Food Supplements
for healthier citizens & a stronger economy in the EU

An EHPM manifesto for the food supplement sector in Europe

ehpm
European Federation of Associations of Health Product Manufacturers

Food supplements for a healthy, innovative and prosperous Europe.

Executive summary

Overwhelming evidence now supports the beneficial effects of food supplements on health, and within a balanced and healthy diet, the intake of food supplements contributes to keeping people healthy and containing healthcare costs. The European Federation of Health Product Manufacturers – representing approximately 1,600 specialist health-product manufacturers and distributors (mostly SMEs) – aims to improve the enabling legislative environment for the sector that promotes innovation, supports economic growth and fosters cooperation with national healthcare systems for the benefit of all Europeans.

While the European Food Supplement Directive has been an important tool in achieving sustained growth for the European food supplements sector in the recent years, additional regulatory improvements are needed to reach the sector's full potential. As a new political term at the EU level is starting, EHPM is committed to work on the following enablers to ensure that the food supplement sector contributes to healthier citizens and a stronger economy in the years ahead:

Mutual Recognition and General Food Law review
As many companies in the food supplements sector have had difficulties accessing the full EU market, EHPM welcomes the revised Mutual Recognition Regulation that is expected to facilitate the free movement of goods in the EU. EHPM will continue to facilitate the implementation of the revised regulation. Additionally, EHPM has called for the implementation of meaningful pre-submission consultations between companies and the European Food Safety Authority (EFSA) in the revised General Food Law Regulation.

REFIT of EU Legislation on Nutrition and Health Claim
EHPM has contributed to the Regulatory Fitness and Performance (REFIT) evaluation process of the EU legislation on nutrition and health claims. The current framework is alien to the culture of the food industry and beyond its expertise and resources, which is why only a small number of health claims have been authorized, thereby limiting the information available to consumers. EHPM has been working on an authorization process that would address the requirement for scientific stringency, be practical for the industry and, above all, provide consumers with the of information that they demand on the foods they purchase and consume.

A tailored approach to the safety assessment of botanicals
EHPM calls for a tailored approach to the use of Art. 8 of Regulation 1925/2006, which is the legislative tool used to assess the safety of ingredients. This procedure can be applied to botanicals, that represent more than 60 percent of the food supplements market in Europe. EHPM is therefore working in cooperation with academics from multiple EU Member States to develop proper guidelines for the safety evaluations of botanicals.

Acknowledgement of the term "Probiotic"
EHPM believes that the use of the term "contains probiotics" should be permitted in the EU. This will create a labelling environment that consumers can trust and will allow consumers to make informed choices about the products they purchase and consume.

Support innovation
Innovation is key for the development of the food supplements sector and essential in order to provide consumers with products that meet their current demand for more natural solutions. Under the current EU regulatory framework, investments in innovation are strongly hindered as companies cannot afford to invest in innovation without the certainty that the ingredients they use and the health claims they make will be authorised in the EU market. This is especially true for SMEs.

E-commerce and fake news
EHPM recognizes the opportunities imbedded in e-commerce but asks for a level playing field to avoid unfair competition from countries with less strict rules. In addition, EHPM believes that promoting effective, truthful and professional communication to all stakeholders to clearly define the identity and function of food supplements is central to overcome flawed comparisons with other products.

Safety and quality
EHPM developed the EHPM Quality Guide to provide a practical guidance for companies throughout the production process to ensure high quality standards. That is why EHPM supports the implementation of a post-market vigilance system for food supplements, that would allow the companies to collect a high amount of useful data on their products, including their adverse effects.

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About EHPM

Who are we?

The European Federation of Health Product Manufacturers (EHPM), created in 1975, represents approximately 1,600 health-product manufacturers and distributors in Europe, the majority of which are Small and Medium Size Enterprises (SME's). EHPM represents National Associations of the food supplement sector in 14 European Countries, as well as expert individual member companies.

What we do?

We help develop solutions to improve the EU regulatory framework for food supplements through our technical working groups. We establish and promote industry best practices for product quality, safety and efficacy.

What is a food supplement?

