

Annual Report

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Introduction by EHPM Chair and Director General



2023 was a year of challenges, but also one of resilience and growth; the pandemic still left challenges and the Russian aggression on Ukraine created new ones; the international situation became more complicated in the latter part of the year with Hamas' attack on Israel and Israel's counter-offensive in the Gaza Strip; in addition, recent attacks by Yemeni rebels in the Red Sea threaten to put the shipping industry and world trade in great difficulty, with greatly negative repercussions on the world economy and a sharp increase in the prices of many products, especially in Europe and also in our industry. Last year will go down in history as the hottest year ever since weather records began, with highly negative future environmental prospects.

Despite these problems, the past year has seen a weak economic recovery at least in some countries; the COP28 climate talks in Dubai ended with an agreement urging nations to move away from fossil fuels, an important step in the fight against climate change; the space race has resumed by several countries and there is a lot of momentum in artificial intelligence research; let's hope that these positive signs will be consolidated in the current year and that, above all, guns will fall silent and peace will prevail.

In 2023, EHPM has continued to assert its role as the voice of the food supplements industry in the EU, through the passionate commitment of the Secretariat and the valuable collaboration and high-level expertise of our Members, including new ones, National Associations and Companies; all of whom have provided valuable and meaningful engagement in Working Groups and Task Forces, also supported by external consultants, in order to achieve these results.

The results achieved are well described in this Annual Report, which shows the EHPM's contribution in striving to achieve harmonised and proportionate EU legislation in our sector, to the benefit of all its members, with the main aim of always providing consumers with safe and high-quality products.

I would therefore like to thank all those who have contributed to the growth of EHPM over the last year, with their active commitment and dedication. My special thanks also go to the other members of the Board of Directors, whose contribution and support have been crucial in achieving our goals.

My wish is that we have a great 2024 and achieve all our goals. Let us all work together to achieve them!

Antonino Santoro
EHPM Chair

The food supplements sector within the European Union (EU) has experienced noteworthy growth in recent years, propelled by consumers' will/attitude to actively take care about their health and well being in order to stay healthy longer. Yet, as growth unfolds, it brings forth challenges that demand careful management. EHPM, representing the food supplements sector in 17 European countries through its national associations and companies, stands at the forefront, aiding its members in deftly manoeuvring this heterogeneous yet promising regulatory landscape.

As a sector, we stand at a pivotal juncture, confronted with both challenges and opportunities. Many crucial dossiers addressed in 2023, such as the setting of maximum levels for vitamins and minerals, approaches to the use of Article 8 of Regulation (EC) 1925/2006 and the Novel Foods Regulation, the implementation of Mutual Recognition, the use of the term *probiotic* and the long-standing issue of 'on-hold' claims, will accompany the sector in 2024. In addition, more than 400 million citizens will be called upon in June 2024 to renew the European Parliament. The outcome of this democratic exercise will significantly influence the work programme of the next European Commission for the forthcoming 5 years.

In a context marked by several regulatory challenges and widespread scepticism there is a need to develop a thoughtful strategy and put forward concrete proposals proactively.

EHPM strategy for 2024 will be based on the concrete tools developed in the framework of our working groups and task forces such as the EHPM Quality Guide; the EHPM guideline on adverse report management (vigilance), the EHPM model on Maximum Levels of Vitamins & Minerals, the EHPM Guidelines on Probiotics etc.

Signifying the role of food supplements in the betterment of citizen's health will also be key. We will do it through reinforcing our partnerships and cooperations with Universities and researchers.

We have a challenging year in front of us but also a year filled in with opportunities and new perspectives. The EHPM Secretariat will dedicate all its efforts and commitment in reaching our objectives. We believe that fostering a transparent dialogue with National and European institutions, alongside efficient cooperation with Food Business Operators and industry stakeholders, and forming partnerships with research institutions, can facilitate the exchange of knowledge and best practices. Collaborative efforts addressing common challenges, can streamline processes and alleviate individual burdens. Moreover, such collective endeavours contribute significantly to building a positive industry image

Livia Menichetti
EHPM Director General



About us

WHO WE ARE

The European Federation of Associations of Health Product Manufacturers (EHPM) was established in 1975 and, since then, EHPM has been the voice of the food supplement sector in Europe. With its 15 National Associations and its Member Companies, EHPM represents manufacturers and distributors, most of whom are small and medium-sized enterprises (SMEs), in 17 European countries.

OUR MISSION

EHPM represents the food supplement sector in Europe. We aim at improving the European regulatory framework for food supplements

Our ultimate goal is to ensure a thriving environment where consumers have access to safe, science-based, and high-quality food supplements, fostering a healthy, sustainable, and innovative Europe.

manufacturers, distributors and suppliers in Europe. To this end, we proactively develop proposals, guidelines and tools, in the framework of our technical Working Groups and Task Forces, where the expertise of industry leaders meets.

EHPM establishes and promotes industry best practices for product quality, safety and efficacy, with the objective of providing consumers with safe, science-based, high-quality food supplements for a healthy, sustainable and innovative Europe. We also guarantee access to accurate and helpful information in order to educate consumers about the nutritional value and use of the products placed on the market.



OUR CORE VALUES

- **Contributing to Public Health:** EHPM believes in the pivotal role our sector can play in the European Commission's Farm to Fork Strategy, addressing micronutrient deficiencies and reducing healthcare costs associated with major diseases.
- **Advocacy for Fair Recognition:** We strive to secure a fair and legitimate position for the food supplement sector within the EU regulatory framework.
- **Ensuring Quality and Safety:** EHPM works to ensure that food supplements are high-quality and safe products, adhering to rigorous standards from production to post-market stages.
- **Informed Consumer Choices:** Legislation should empower consumers with clear and consistent labelling information, aiding them in making informed choices about the products they use.
- **Championing Responsibility:** Committed to ethical practices, we have endorsed the European Code of Conduct on Responsible Food Business and Marketing Practices for a healthier and more sustainable Europe.
- **Transparent Dialogue:** We value transparent and proactive engagement with European and National Institutions, as well as other EU stakeholders.
- **Promoting Fair Competition:** We advocate for fair competition among Member States, ensuring the smooth operation of the internal market.
- **Embracing Innovation:** Recognising the dynamic nature of nutrition science, we encourage innovation to provide consumers with safe and tailored food supplements that cater to evolving needs.

At EHPM, we are dedicated to shaping a positive future for the food supplement industry, and we invite you to join us on this transformative journey towards a healthier, sustainable and innovative Europe.

EHPM NETWORK

Since 2022, EHPM proudly joined forces with Food Drink Europe (FDE), the preeminent European association championing the diverse and vibrant food and drink sector. As part of FDE, we stand shoulder to shoulder with 80 Members across Europe, including influential food and drink companies, National federations, and specialised sectoral associations. This collaborative synergy is paramount as we navigate the ever-evolving challenges confronting the food supplement sector.

Furthermore, to gain a comprehensive global perspective, EHPM has long-standing membership with IADSA, the International Alliance of Dietary/Food Supplements Associations. Our commitment extends beyond borders, actively engaging with European and National Institutions, relevant trade and consumers' associations, esteemed scientists and academic experts, and fostering meaningful connections on the international stage.

