2002

20 years of the Food Supplements Directive

MAJOR ACHIEVEMENTS AND THE WAY FORWARD

ehpm
European Federation of Associations of Health Product Manufacturers

The Food Supplement Sector in Europe before 2002

Since ancient times people have been seeking solutions to enrich their diet with natural and nutrient-rich food sources. Ranging from royal jelly, yeast preparations to cod liver oil after World War II to modern multivitamin and botanicals complexes, the history of food supplements in the form we know them nowadays in Europe began in the early 1960s.

However, their introduction to the different national markets was not immediately accompanied by a legal framework since in different European countries different national regulatory frameworks as well as different categorisation and denominations were in place: from natural health products, to special foods and foodstuffs, to dietary supplements and nutraceuticals.

By 1975 it had become clear that the European Common Market, as it then was, would eventually affect trade in health products between Member States. This meant that it was essential that the national associations within Europe had a forum in which they could debate the many issues, legal systems and cultural differences within the various markets in order to be able to work towards a common position[1].

It was felt that having achieved a common position we would be able to speak with one voice to the European Commission in Brussels, thereby establishing a **mutually helpful and credible dialogue**.

The constitution of the European Federation of Associations of Health Product Manufacturers "EHPM" was developed and signed during a meeting between the British Health Food Manufacturers Association (HFMA) and the German *Verband der Reformwaren-Hersteller* (VRH) in Amsterdam on 29 August 1975.

The EHPM then invited all other European countries to join. The EHPM quickly grew to become fully representative and has worked closely with the European Commission and the European Parliament, drawing on expert help from all its members.

In 1995 a revised constitution was adopted by the representatives of 10 European countries shaping EHPM to its present status as the European Association supporting and promoting the creation and maintenance of a successful and credible health product industry in Europe.

In fact, in the 1990s food supplements were a booming market across the EU, but they had no official regulatory status. The different treatment of food supplements in the Member States created potential restrictions on trade, resulting in the disruption of the free movement of goods and competition which the European Commission was mandated to resolve.

EHPM played an active role in the exchanges with regulators and in highlighting the existing restrictions and pushing for their resolution with EU legislation.

The Food Supplements Directive: a game changer for the European sector

At the turn of the new millennium, all parties involved committed to overcoming these uncertainties and challenges. This successfully led to the adoption, in June 2002, of the Directive 2002/46/EC on the approximation of the laws of the Member States relating to food supplements: the so-called "Food Supplements Directive".

[1] The Constitution of the European Federation of Associations of Health Product Manufacturers, 19 October 1995.

The development of this game-changing directive, which laid the foundation of the current regulatory framework for food supplements in Europe, was possible also thanks to a frank dialogue between authorities, institutions, experts from the sector and European stakeholders including EHPM.

The objective of the Directive was two-fold. First, to set out a general framework and safety rules for vitamins and minerals and other ingredients with a nutritional and physiological effect in the European Union.

Second, to give the consumer detailed information with labelling allowing a better control of the sector and high quality of the products on the market.

The Food Supplements Directive, in establishing the European framework, for the first time provided a European definition of food supplements:

"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." [2]

[2] Art. 2 A of Directive 2002/46/EC

The Directive also:

- Limited the vitamins and minerals permitted in food supplements to those listed in Annex I and the forms in which these can be presented to those listed in Annex II;
- Required that maximum levels of vitamins/ minerals permitted in Food Supplements be set and identified considerations that should be taken into account when doing so;
- Identified the labelling regulations that will apply to food supplements;
- Allowed Member States to implement a notification system if they wish to do so.

The Directive allowed for a better control of the sector guaranteeing high quality of the products on the European market.

In addition, the Food Supplements Directive recognised the role and need of food supplements for optimal nutrition and for the betterment of citizens' health. Recitals 3 and 4 of the Food Supplements Directive, in fact, highlight that:

- *(3) "An adequate and varied diet could, under normal circumstances, provide all necessary nutrients for normal development and maintenance of a healthy life in quantities which meet those established and recommended by generally acceptable scientific data. However, surveys show that this ideal situation is not being achieved for all nutrients and by all groups of the population across the Community."* [3]
- *(4) "Consumers, because of their particular lifestyles or for other reasons, may choose to supplement their intake of some nutrients through food supplements."* [4]

[3] Recital 3, 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

[4] Recital 4, 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

The role of a food supplement: a tool to address nutritional deficiencies and reach an optimal nutritional status

Overwhelming evidence now supports the beneficial effects of food supplements on health, and within a regular diet, the intake of food supplements contributes to keeping people healthy and containing healthcare costs. Soil degradation and over-cultivation[5] offer crops which are poorer in nutritional value compared to 100 years ago, while limited access to raw foods, overconsumption of processed food and socio-economic conditions (declining incomes, limited time availability, etc.) make it difficult to ensure access to nutrient-rich food sources daily. In addition, the bodily demand for those nutrients increases in cases of smoking habits, extreme stress or disease.

Moreover, Europe's population is getting older, facing a substantial growth of the over 65 population, which is expected to increase in the following years. This pattern corresponds to an essential increase in the development of chronic diseases and noncommunicable diseases (NCDs) most of which are diet-related. Consequently, the EU's socio-sanitary needs and related costs are also increasing, putting at risk the sustainability of healthcare systems and welfare in general. Therefore, healthy behaviour, lifestyles and products able to reduce the risk factor for specific pathologies, and enhancing health, well-being and quality of life are of ever-increasing importance. Food supplements are efficient tools that help improve the quality of life of healthy citizens with a longer life expectancy and higher exposure to chronic risk. This also has a positive impact on keeping the cost of the EU healthcare systems under control.