Food supplements are foodstuffs containing concentrated sources of nutrients, vitamins, minerals or other substances, such as probiotics, essential fatty acids, herbal extracts, with a nutritional or physiological effect, helping people reach an optimal nutritional intake by "supplementing" their diet. Food supplements are marketed in dose form 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 .[..][1]"

What do food supplements do?

As with other foods, food supplements contribute to maintaining the normal state of homeostasis[2] in the body and are not meant to prevent or treat any disease. Food supplements function to maintain or improve health or to reduce the risk factors associated with disease. Food supplements are not meant to replace a balanced diet.

For instance, Calcium and vitamin D[3] can be used to reduce the risk of osteoporosis, folic acid[4] to reduce the risk of certain births defects such as spina bifida, DHA and EPA to reduce high cholesterol[5], abnormal blood pressure and triglycerides, Ginkgo biloba to promote normal blood circulation, and Milk Thistle[6] to protect liver health. As such, food supplements, together with a healthy lifestyle, contribute to the improvement of citizens' health and wellbeing, and to the reduction of the financial burden of healthcare systems on Member States. The reduction of diet-related risk factors for several diseases is a sustainable option, which serves the needs of the EU population first and foremost. This is particularly important in the EU, as an increasing 20 percent of the population is aged 65+.

[1] Art. 2 of 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.

[2] "[..]Homeostasis can be defined as the status of a person whose physiological parameters function within the limits considered as normal[..]. P.8 of Homeostasis a method to distinguish between food and food supplements and medicinal products, Council of Europe 07/02/2008.

[3] 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.

[4] 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.

[5] 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.

[6] Gingko Biloba & Milk Thistle are on the list of the on hold Article 13 (1) "on hold" claims.

Food supplement sector in Europe:

Facts and figures

A sector lagging behind its full potential

The European food supplements sector has experienced sustained growth in the recent years, with a Compounded Annual Growth Rate (CAGR) of over 6% since 2014, reaching € 11.6 bn in 2018[7]. Moreover, as of 2016, the number of employees in the European food supplement sector was approximately 111,000[8]. Despite this trend, Europe's food supplement sector is lagging behind its full potential. This is clearly seen in Italy, where a more supportive approach to people taking personal responsibility for their health has resulted in market sales of €3.6bn[9].

While the European Food Supplement Directive has been an important tool to support this positive trend, regulatory improvements are still needed, such as access to market and mutual recognition; implementation of the pre-submission advice foreseen in the revised General Food Law Regulation[10]; REFIT of the Nutrition and Health Claims Regulation[11]; use of Art. 8 of Reg. (EC) No 1925/2006; acknowledgment of the term probiotic. According to a recently published study[12], appropriate developments of the EU regulatory framework could create around 82.000 jobs in the EU.

[7] A case for an EU reform of the food supplements regulation to support the industry competitiveness, Study sponsored by SYNADIET, Monitor Deloitte 2019.