At EHPM, we understand the power of collaboration and the strength that comes from aligning with influential organisations. By joining FDE and IADSA, we reinforce our dedication to navigating the complexities of the food supplement sector while actively contributing to the broader dialogue on a global scale. Together, we are shaping a future where the food supplement industry thrives and positively impacts the well-being of individuals in Europe.

EHPM Structure

THE EHPM BOARD

The EHPM Board is composed of nine Members from the National Member Associations, with Antonino Santoro as EHPM Chairperson since February 2021. Board Members are nominated during the EHPM General Assembly for a period of two years, by a majority vote. In 2023, the Board and Chairperson have been confirmed by the General Assembly.



Antonino Santoro
The Chair



Michel Horn
Vice Chair



Martin Last
Vice Chair



Nicolas Cappelaere
Vice Chair



Magdalini Selanikli
Vice Chair



Bolke Koster
Treasurer



Harald Dittmar
Board member



Jonathan Griffith
Board member



Bartosz Demianiuk
Board member



THE EHPM SECRETARIAT

The EHPM Secretariat is based in Brussels and is composed of two dynamic collaborators:

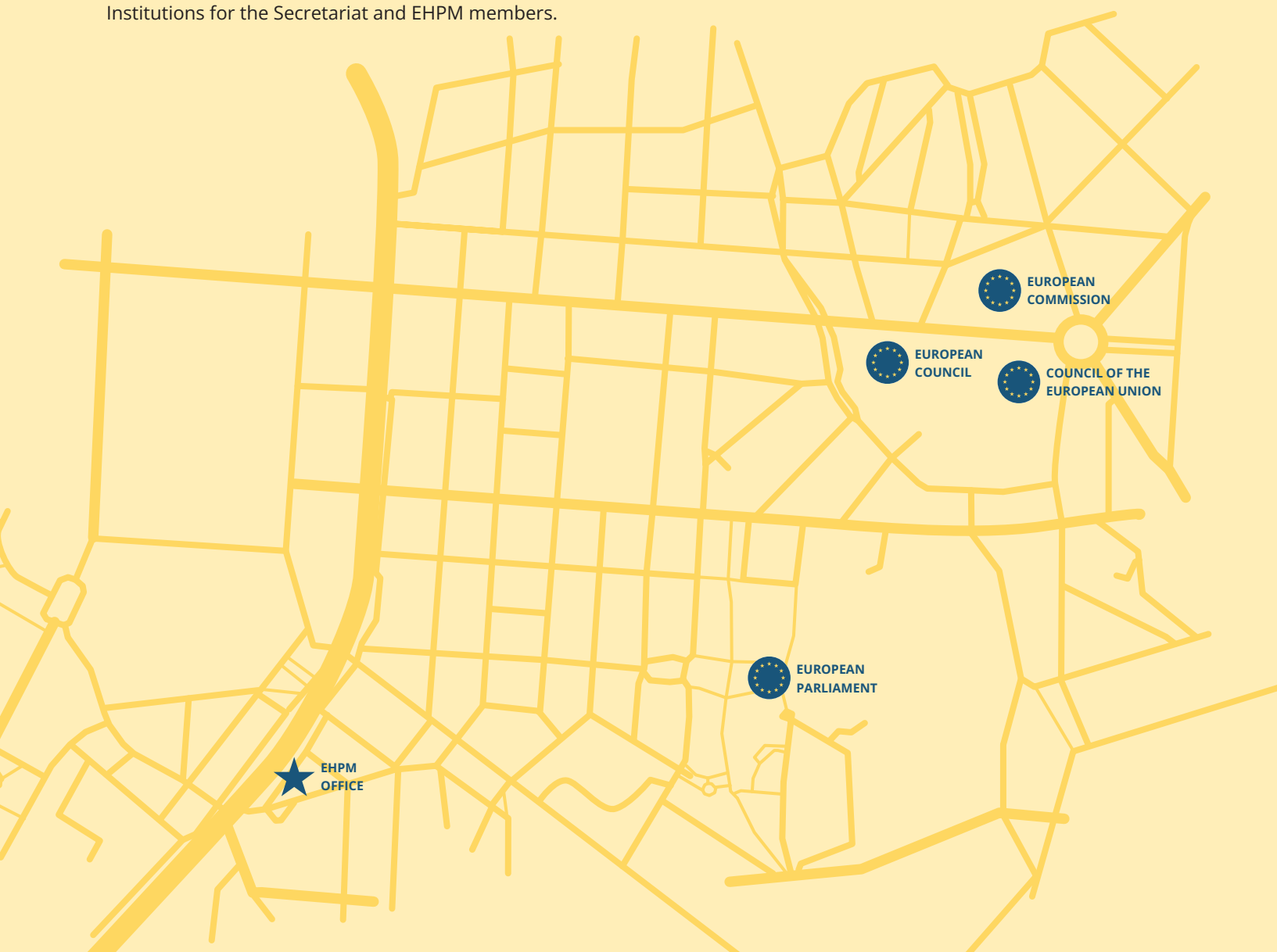
- **Livia Menichetti**
Director General
- **Cataldo Enrico Rizzo**
Policy Officer



From left to right: Livia Menichetti and Cataldo Enrico Rizzo.

EHPM OFFICE

The EHPM office is located at Tribes Brussels Avenue Marnix (17 Avenue Marnix, 1000 Brussels), a 5-minute walk from the European Parliament and easily accessible by train, metro and bus. The location provides excellent access to the European Institutions for the Secretariat and EHPM members.



EHPM's 2023 Main Achievements *in a Nutshell*

1

Conference on Quality and Safety in Food Supplements: from Farm to Fork

In April 2023, EHPM hosted a gathering in Brussels focused on Quality and Safety in Food Supplements. This was a collaborative space featuring the DG SANTE Unit dealing with novel foods, National Authorities, market-data and quality-assurance experts, industry leaders, and EU stakeholders. Ideas flowed, collaborations sparked, marking the event as a 2023 EHPM milestone.

2

Publications Highlighting Our Commitment

EHPM doesn't just host conferences; we share insights through impactful publications. In 2023, we proudly launched the EHPM Annual Report 2022 and the 3rd edition of the EHPM Quality Guide. Additionally, we finalised two significant publications – the EHPM Probiotics Guidelines & Position Paper, and the EHPM Guidelines for food supplement companies on the management of adverse event reports.

3

Enhanced Engagement with EU Institutions

EHPM actively engages with EU Institutions, contributing to crucial dossiers relevant to the food supplement industry. Through dialogue and connections, we play a meaningful role in making the sector voice heard and fostering collaboration.

4

Building Collaborative Alliances

Ties matter, and at EHPM, we excel at building sectoral and cross-sectoral alliances. Playing a bigger role within Food Drink Europe, the largest food and drink association at the EU level, and liaising with other relevant stakeholders like AESGP, EU Specialty Food Ingredients, and Food Supplements Europe, we advocate collectively for the interests of the food supplement industry.

5

Advocacy and Proactive Initiatives

EHPM's success stories in advocacy include championing crucial Article 8 dossiers, skilfully navigating issues such as the potential ban of red yeast rice. Our proactive Vigilance Pilot Project on Red Yeast Rice reflects our commitment to data-driven decisions during scrutiny periods. Relevant initiatives were also undertaken for the dossiers on alpha lipoic acid and berberine.