Food supplements are not meant to prevent or treat any disease, but the scientific community recognises their role in reducing the risk factor of several diseases: calcium and vitamin D[6] can be used to reduce the risk of osteoporosis, folic acid[7] to reduce the risk of certain birth defects such as spina bifida, DHA and EPA[8] to reduce high cholesterol, abnormal blood pressure and triglycerides.

Therefore, food supplements are a safe and efficient tool for ensuring optimal nutrition, and alongside other factors, optimal health.

The proportionate and fact-based approach determined by the Food Supplements Directive allowed greater consumer protection, the development of products that contribute to the maintenance of consumer health, and a growth of the European food supplement market that today is worth more than EUR 12 billion and sustains well over 100.000 jobs and experienced a growth of 6,2% in 2021 compared to 2020[9].

[5] Carla S.S. Ferreira, Samaneh Seifollahi-Aghmiuni, Georgia Destouni, Navid Ghajarnia, Zahra Kalantari, Soil degradation in the European Mediterranean region: Processes, status and consequences, Science of The Total Environment, Volume 805, 2022, 150106, ISSN 0048-9697, https://doi.org/10.1016/j.scitotenv.2021.150106. & Ferreira, Carla S S et al. "Soil degradation in the European Mediterranean region: Processes, status and consequences." The Science of the total environment vol. 805 (2022): 150106. doi:10.1016/j.scitotenv.2021.150106

[6] Calcium and Vitamin D are listed among the permitted health claim for reducing the loss of bone mineral in post-menopausal women which is a risk factor for osteoporosis. Low bone mineral density is a risk factor for osteoporotic bone fractures, Annex I of Commission Regulation EU No. 1228/2014 of 17 November 2014 authorising and refusing to authorise certain health claims made on foods and referring to the reduction of disease risk.

[7] Folic acid is listed among the permitted health claims in the Annex of Commission Regulation EU No 1135/2014 of 24 October 2014 on the authorisation of a health claim made on foods and referring to the reduction of disease risk

[8] DHA & EPA are listed among the permitted health claims in the Annex of Commission Regulation (EU) No 432/2012 of 16 May 2012 establishing a list of permitted health claims made on foods, other than those referring to the reduction of disease risk and to children's development and health.

[9] Syndicat National des Compléments Alimentaires SYNADIET, General Assembly, 29 March 2022

Ongoing challenges & next steps

Although the harmonisation process begun in 2002 bore important fruits, the full harmonisation of the European regulatory framework sought by the Food Supplements Directive is yet to be achieved. For instance, the European harmonisation of maximum and minimum levels for vitamins and minerals has only recently seen re-energised momentum. The lack of a harmonised proportionated methodology to the assessment and authorisation of botanicals health claims is another important area requiring further harmonisation. In a similar way, the lack of a harmonised proportionate approach to the use of the term “probiotic” holds uncertainty for the industry and consumers, as well as falling short of the aspirations and objectives of the Food Supplements Directive.

EHPM proactive approach

EHPM has adopted a proactive approach to support and contribute to the fulfilment of the missing achievements of the Food Supplements Directive. Over the last few years, EHPM has developed two important proposals, one on the assessment of botanical health claims and truthful information to consumers and the other on setting maximum and minimum levels of vitamins and minerals.

With the former, EHPM proposes a **Graded Approach to the assessment of Botanical Health Claims** to serve as a reference for future discussions between Member States, European Commission and other EU stakeholders. At the same time, EHPM wants to encourage the European Commission and Member States to address this topic in order to safeguard both the proper functioning of the internal market and consumer choice, while protecting their safety.

With the latter, EHPM proposes a **Model for setting Maximum and Minimum Levels for Vitamins and Minerals** for food supplements for adults and children that are safe for consumers and based on a robust scientific approach. This model is being presented to the experts of the European Commission and National Authorities that are working on the setting of the harmonised European Maximum levels.

In order to further enhance consumer safety, EHPM is also finalising its manifesto on **Nutrivigilance** that would ignite the establishment of an industry-led Europe-wide post-market surveillance scheme for food supplements.

In addition, EHPM is developing its proposal on the use of the term **"probiotics"** that would safeguard the proper functioning of the internal market and guarantee equal conditions of competition across the Union, as well as safeguard consumer choice and accurate information.

EHPM Upcoming publications

EHPM, with its technical experts, continues to work on proportionate and science-based proposals that would enhance the harmonisation of the European regulatory framework for food supplements.

UPDATED QUALITY GUIDE

EHPM published the first edition of its Quality Guide back in 2004. The upcoming updated version covers all aspects of food supplement quality, including the incorporation of national best practice from several EU Member States concerning botanical preparations. Implementing the EHPM Quality Guide is therefore the best way for food supplements producers to ensure both the safety and the satisfaction of the growing number of European citizens who use food supplements every day.

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Addressing the challenges that the food supplement sector is facing is crucial to allow the full operation of the internal market and guarantee consumer safety as well as consumer choice. In order to achieve these objectives a constructive and transparent dialogue between regulators and stakeholders is essential.

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