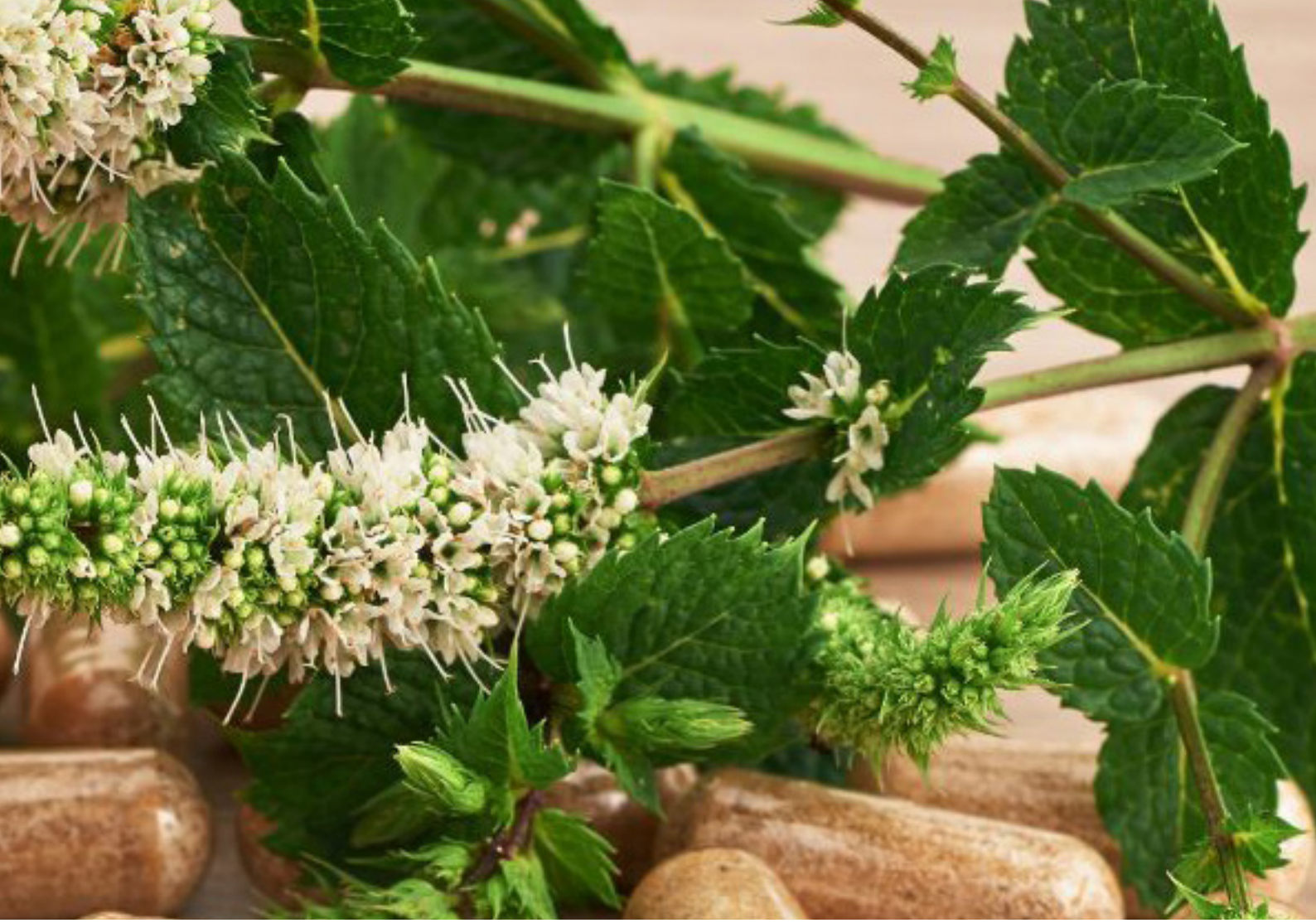
[8] "Industry Mission : Business sector study Europe plant food supplements", Expansion Consulteam on behalf of Synadiet, May 2016.

[9] 2019 IQVIA data for Federsalus.

[10] Regulation (EU) 2019/1381 of the European Parliament and of the Council of 20 June 2019 on the transparency and sustainability of the EU risk assessment in the food chain and amending Regulations (EC) No 178/2002, (EC) No 1829/2003, (EC) No 1831/2003, (EC) No 2065/2003, (EC) No 1935/2004, (EC) No 1331/2008, (EC) No 1107/2009, (EU) 2015/2283 and Directive 2001/18/EC.

[11] Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods.

[12] A case for an EU reform of the food supplements regulation to support the industry competitiveness, Study sponsored by SYNADIET, Monitor Deloitte 2019.



Recent European Regulatory Developments

Mutual Recognition and General Food Law review: expectations and opportunities for the sector

Access to market and mutual recognition

Accessing the EU market has often been difficult for companies in the food supplement sector due to resistance from various Member States to comply with the Mutual Recognition Regulation[13]. The revised Regulation (EU) 2019/515, that will become applicable as of April 2020, is expected to facilitate the free movement of goods including food supplements. EHPM has concretely contributed to the preparatory work that the European Commission has performed on this file and will continue to contribute to the facilitation of the implementation of the new Regulation.