6

Dynamic Task Force on Novel Foods

Legal certainty is at our core. In 2023, we established the Task Force on Novel Foods, dedicated to addressing novel food challenges faced by the food supplement sector and developing creative solutions.

7

Thoughtful Statements and Collaborations

EHPM communicates thoughtfully. We issued statements, contributed to important dossiers, and collaborated on joint letters with EU stakeholders. Our voice resonated in influential corridors, contributing to meaningful industry discussions.

At EHPM, each achievement marks a step towards a more resilient future for the food supplement industry. Join us in our journey of innovation, collaboration, and commitment to excellence.



2023 EHPM Events

22 FEB



EHPM General Assembly 2023

Breaking free from the online format, the EHPM Annual General Assembly finally embraced the energy of an in-person event in Brussels. Director General Livia Menichetti unveiled the EHPM Annual Report 2022 and presented the Public Affairs Strategy 2023. The day included reports from chairpersons and vice-chairpersons of EHPM's working groups, and Full Members voted on statutory positions, renewing their trust and confidence in the current team. As tradition, Members shared best practices and major achievements from the previous year.

The EHPM General Assembly 2024 will be held in Brussels on 28 February 2024.

23 FEB



EHPM Brainstorming on Novel Foods

Following the General Assembly, EHPM convened its Task Force on Novel Foods for a dynamic in-person brainstorming session to lay robust foundations for the Task Force's work. Presentations from Nutraveris, BDIH, and BE-SUP provided insights into article 4 of the new Novel Food Regulation, legal aspects, and the case of the Belgian Royal Decree on Plants. Results were later presented at the high-level event in April 2023.

20 APR



EHPM Conference on Quality and Safety in Food Supplements: From Farm to Fork

The highlight of 2023 was the EHPM Conference on Quality and Safety in Food Supplements. A gathering of European and National Authorities, industry experts, and stakeholders explored best practices in the food supplement sector. Participants engaged in a transparent and direct dialogue with DG SANTE Officials, experts and with industry champions. The third edition of EHPM's Quality Guide for food supplements was unveiled, offering guidelines for maintaining high-quality and safety standards. The conference delved into critical topics such as harmonisation in the European framework, authorisation processes for novel foods, and post-marketing vigilance for red yeast rice. The event showcased EHPM's commitment to collaboration, transparent communication, and consumer protection.

At EHPM, 2023 was a year of lively engagement, innovative discussions, and impactful initiatives. Join us on this exciting journey as we continue to shape the future of the food supplement industry.

Participations to events & conferences

Throughout 2023, EHPM also attended 17 events organised by EHPM Members, other European stakeholders, and institutions. In some of these events, Director General Livia Menichetti participated as a speaker.

-
- February
 - Integratori & Salute Conference
 - BESUP General Assembly
 - April
 - BESUP Happy Hour
 - May
 - Plenary Meeting of the European Commission Advisory Group on Sustainability of Food Systems
 - June
 - IADSA World Supplement Forum and World Supplement Forum
 - Integratori & Salute General Assembly
 - PEC Pharma Conference
 - July
 - SAFE's 2023 CONSUMERS COME FIRST Conference
 - Ad hoc meeting of the European Commission Advisory Group on Sustainability of Food Systems
 - October
 - BESUP Conference
 - IHTA General Assembly
 - November
 - EFSA Stakeholder Forum 2023
 - HFMA Working Group
 - Plenary meeting of the European Commission Advisory Group on Sustainability of Food Systems
 - Integratori & Salute Webinar
 - in-vitality 2023
 - December
 - Meeting of the EU Code of Conduct on responsible food business and marketing practices



2023 EHPM Publications



EHPM Annual Report 2022

During the EHPM General Assembly held on 22 February 2023, Director General Livia Menichetti launched the EHPM Annual Report 2022. This comprehensive publication delves into the highlights of EHPM's activities and achievements in 2022, providing an insider's look at our public affairs strategy and priorities for the year ahead with captivating visuals.

EHPM Quality Guide (3rd Edition)

At the core of our values is an unwavering commitment to top-notch quality and safety in the development, production, and promotion of food supplements. Crafted by industry experts in 2007 and diligently updated in 2014 and 2022, this guide is your compass from "Farm to Fork." Tailored to align with EU regulations, it guides businesses through the complexities of quality and safety controls, ensuring the production of high-quality, safe food supplements. The 3rd edition was launched at the high-level conference in 2023.



EHPM Guidelines for food supplement companies on the management of adverse event reports

2023



EHPM Guidelines for food supplement companies on the management of adverse event reports

In 2023, EHPM finalised its Guidelines for food supplement companies on the management of adverse event reports. This user-friendly document simplifies the post-market vigilance system, providing a clear path for companies to collect and manage adverse events related to their products on the EU market. Tailored for all companies, especially small and medium enterprises (SMEs), these non-mandatory self-regulating guidelines serve as a valuable tool for developing and implementing internal vigilance systems.

The EHPM Guidelines for food supplement companies on the management of adverse event reports will be launched in a public event in 2024.

Engagement with European Institutions

In 2023, EHPM actively engaged in a dynamic dialogue with key officials from the European Commission, fostering a collaborative relationship that extended across various units, including DG SANTE (Units A.1, E.2) and DG GROW (Unit E.4). This fruitful interaction was marked by a series of meetings and thought-provoking events organised by EHPM, where the European Commission officials actively participated.



The heart of these exchanges revolved around pivotal topics such as the Novel Foods Regulation, the Novel Food Catalogue, Member States' approaches to novel foods, and the implementation of the Mutual Recognition Regulation. In-depth discussions also delved into dossiers under Article 8 of Regulation (EC) 1925/2006, and on the ongoing work regarding the definition of maximum levels for vitamins and minerals in food supplements.

The collaboration with DG GROW and DG SANTE Officials has resulted in the cultivation of a stable, transparent, and respectful working relationship. Regular exchanges and targeted consultations on specific dossiers underscore the productivity of this partnership. EHPM proudly welcomed representatives of the European Commission as honoured speakers at its 2023 Conference on Quality and Safety in Food Supplements, reinforcing the collaborative spirit and mutual commitment to shared objectives.

EHPM actively participated in consultations initiated by the European Commission and EFSA, contributing significantly to ongoing discussions and data calls, and engaged with Members of the European Parliament on crucial dossiers.

Within EFSA's initiatives, EHPM actively participated in consultations on crucial topics such as the tolerable upper intake level (UL) for vitamin B6, the UL for vitamin D and derivation of a conversion factor for calcidiol monohydrate. Public consultations on Folate further highlight EHPM's dedication to promoting nutritional safety. In the context of EFSA's work under Article 8 of Regulation (EC) 1925/2006, EHPM contributed to public consultations on safety assessment protocols for fennel, berberine, and hydroxycitric acid, and to the public consultations on the safety assessment of berberine, emphasising its commitment to product safety and efficacy.

Simultaneously, EHPM actively participated in consultations initiated by the European Commission on key topics such as the future EU Framework for Sustainable Food Systems, the Packaging and Packaging Waste Regulation, and the Green Claims Directive. Targeted consultations on maximum levels (MLs) for inorganic arsenic in fish and other seafood demonstrate EHPM's commitment to contributing to shaping policies for sustainability and health-conscious practices.

