins and minerals;
- ✓ the principle of mutual recognition does not apply unlimitedly, but by its correlation with the negative and positive list of prohibited / allowed plants in food supplements, existing in Romania, so as not to discriminate Romanian producers compared to food supplements producers in EU Member States or other states.

The European Commission considers that the existing EU legal instruments already provide a sufficient legislative framework for the regulation of food supplements and does not consider it appropriate to establish specific rules for substances other than vitamins or minerals intended for use in food products.

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