General Food Law Review: Pre-submission advice

The General Food Law Regulation is the foundation on which the entire regulatory framework for food in the EU is based. EHPM has followed with great interest the negotiations on the new transparency regulation that will become applicable in March 2021. EHPM has called for the introduction of meaningful pre-submission consultations between companies and EFSA, where all elements of evidence needed to support applications for a product or claim authorization could be open for discussion in detail, particularly clinical trials.

Although the final text of the approved regulation does not foresee the possibility to discuss clinical trials, EHPM welcomes the introduction of art. 32 a, on pre-submission advice. EHPM hopes that the guidance document on the application of the new transparency regulation, that EFSA is currently working on, will open the way to a constructive dialogue between companies and EFSA and that the Authority will contribute to provide the clarity, certainty and indications needed for companies in the food supplement sector to continue to invest in product development and innovation without compromising EFSA's staff independency.

[13] Regulation (EU) No. 764/2008 of the European Parliament and of the Council of 9 July 2008 laying down procedures relating to the application of certain national technical rules to products lawfully marketed in another Member State.

Food supplement sector in Europe:

Challenges and EHPM's proposals

REFIT of EU Legislation on Nutrition and Health Claims: the EHPM proposal

Regulation (EC) No 1924/2006[14] on nutrition and health claims made on foods ("NHCR") governs the use of such claims in labelling, presentation and advertising. In its Preamble, the NHCR aspires to facilitate informed choice, alongside the protection of consumers and the encouragement of legitimate business in the food industry. However, an inappropriate demand for medical-style scientific proof has resulted in an impractical authorization process that is alien to the culture of the food industry and beyond its expertise and resources. As a result, only a small number of the more than 4000 health claims identified on the market have been authorized. The vast majority of these health claims are based on established science about the impact of vitamins and minerals on health, instead of innovative scientific research on the role of food in achieving better health results. The effect is that consumers do not have access to the information that they are increasingly looking for on the health benefits of the foods, and particularly the food supplements, that they purchase. As a consequence, consumers are increasingly turning to uncontrolled sources for information, such as the internet – increasing the likelihood of them being misled. Furthermore, this regulatory uncertainty discourages food supplement companies from investing in innovation.

In May 2015, the European Commission announced its plan to carry out a Regulatory Fitness and Performance (REFIT) evaluation of the EU legislation on nutrition and health claims in order to find a solution to this situation. EHPM has contributed to the REFIT process and is expecting the publication of the EC Staff Working Document to be published soon. Therefore, EHPM has been working to develop a balanced solution, that would address the requirement for scientific stringency, be practical for the industry and above all else provide consumers with the sort of information that they are looking for on the foods that they purchase and eat.

EHPM's graded approach is a concrete proposal that adapts the current assessment process

in order to evaluate the over 2000 botanicals' health claims currently on hold. Three grades of claim assessment are proposed, each supported by appropriate levels of evidence: scientifically accepted claims, claims that are scientifically well-supported, and 'traditional use claims'[15] . Furthermore, when it comes to the wording of the claims it is important to stress that consumers need to have access to clear and easy-to-understand information.

The use of Art. 8 of Reg. 1925/2006 and Safety assessment of botanicals: a tailored approach needed

Botanicals, representing more than 60% of the food supplements market in Europe, fall into the category of ingredients that are not harmonised by any EU law. As a consequence of the lack of a harmonised framework, Art. 8 of Reg. (EC) 1925/2006 is the legislative tool used to assess the safety of ingredients when a safety concern arises. This procedure can lead to the ban of an ingredient in the food supplement market.

Unfortunately, the sector is experiencing an increasing use of this procedure by the European Commission prompted by certain Member States, sometimes driven by a product classification purpose, rather than a safety concern and emergency tool. Moreover, the shortcomings of the implementing rules[16] require economic operators, mainly SMEs, to provide cancerogenic and genotoxicity data in an unrealistic time-laps without specific indications on the methodology to be applied. Furthermore, due to the lack of proper methodologies applied to the safety assessment of botanicals, the scientific evaluation tends to have negative outcomes for the relevant substances. This is an issue not only when it comes to safety but also in relation to the efficacy of these substances. In fact, botanicals are complex natural substances that differ from isolated substances and therefore need a specific approach when it comes to their assessment.