EHPM's dedication to open communication and cooperation is further highlighted by the sharing of a Position Paper on Alpha Lipoic Acid within the framework of the procedure under Article 8 Regulation (EC) 1925/2006. This document, communicated to the European Commission and National Authorities, underscores EHPM's commitment to responsible contributions to discussions that impact the European food supplement industry, with an unwavering commitment to ensuring the highest standards.

In the latter half of 2023, EHPM eagerly embraced the momentum of the European Parliament's initiative on botanical health claims – a pivotal concern for the food supplements industry. We seamlessly connected with Members of the European Parliament, ensuring they were privy to our industry's perspective through a carefully crafted position paper and shared with them the EHPM proposal, advocating for a graded approach to botanical health claims. This dossier will receive particular attention in the 2024 Public Affairs strategy.



Support of EHPM Members



EHPM supports its Members through its expertise and the valuable contributions of the expert network of its National Associations and Companies. Here is a non-exhaustive list:

DATA COLLECTION SUPPORT

Most requests from EHPM Members in 2023 concerned the (non-)novel status of specific ingredients. When the EHPM team receives such requests, it issues internal calls to action, inviting all EHPM Members to participate in knowledge-sharing exercises. The feedback received from Members is then assembled into a coherent document and shared with relevant National and European Authorities.

In 2023, EHPM issued several Calls to Action on behalf of its Members, e.g., on sodium hyaluronate / hyaluronic acid (hyaluronan/ HA), *Pygeum africanum* and *Eucalyptus radiata*, *Vaccinium myrtilloides*, *Astragalus membranaceus*.

Dissemination of the EHPM Model for Maximum and Minimum Levels for Vitamins and Minerals

EHPM continued to support its Members in presenting the EHPM proposal to their National Authorities. In 2023, the model was presented to the Romanian Authorities.

SUPPORT TO BESUP

In Belgium, National Authorities raised doubts about the non-novel of 55 botanicals as early as 2021. In cooperation with BESUP, EHPM launched several calls for data and liaised several times with the responsible Unit of DG SANTE. These actions contributed to reducing the list of botanical substances at risk from 55 to 39. At the same time, in cooperation with BESUP and EHPM, SYNADIET and other EHPM members had several exchanges with their respective National Authorities. This contributed to the number of negative comments submitted by National Authorities to the Belgian initiative. As a result, in 2023, the Belgian Authorities decided not to withdraw 38 of the 39 botanical substances. This result was a great success of the EHPM's network and public affairs strategy.

SUPPORT TO KRSiO

In Poland, the National Authorities launched a consultation on the draft amendment to the Polish Food Safety and Nutrition Act that includes unreasonable requirements for the labelling and placing on the market of food supplements. EHPM prepared a letter supporting the position presented by its Polish member, KRSiO, sharing their concerns about the potential impact of the proposed amendments on the functioning of the European internal market for food supplements.

Engagement with European & International Stakeholders

EHPM confirmed its membership of **Food Drink Europe**, the biggest and most relevant food and drink association in Europe, and of **IADSA**, the international alliance for the food supplement industry. Over the course of 2023, EHPM actively contributed to the work of **Food Drink Europe** Working Groups and participated in **IADSA** events and initiatives with EHPM Chair Antonino Santoro, EHPM Vice-Chairs Magdalini Selanikli and Martin Last, EHPM Director General Livia Menichetti, and EHPM Members Saskia Geurts (NPN) and Elodie Veyret (SYNADIET). EHPM also wrote an article for IADSA on post market vigilance for food supplements.

The collaborative efforts extended beyond memberships, with EHPM aligning and cooperating on several matters with stakeholders such as **AESGP, AIBI, COCERAL, EIHA, EU Specialty Food Ingredients, Food Drink Europe, Food Supplements Europe, IPA International, IPA Europe, SAFE Food Advocacy Europe, Specialised Nutrition Europe, Unistock Europe.**

One significant outcome of this collaboration was a joint stakeholder letter addressed to DG SANTE Director General Sandra Gallina. AESGP, EHPM, EU Specialty Food Ingredients, Food Drink Europe, and Food Supplements Europe collectively advocated for greater transparency and stakeholder involvement in discussions regarding maximum levels of vitamins and minerals.

EHPM's journey in 2023 was marked by meaningful participation, stakeholder alliances, and contributing to vital industry discussions. Such involvement underscores a commitment to a collaborative and thriving industry.



EHPM Working Groups'

Main Achievements

EHPM has **3 working groups (Botanicals, Regulatory & Quality and Probiotics)**, composed of experts from our Members. Proactive proposals and guidelines are developed within these groups. To ensure that the EHPM covers current and potential issues of interest to our Members, the Groups receive input from the Board and Members when setting their agenda. All meetings were held online in 2023.



BOTANICALS WORKING GROUP

The Botanicals Working Group (BWG) met 'virtually' 4 times in 2023. Each meeting reviewed developments in the areas of botanical health claims, quality assurance and safety assurance. Members also participated in the work of the Matrix, Vigilance and Novel Foods projects.

The BWG has identified that Food Supplement Business Operators need to have advanced systems in place to manage the quality safety and effectiveness of the botanical products placed on the market.

The botanicals section of the *EHPM Quality Guide* was upgraded last year; the paper on a *Graded Approach to Botanical Health Claims* addresses the effectiveness issue; the BWG continues to work on a Safety Paper which is designed to identify the methods that businesses should have in place to assess and manage the inherent safety of botanical ingredients. In the meantime, EHPM Members should be aware of the following recurrent challenges:

- There was little progress on **health claims** until the end of the year, when an initiative in the European Parliament led to an Opinion being adopted that excluded the use of traditional use for botanical health claims. This is a very worrying development and EHPM will need to give serious consideration in 2024 as to how to respond.
- The risk of **raw material contamination** either with other plant material, as with pyrrolizidine alkaloids, or with externally applied chemicals, as with ethylene oxide, is significant and all food supplement business operators are advised to have appropriate risk management measures in place to identify, assess and manage these risks.
- The continued use of **article 8 of the Addition of Vitamins, Minerals and Other Substances Regulation** to limit the supply of botanical ingredients remains a threat to the food supplement industry. Current botanical ingredients effected are:
 - HAD containing parts of Aloe, Rheum and Rhamnus species, which were historically used in food supplements, are effectively prohibited;
 - Monacolin levels in food supplements containing red yeast rice are no limited to below 3mg a day.
 - Green Tea Catechins are limited to 800mg of (-)-epigallocatechin-3-gallate and are subject to additional labelling requirements;
 - Other botanical ingredients under review are Alpha lipoic acid, botanicals containing berberine, sweet and bitter fennel and hydroxycitric acid (as typically found in Garcinia Gambogia).





REGULATORY & QUALITY WORKING GROUP

The **EHPM Regulatory & Quality Working Group's** goal is to address the numerous regulatory and technical challenges facing the food supplement industry. The Working Group met 4 times in 2023 and is coordinated by the Chair **Martin Last** (HFMA) and Vice-Chair **Penelope Viner** (HFMA).

The main achievements in 2023 were:

- The EHPM Proposal for Maximum Levels for Vitamins and Minerals continued to be presented to member states for discussions with their national authorities in cooperation with the EHPM Secretariat. Regular updates on data collection of Other Substances augment the work on Maximum Permitted Levels as part of internal data to assist lobbying efforts.
- The Probiotics guidelines and political statements have been written with the intention of an launch event to follow early in 2024.

- On Novel Foods: Work continues to review and agree appropriate reactions to the ongoing challenges and a planned event in 2024 to outline proposals.
- On Additives, particularly the review of those used in foods for infants and young children: progress has been slow at EU level, but the Working Group continues to monitor and lobby on this area.
- On Article 8 procedure: the list of substances under scrutiny grew in 2023 and much effort has been spent generating technical input to address this. The current dossiers monitored and lobbied upon are HADs, red yeast rice, alpha lipoic acid, Garcinia Cambodia, green tea catechins, berberine, sweet and bitter fennel, and hydroxycitric acid.
- Regarding the need for vigilance guidelines for food supplements, the Working Group has now established a Vigilance Sub-Group and an event in Brussels is to be held after the General Assembly in 2024.

For 2024, the Working Group plan is to focus on:

- Continued efforts to disseminate the Maximum Levels Proposal to more Member States' National Authorities.
- Continued monitoring of all regulatory issues.



PROBIOTICS WORKING GROUP

The Regulatory & Quality Working Group created the **Probiotics Working Group** in 2020, with the aim of drafting EHPM's guidelines on probiotics and addressing all regulatory challenges concerning probiotics-based supplements. The Group is chaired by **Mr Last** (HFMA) and vice-chaired by **Ms Vercammen** (BE-SUP).

In 2023, the Working Group met twice: in April and October. The **EHPM Probiotics Guidelines**, are ready for publication.

The **political statement** was also finalised. Both the Probiotics Guidelines and the political statement are expected to be launched over the course of 2024. Special thanks go to Laura Jost from Lallemand Health Solutions for her active role in the redaction of the Guidelines.

Over the past years, there has been a **positive evolution across Europe regarding probiotics. An increasing number of Member States (Czech Republic, Denmark, France, Italy, Netherlands, Poland, Spain, etc.) now allow the use of the term "probiotics" as a category.**

In fact, the lack of a harmonised proportionate approach represents a huge obstacle to the full operation and development of the probiotics market. The difference of treatment between the Member States creates barriers to trade within the internal market and unfair competition for food supplements operators, as well as an unequal treatment between European consumers in different countries.

As EHPM, we welcome the Member States' initiatives to allow the use of the term *probiotics* as a category and we hope that our guidelines will contribute to this positive trend.



EHPM Task Forces'

Main Achievements

EHPM has **5 ad hoc Task Forces (Red Yeast Rice, Novel Food, Ethylene Oxide, HADs and Alpha Lipoic Acid)**, which are called as needed. They report back to the Board and Working Groups with the outcome of the discussions, updates and any further actions to be reviewed.



TASK FORCE ON NOVEL FOOD

In light of the increasing number of novel food issues, a dedicated **Task Force on Novel Foods** was set up in September 2022, with the aim of addressing the industry-related novel food issues and their impact, as well as developing creative and practical solutions. Chaired by **Ms Selanikli** (SESDI) and vice-chaired by **Ms Vercammen** (BE-SUP), the Task Force met 4 times in 2023.

In the past year, the industry has been confronted with an increasing number of alarming developments concerning the classification of foods, in particular food supplements, which were not previously considered as novel foods. These practices are mainly happening at the national level. However, they have an impact on the lawful circulation of products across the EU, such as changes of classification on the European Commission Novel Food Catalogue. Although this registry is not legally binding, it has an impact on the perception and classification of foodstuffs at a national level.

The Task Force has identified the following **major problems** related to the application of the Novel Food Regulation (Reg. (EU) 2015/2283):

- Creation of legal uncertainty and interpretation issues on what constitutes a novel food;
- Misuse of the spirit of the Novel Food Regulation by certain National Authorities and FBOs;

- Problems regarding the type of evidence acceptable and required to support the non-Novel Food status of the food/ food supplement.
- National lists of plants are challenged by Member States, as there is a lack of solid evidence of consumption before May 1997. It is therefore difficult to prove the “non-novel” status of these plants.
- The Novel Food Regulation cut-off date, i.e., 15 May 1997, predates the publication of the Food Supplements Directive, rendering it difficult to obtain proof of history of use.
- To create a database of bibliographies for “risk ingredients”, which could support the substantiation of the “non-novel” food status of those ingredients;
- To provide our Members with tools, based on existing EU regulations, to continue benefiting from the free movement of safe and healthy foods in the internal market.

Brainstorming session on novel foods:

On 23 February 2023, a brainstorming session on novel foods was held in order to sit around the table and discuss creative solutions.

Technical and political paper

The Task Force started the drafting of 2 papers: a technical one and a political one.

The political paper will be used to send an external Message to the National Authorities & EU Regulators, to develop solutions for the future (expectations of amendment of the Novel Food Regulation);

The technical paper will be an Internal Guidance to EHPM members on how to apply the NF Regulation, develop a check list of suitable proof of significant consumption.

Task Force Objectives:

- To address specific problems about the application of the Novel Food Regulation, such as the cut-off date of 15 May 1997;
- To draft a position paper on novel food classification on the basis of the Reg. (EU) 2015/2283, national practices and industry expertise;
- To provide valuable guidance and address interpretation issues on existing novel food classification problems such as the case of the list of 39 plants and plant parts (Belgian decree);



TASK FORCE ON MONACOLINS FROM RED YEAST RICE (RYR)

The EHPM Task Force on Red Yeast Rice was established in 2020 to address issues raised by the initiation of the Article 8 procedure for supplements containing monacolins from red yeast rice. The Task Force's endeavours, along with the lobbying strategy formulated by the EHPM Secretariat, played a crucial role in preventing for the moment a complete ban on monacolins from red yeast rice in food supplements.

Following the publication of Regulation (EU) 2022/860 on June 2 2022, which restricted the use of monacolins from red yeast rice in foodstuffs at dosages below 3 mg/day, the Task Force shifted its focus to collecting data supporting the safety of food supplements containing red yeast rice during the 24-month scrutiny period.

The pilot project "**Companies' Alliance for a Vigilance System for Food Supplements containing Red Yeast Rice**" was finalised by the EHPM Task Force at the close of 2022 and officially started in early 2023. This pilot project proposes the implementation of a vigilance system for food supplements containing red yeast rice. The alliance's objective is to collect adverse event data, if any, related to products containing red yeast rice during the scrutiny period outlined in the Regulation. Twelve companies from Belgium, Italy, and the Netherlands have agreed to actively participate in the alliance and data collection in 2023 and early 2024. All information concerning reported adverse events and distributed product units are handled confidentially by academic experts from the University of Bologna. A final independent report will be issued by these experts and submitted to EFSA before the scrutiny period concludes. The report aims to demonstrate the safety of food supplements containing red yeast rice and highlight the extremely low likelihood of adverse events associated with their intake.

Post-market vigilance is a critical aspect of food supplement safety and is already mandatory in certain Member States. EHPM established a Sub-Group on Vigilance at the end of 2022. The Sub-Group developed and finalised the ***EHPM Guidelines for food supplement companies on the management of adverse event reports***. The objective is to proactively propose a vigilance model for voluntary adoption by food business operators for their products. The proposal will be launched in early 2024.