EHPM is working in cooperation with academics from multiple EU Member States for the development of proper guidelines for the safety evaluation of botanicals that we would like to share with the European Commission and EFSA. Instead of conducting a de facto negative harmonisation, we encourage the European

Commission to further develop the regulatory framework based on national good practices and experiences. Having additional certainty from a regulatory point of view would provide both National Authorities and companies with adequate tools to guarantee product safety. That is why EHPM supports the creation of a European nutri-vigilance system (see page 8).

Acknowledgment of term "Probiotic"

Although there is consolidated scientific proof of the value of probiotics in various physiological functions of the human body, the EU does not recognize any health or nutritional claim for probiotics. Also, the EU Commission, based on the 2007 Guidance document on the implementation of Regulation No.1924/2006[17], considers the term "probiotic" as well as the phrase "contains probiotics" as health claims. In line with that, most Member States do not allow the use of the word "probiotic" on the products' packaging. This creates a severe disruption of the internal market, difficulties for companies accessing the EU market as well as confusion among consumers.

While several national and international authorities worldwide have recognized the potential physiological and health benefits of probiotics[18] and authorized such claims, little progress has been made at the EU level. It is crucial to create a labelling environment that the consumers can trust, and that allows consumers to make informed choices. In fact, consumers are in any case exposed to "probiotics", either because products containing them are legally commercialized, or because conversations on probiotics take place in the public domain but without any frame or criteria. EHPM believes that the use of the term "contains probiotics" should be permitted in EU, with clear and appropriate conditions of use, that authorities can verify using some simple criteria to distinguish probiotics from other live microorganisms. This will allow consumers to make informed choices.

Need to support Innovation

Innovation is key for the development of the sector and essential in order to provide consumers with products able to meet their current demands for more natural solutions. Unfortunately, investments in innovation are strongly hindered by the current uncertainty in the European regulatory framework. In fact, the process for claim authorisation provided by the Nutritional and Health Claim Regulation, has proven to be extremely unpredictable for companies: only 12 claims based on new scientific evidence have been officially approved by the European Commission. This incredibly low rate of approval (6%) has led to a substantial reduction of the number of applications submitted to EFSA: in 2019 75% fewer applications were submitted to EFSA compared to 2011. Innovation in the food business has been durably hindered by this situation. That is why EHPM calls on a modification of the health claims evaluation process using a graded system (see page 5). Companies cannot invest without knowing that the ingredients they use and the health claims they make will be authorised in the EU. This is especially the case for SMEs.

Internet sales and fake news

Internet sales or e-commerce is increasing and driven by consumer demand, the distribution model is changing. Experts expect e-commerce to further increase in the coming years. It is important that products sold on e-commerce respect the same rules than the products sold by the traditional distribution channels. E-commerce is an opportunity for the EU food supplements industry, but EHPM asks for a level playing field to avoid unfair competition from countries with less strict rules.

EHPM wants to be a reliable partner to provide correct information to all the stakeholders and act against fake news. The web and social networks have dangerously amplified the flow of false myths and fake news affecting entire sectors and individual products. The food supplements sector has also been affected: fake news and misleading information find greater grip on the media, opinion leaders, sometimes even institutions, which feed the noise and uncontrolled voices on the identity, the functional value and the characteristics of food supplements that prevent consumers from grasping their real social value[19]. EHPM firmly believes that promoting effective, truthful and professional communication to all stakeholders to clearly define the identity of the food supplement and its functional and social value is central to overcoming visions and erroneous juxtapositions with other products.

[14] Regulation (EU) No. 1924/2006 is the legal framework used by food business operators when they want to highlight the beneficial effects of their products in relation to health and nutrition on the product label or in its advertising. The regulation foresees 4 types of claims, notably: General

function health claims Art.13.1, Disease-risk factor reduction 14.1 a, Claims related to children development and health 14.1b

[15] Botanical health claims for food supplements-an EHPM proposal.

[16] Commission Implementing Regulation (EU) No 307/2012 of 11 April 2012 establishing implementing rules for the application of Article 8 of Regulation (EC) No 1925/2006 of the European Parliament and of the Council on the addition of vitamins and minerals and of certain other substances to foods.