OTHER TASK FORCES

The EHPM Task Forces on Alpha Lipoic Acid (ALA), on Hydroxyanthracene Derivatives, and on Ethylene Oxide (EtO) continued monitoring these dossiers, on which the EHPM Secretariat exchanged multiple times with DG SANTE.



Our Members

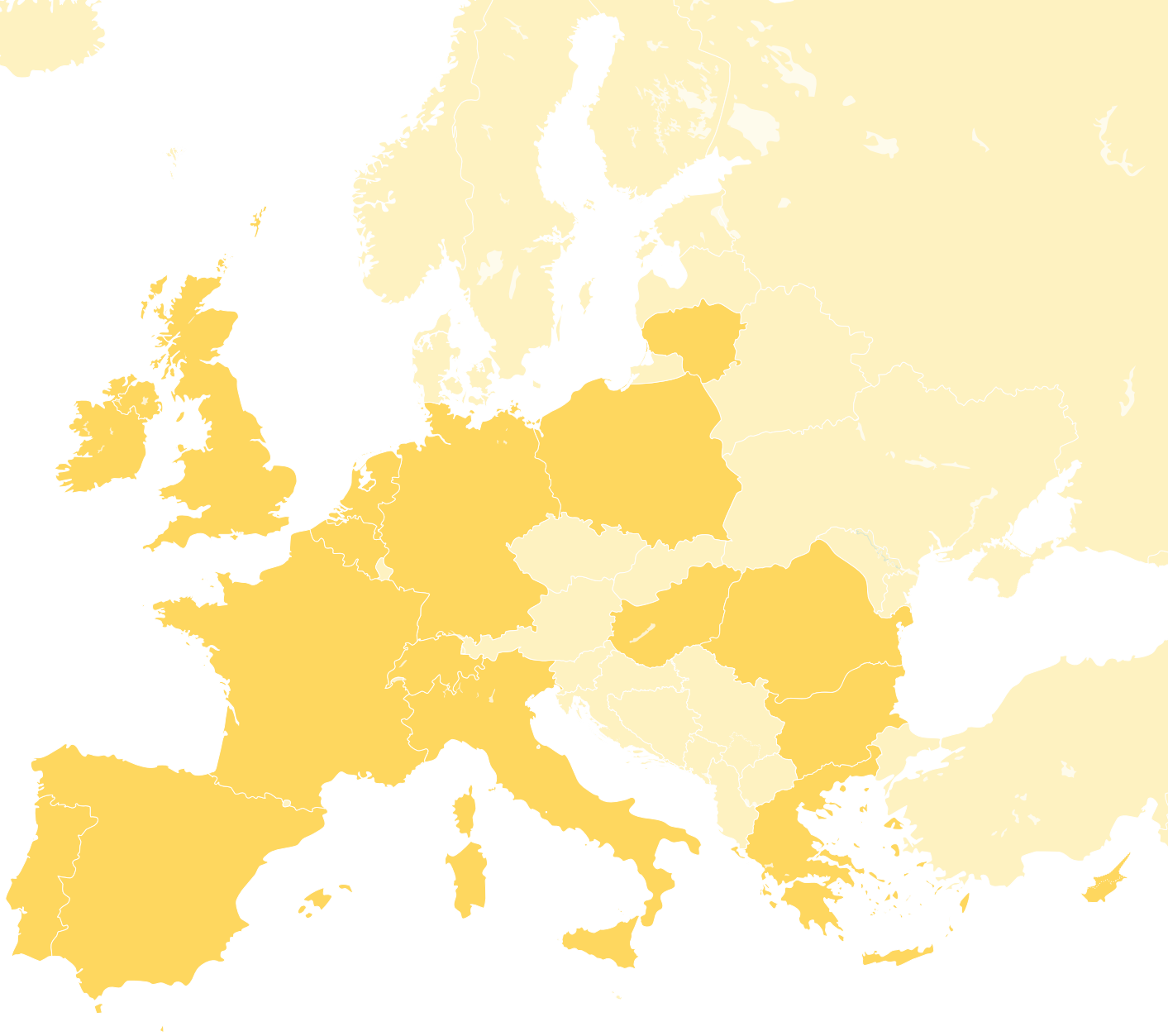
EHPM incorporates 15 National Member Associations and, since 2018, has also integrated 12 companies as Direct Members. Through its members, EHPM represents, unites, inspires and supports manufacturers, distributors and suppliers of health products in 17 European countries.

Throughout 2023, we received numerous enquiries and expressions of interest for membership from national associations and companies. Over the past three years, our network has grown significantly and 2023 was no exception to this trend. We are proud to have welcomed two new members: **Planta Romanica** and **Rosapharma**.

In addition, EHPM has already welcomed a new member in early 2024, **Complife**, and online meetings with other candidates are planned.

Together, we are stronger and we look forward to continuing our great collaboration in 2024!





MEMBER ASSOCIATIONS



MEMBER COMPANIES



EHPM's Collaborations

COLLABORATION WITH SPECIALISED ADVISORS



Ms P. Viner

EHPM has a long-term collaboration with **Ms Viner** (President of HFMA), who provides valuable technical advice to the Secretariat. In addition to her dedication and work within EHPM working groups and her active role in updating the Quality Guide, Ms Viner prepares the content of EHPM quarterly **International Regulatory Supplements**, which provide our Members with a comprehensive overview of the main regulatory developments affecting the food supplement industry worldwide.

Foodie Communications



Dr. Troy from **Foodie Communications** is a former staff member of the EHPM Secretariat and has continued to work with the EHPM Secretariat in recent years. He is responsible for the compilation of the EHPM **Weekly Snapshots**, which provide Members with a comprehensive and timely overview of scientific articles published in peer-reviewed journals.

Rank Nutrition Ltd



Since 2021, the EHPM has been collaborating with **Dr Sadler** from **Rank Nutrition Ltd**, an independent nutrition and biochemistry expert. Thanks to her valuable input, the new version of the **EHPM Proposal for Maximum and Minimum Levels for Vitamins and Minerals** was finalised and published at the end of December 2021 and officially launched in early 2022. On 21 March 2022, Dr Sadler provided an online training for EHPM members on the proposal and the related dissemination toolkit and provided assistance to our members in presenting the proposal to their national authorities.

COLLABORATION WITH ACADEMIC EXPERTS



During 2023, EHPM strengthened its relationships with academic experts and expanded its network of specialised doctors and professors. Professor Biagi from the University of Parma and Dr Giovanna Rigillo provided technical and scientific assistance to the Secretariat on several dossiers, including the Article 8 berberine dossier. In addition, EHPM continued its partnership with the University of Bologna to collect data on red yeast rice in the context of the review period under Regulation (EU) 2022/860 on monacolins from red yeast rice. For this pilot project, Professor Arrigo Cicero and Dr Federica Fogacci are evaluating the data received and will produce a final report.



COMMUNICATION COLLABORATIONS



Nashi Creative Studio

During 2023, EHPM continued its collaboration with **Nashi**, a graphic design company that helped the EHPM create an appealing and consistent brand. Thanks to Nashi, several publications were completed in 2023: the Annual Report 2022, the EHPM Guidelines for food supplement companies on the management of adverse event reports, the Probiotic Political Statement. Our graphic designer continues to work on future publications in 2024, including this Annual Report 2023.



EURACTIV

EHPM is a member of **EURACTIV**, which helps to increase the visibility of EHPM activities and events in the EU media, through press releases, banner campaigns and articles, as part of the membership agreement.

OTHER COLLABORATIONS



Fiscal Note / EU Issue Tracker

EHPM continued its membership/subscription to **Fiscal Note / EU Issue Tracker**, which monitors EU policy changes with analysis from regulatory experts in Brussels. This partnership provides the EHPM team with an additional monitoring tool and provides our Members with the latest and most comprehensive information on EU policies.



Excellium Solution

EHPM cooperates with **Excellium Solution - Accounting & Management** to support the Secretariat with accounting, budgeting and other administrative tasks concerning the association.

2023 Communications Review

During 2023, the EHPM undertook a number of communication activities, including email updates to our Members and an active presence on social media. EHPM continued to design and manage its communication strategy 100% in-house.



EMAIL UPDATES

During 2023, EHPM provided Members with 68 updates through the three newsletters. The average open rate increased from 31% in 2022 to 47%, with a peak in April of 64%.

- **48 snapshots** (compared to 47 in 2021), a weekly newsletter summarising the most important scientific articles published in peer-reviewed journals;
- **16 policy updates**, a newsletter containing updates on regulatory issues and discussions at EU level relevant to the food supplement industry;
- **4 international regulatory supplements**, a quarterly newsletter on international regulatory updates outside Europe.

Moreover, we have also sent **more than 50 urgent email updates** on national and EU-wide regulatory issues relevant to the dietary supplement industry.

SOCIAL MEDIA REVIEW

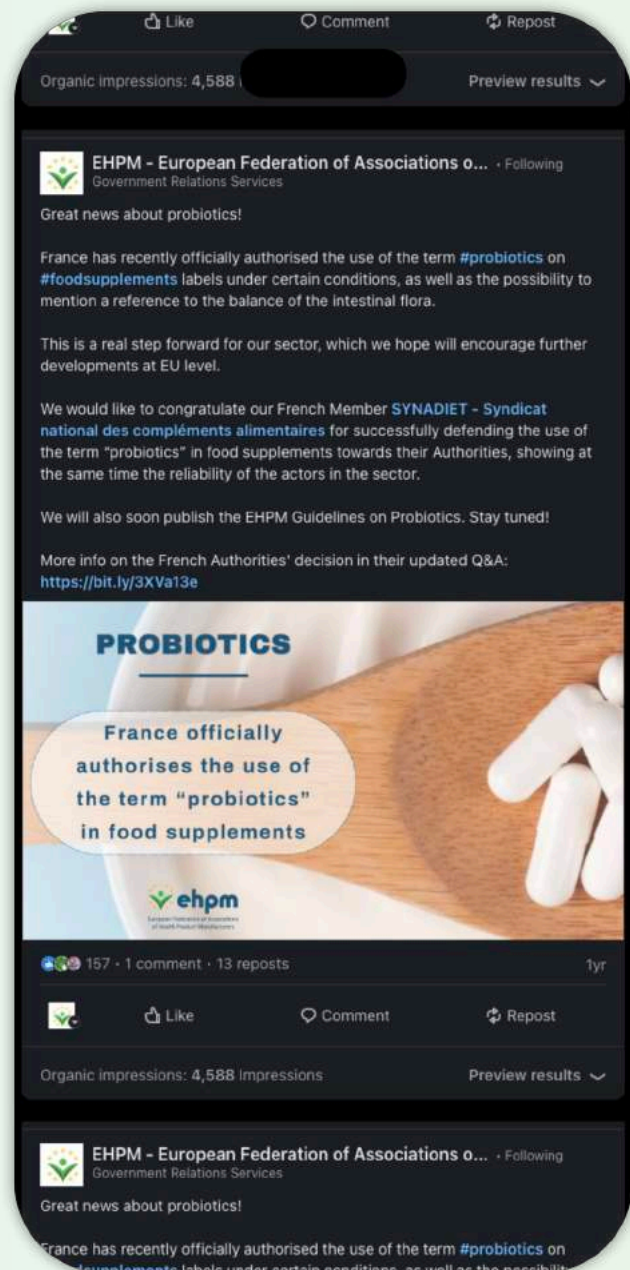
Since the beginning of 2023, EHPM has implemented its social media strategy in-house. Our overall goal is to increase EHPM presence and reach a wider audience on Twitter and LinkedIn. This communication strategy has allowed us to raise awareness of EHPM activities and events, but also to create opportunities to attract new members, as we have received several enquiries from companies interested in joining EHPM.



LinkedIn

In 2023, EHPM significantly increased its LinkedIn presence by regularly sharing content about its activities and industry updates, up from an average of two posts per month in 2023. As a result, EHPM LinkedIn page experienced significant growth in followers. It received **378 new organic followers** and 1.431 page views, reaching **1.878 followers by the end of 2023**. The 27 posts published in 2023 gained more than 30.000 impressions and generated more than 3.000 clicks, 920 reactions, 24 comments and 67 reposts. The highest peak performance was reached in February, when we reported the important news from France about the French authorities' new approach to probiotic products.

Also in 2023, LinkedIn was EHPM's strongest channel!





Twitter

EHPM's performance on Twitter remained constant in 2023 **approaching the 400-follower threshold**. Around 39 tweets were shared, reaching more than 2.000 impressions. The highest performance peak was reached with the coverage of the EHPM events. (see 2023 Events section).