[17] Pag. 11 of the Guidance on the implementation of regulation n° 1924/2006 on nutrition and health claims made on foods conclusions of the Standing Committee on the Food Chain and Animal Health,14 December 2007.

[18] For example: in Italy the claim "supports the intestinal flora balance" is recognised and in Canada the following claims are accepted: " helps support gastrointestinal health" source of probiotics could promote a favourable gut flora.

[19] CENSIS, Italian Research Institute on Social Investments, developed a report on the Social Value of food supplements that was presented for Federsalus in Rome on the 20th of June, 2019.The study highlights the important role of food supplements in the lifestyle of citizens who are more and more responsible for their own health and wellbeing; and also the role food supplements might play in congaing the costs borne by health-care systems.

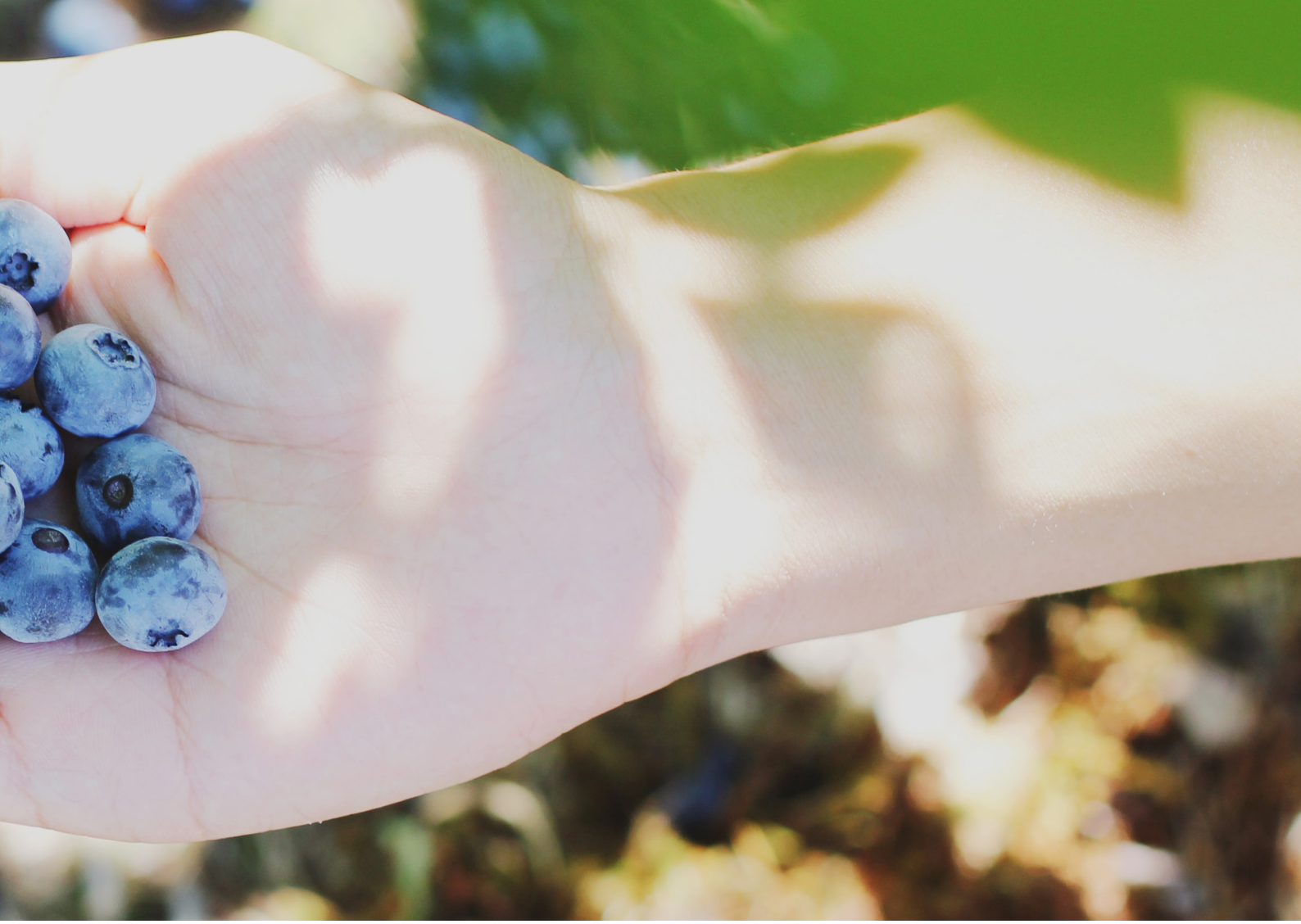
Food supplements for healthier citizens and a stronger economy in the EU

EHPM's priorities for 2019-2024: safety, quality, sustainability, transparency for consumers.