Strengthened connections with the press

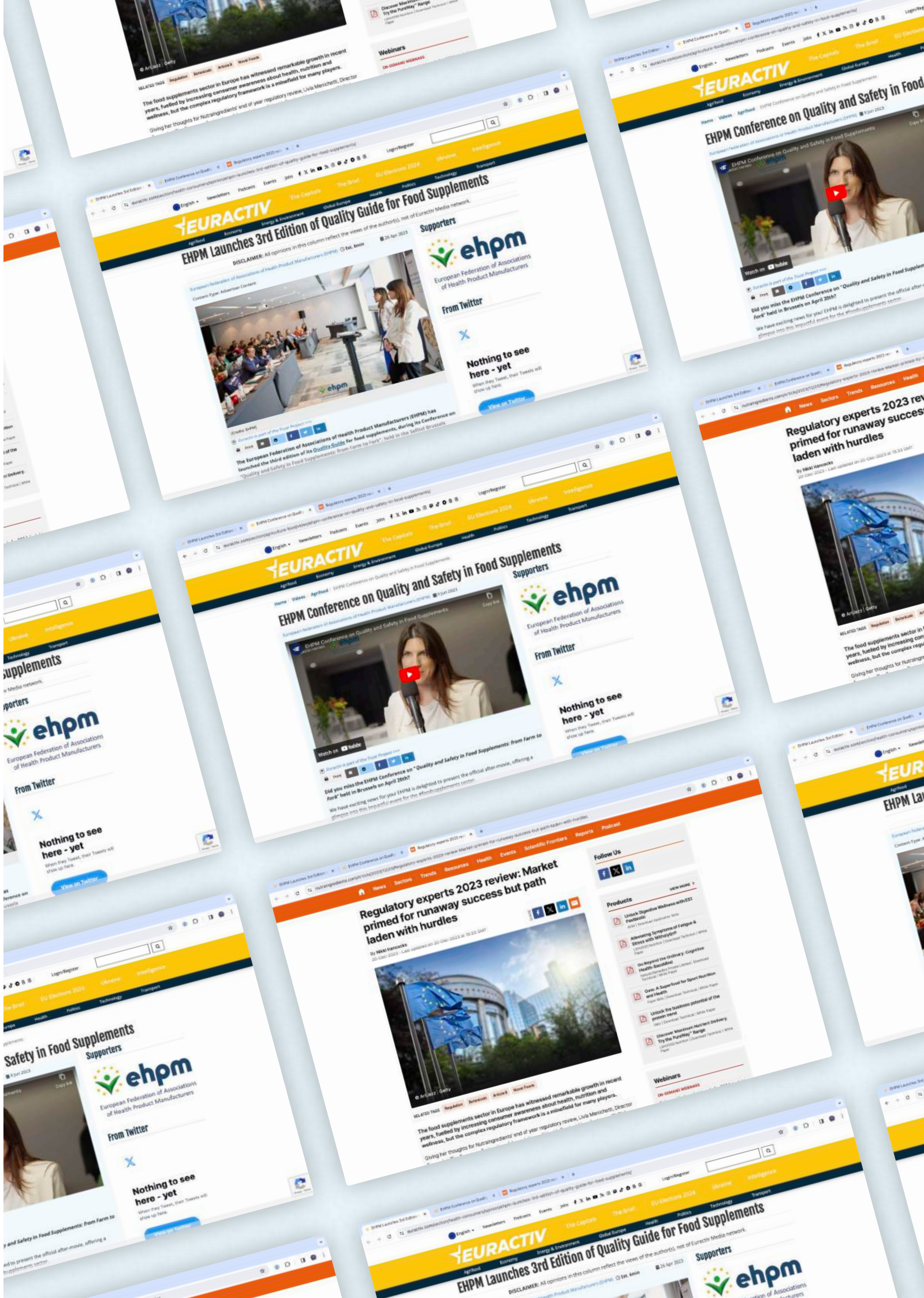
As part of EHPM's communications strategy, we continued engaging with the press in 2023 and secured key pieces of coverage.

In April and June, EHPM published two pieces on EURACTIV to cover the launch of the Conference on "Quality and Safety in Food Supplements: from Farm to Fork" and the launch of the third edition of the Quality Guide for food supplements.

In May, EHPM wrote an article for IADSA on post market vigilance for food supplements, introducing the *EHPM guidelines for food supplement companies on the management of adverse event reports and the EHPM pilot project: Companies' Alliance for a vigilance system for Food Supplements containing Red Yeast Rice*.

In December, EHPM Director General Livia Menichetti was interviewed by NutraIngredients Editor Nikki Hancocks for her: 'Regulatory experts 2023 review: Market primed for runaway success but path laden with hurdles'.





EURACTIV
AgriFood Economy Energy & Environment Global Europe Health
EHPM Launches 3rd Edition of Quality Guide for Food Supplements
DISCLAIMER: All opinions in this column reflect the view of the author(s), not of Euractiv Media network.
26 Apr 2023
Supporters
eHPM
European Federation of Associations of Health Product Manufacturers
From Twitter
Nothing to see here - yet
When they Tweet, their Tweets will show up here.
View on Twitter

EURACTIV
AgriFood Economy Energy & Environment Global Europe Health
EHPM Conference on Quality and Safety in Food Supplements
Did you miss the EHPM Conference on "Quality and Safety in Food Supplements: From Farm to Fork" held in Brussels on April 20th?
We have exciting news for you! EHPM is delighted to present the official after-movie, offering a glimpse into this impactful event for the food-supplements sector.

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By Nikki Hancock
20 Dec 2023 - Last updated on 20-Dec-2023 at 15:33 GMT
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EHPM Priorities for 2024

The June 2024 European Parliament elections will shape the European Union for the next 5 years and will influence the priorities of the mandate of the new European Commission. EHPM wants to actively be involved in this process by implanting its public affairs strategy. Building new alliances and creating /enlarging the network of supporting MEPs will set the base for a successful public affairs strategy both at National and European level. EHPM will count on the commitment of the EHPM Secretariat, its members and strategic partnerships to successfully implementing its public affairs strategy.

In 2024, EHPM will draft, publish and disseminate its Manifesto ahead and after the European elections with the aim to influencing the work programme of the next European Commission and position the sector as a trusted partner vis-à-vis EU institutions.

Our focus will be on 5 major dossiers:

1. Setting Maximum Levels of Vitamins & Minerals: calling for an impact assessment to be done by the EC and for realistic levels that take into account market practice and different Member States approaches;
2. Addressing in a fair and targeted way the implementation of the Health Claims regulation for botanicals used in foods. Before resuming the assessment of the claims on hold a targeted methodology applicable to botanicals used in foods should be agreed. Tradition of use should be used as a criteria to assess safety of botanicals used in foods. Innovation should also be allowed;
3. Making sure that legal certainty is guaranteed within the European Regulatory framework: EHPM will call for a coherent and transparent application of the Novel Food Regulation;
4. Assuring the full operation of the internal market by a full and coherent implementation of the Mutual Recognition principle;
5. Addressing the application of Art.8 of Regulation 1925/2006 and calling for a proportionate approach for ingredients used in food supplements.

As we engage on this critical files, we will also highlight the role that food supplements play in the betterment of citizens' health by achieving optimal nutrition, in order to enhance our reputation, change the perception of food supplements, and address the growing scepticism towards our sector.

EHPM's compelling messages will reflect our priorities and focus on:

1

Commitment to Safety and Quality

- EHPM champions the safety and quality of food supplements, actively promoting the standards outlined in the EHPM Quality Guide & the EHPM Guidelines for food supplement companies on the management of adverse event reports (vigilance).
- EHPM promotes and facilitates compliance to European Regulations by promoting and organising workshops and events in cooperation with the EU Institutions.

2

Transparent and Informative information to consumers

- EHPM prioritises providing consumers with truthful and comprehensive information about food supplements.

3

Empowering Health through Nutrition

- Extensive evidence underscores the profound benefits of food supplements on overall health.
- Integrating food supplements into a regular diet not only promotes well-being but also helps contain healthcare costs.

EHPM's steadfast commitment is further exemplified through a proactive and holistic 2024 Public Affairs strategy, comprising three elements:

1 Reputation Enhancement

- EHPM aims to change the perception of the food supplement sector by disseminating its concrete proposals and guidelines on quality, safety, and post market vigilance.
- To promote the role of the role of food supplements in the betterment of citizen's health and well-being by reaching optimal nutrition.
- Positive influence on European decision-making processes and Member States' perspectives underscores our commitment to fostering a favourable regulatory framework.

2 Proactive Contribution

- EHPM takes a proactive and pre-emptive approach to contribute meaningfully to regulatory enhancements.
- Pragmatic and legally sound proposals form the backbone of our initiatives, shaping a future that aligns with our values.

3 Holistic Approach to Advocacy

- The 2024 Public Affairs strategy adopts a holistic approach, addressing multifaceted challenges.
- EHPM aspires to create positive change by actively engaging with stakeholders, influencing policy, and fostering a regulatory environment conducive to the growth and well-being of the food supplement sector.

Thank
you all for
making
this year a
success!

Stay tuned for more initiatives in 2024

23

20



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