Europe's population is getting older: we are currently facing a substantial growth of the over 65 population, which is expected to increase in the next years. This pattern corresponds to an important increase in the development of chronic diseases as well as diet related diseases. As a consequence, 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, habits and products able to reduce the risk factor of certain pathologies, and enhancing health, well-being and quality of life play an important role. In fact, food supplements are efficient tools that help improving 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. Citizens in the EU today enjoy a high level of food safety standards and our food safety system is recognised as an example of a global best practice. European citizens, however, are more and more concerned about the food they eat, the impact of diet and lifestyle on health and are more committed to adopt conscious changes in their daily life for health enhancement. In concrete terms, this means that people dedicate time to find information and knowledge to adopt a lifestyle aimed improved well-being and reduced risk of certain pathologies. At the same time, there is an increasing need of transparency on the methods of food production, including origin, nutritional value and the quality of food that citizens eat. Consumers want to have transparent information through clear labelling and accessible information.

Moreover, within the agricultural sector in Europe, the cultivation of botanicals is growing. It represents a high added value for farmers willing to diversify or modify their production.

Thus, EHPM fully supports the EU Farm to Fork strategy that will pay particular attention to transparency across the entire supply chain so that citizens can be sure that they are buying "healthy food from a healthy planet." EHPM believes that



because of its role as a vehicle for better health and the betterment of human nutrition, food supplements will have a role in the implementation of the EC Farm to Fork strategy by promoting the importance of safety and quality of the food ingredients used in our products. In order to do that, food supplements must be safe and of high quality. For that reason, EHPM developed the EHPM Quality Guide that provides a practical guidance for companies throughout the production process to ensure high quality standards.

That is why EHPM supports the implementation of a post-market vigilance system for food supplements, that would allow the companies to collect a high amount of useful data on their products, including adverse effects. EHPM is already working with its members to agree on a nutri-vigilance system that all companies in the food supplements sector could proactively adopt. The adoption of such a measure at EU level would facilitate the work of the authorities when the need to collect data arises. This would also be advantageous for the industry, as the timelines currently foreseen to collect data once a procedure is launched usually are not enough if the company has to gather all necessary data starting from scratch.

The European regulatory framework should provide safety and quality but at the same time allow business to use recognised and validated innovative technologies for the improvement of the quality of products. As the European Commission stated in its 2020 Work Programme, the European way of life is about "finding common solutions to shared challenges and equipping people with the skills they need and investing in their health and wellbeing."

In light of the above, we believe that our sector will play an important role in the EU Green Deal and European Commission's Farm to Fork strategy by contributing to the transformation of the way of living, working, and consuming, so that EU citizens will live healthier longer. At the same time, businesses will become more innovative and competitive, and healthcare systems more sustainable.

Food supplements are safe and truthful products that help EU citizens live healthier longer. Therefore we call upon the European Institutions

to address the challenges the food supplements sector is facing, in order to contribute to a Europe of healthy citizens, who make informed choices about safe, high quality and sustainable food supplements, produced by competitive and innovative companies able to market their products across the EU.

[20] 2018 Aging Report: The 2018 Ageing Report Economic and Budgetary Projections for the EU Member States (2016-2070), May 2018 European Commission Directorate-General for Economic and Financial Affairs.

[21] For instance according to the data from France Agrimer, in France the agricultural area used for botanicals cultivation has grown by 40% since 2010.

[22] EHPM Quality Guide Second Edition, November 2014.

[23] Pag. 7 of the European Commission Work Programme 2020, COM (2020) 37 final, 29/01/2010.

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