



# IADSA CONNECT

**#13** MAY 2023



## DENMARK PREPARES TO WELCOME GLOBAL SUPPLEMENT SECTOR TO COPENHAGEN

FOCUS ON POST-MARKET  
VIGILANCE FOR FOOD SUPPLEMENTS

RAISING AWARENESS OF PREBIOTICS



# #13

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# FOCUS ON POST-MARKET VIGILANCE FOR FOOD SUPPLEMENTS

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EHPM Guidelines for food supplement companies on the management of adverse event reports & EHPM Pilot Project: Companies' Alliance for a vigilance system for Food Supplements containing Red Yeast Rice.

The lack of a post-market surveillance system for food supplements (FS) is often mentioned by National and European Authorities as a factor that casts doubt on the safety of FS and the responsibility and professionalism of Food Business Operators (FBOs) and fuels the general scepticism and mistrust towards the FS sector.

Although some Member States have implemented national vigilance systems for FS, for instance France with its successful system managed by ANSES or others, such as Belgium, are currently working on the development of their own, there is no harmonised European-wide vigilance system for FS, unlike other product categories (e.g. cosmetics and medical devices).

European citizens can benefit from a strong and robust European Food Safety system that guarantees the highest level of consumer protection. FS safety, high quality standards, clear and truthful consumer information and transparency are key priorities of the European Federation of Associations of Health Product Manufacturers (EHPM). Indeed, FBOs are responsible for the safety of the products they place on the market: from product development, through production, to the post-marketing phase, 'from farm to fork'.

It is in this spirit and in line with our proactive approach that the EHPM is developing Vigilance Guidelines for Food Supplements to guide and encourage FBOs, particularly SMEs, to apply a concrete, realistic and easily applicable vigilance system to their products. Through the proposed post-marketing surveillance, FBOs must collect all adverse events (AEs) reported by consumers, healthcare professionals and/or competent authorities (AE reporters), which are suspected to be linked to the intake of their FS alone or in combination with other products.

In fact, we firmly believe that the availability of safety and consumer exposure data is of paramount importance for FBOs to be able to monitor the safety of their products once they are placed on the market and could also be of important help in the context of the application of Art. 8 of Reg. (EC) 1925/2006 or when the safety of an ingredient is questioned. In this context, EHPM has already launched a pilot vigilance project to collect data within the scrutiny period on monacolins from red yeast rice. This project brings together an alliance of 12 companies from 3 European Countries who have agreed to share Adverse Event Reports (AERs) with professors from the University of Bologna (IT) who will assess the causality of the reported AEs. The aim of the pilot project is to collect post-market data to demonstrate that the incidence of AEs possibly linked to the intake of FS containing monacolins from red yeast rice is extremely low, thus negligible. A detailed report will be published by the University of Bologna and submitted to EFSA to support the safety of FS containing this ingredient and prevent its prohibition when the regulation is reviewed at the end of the scrutiny period in June 2024.



Livia Menichetti,  
Director General, EHPM

The soon-to-be-published EHPM Vigilance Guidelines are inspired by existing national vigilance systems, but also by the IADSA Global Guide to Adverse Event Reporting. The Guidelines are a tool that provide guidance to companies in developing and implementing procedures to ensure that the received AERs are handled in a logical, functional and comprehensive manner. The Guidelines are fully adaptable: although examples and templates are provided, these should be adapted as necessary to suit the wide range of FS products, the FBOs that produce them, and the legal framework in which the FBOs operate.

The EHPM Vigilance Guidelines are intended as a non-mandatory self-regulatory guide, in line with the above-mentioned priorities and values of the EHPM and the EU. Where specific national regulations or guidelines apply, these prevail over the Guidelines.

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*The European Federation of Associations of Health Product Manufacturers (EHPM) was created in 1975. With its 14 National Associations and 11 Member Companies, EHPM represents product manufacturers, distributors, the majority of whom are small and medium-sized enterprises (SMEs), in 17 European countries.*





Len Monheit,  
Executive Director,  
Global Prebiotic Association

# RAISING AWARENESS OF PREBIOTICS

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The Global Prebiotic Association (GPA) was founded in 2019 to steward the growth of a burgeoning, but frequently poorly understood category - prebiotics. GPA is the only global trade association solely focused on prebiotics, providing education, insights, and awareness building to drive category growth. Over the past five years, GPA has grown to 42 global members representing many prebiotic types and regions.

Although researched for decades, until recently, the only broadly accepted prebiotics were inulin, FOS (fructo-oligosaccharides) and GOS (galacto-oligosaccharides). Emerging science has shown that XOS (xylo-oligosaccharides), numerous other oligosaccharides, acacia fiber, lactulose, resistant starch, beta-glucans, numerous polyphenols, and even poly-unsaturated fatty acids have prebiotic activity. These emerging prebiotics are often efficacious in gram or sub-gram dose, allowing more applicability in supplement formulation than earlier generation prebiotics. It's an exciting time for the category, but also a confusing one.

GPA is proactively mitigating this confusion by the creation of a series of resource guides and infographics not only describing all prebiotic types, but also discussing efficacious dose range, formulation issues and constraints in addition to educational programs outlining future trends in prebiotics – including a move to precision prebiotics using techniques to modify carbohydrates and their linkages – possibly an important step towards personalized nutrition.



As broader microbiome-based supplements continue to proliferate, the concept of synbiotics, most often thought of as a combination of probiotics and prebiotics has emerged and gained traction - although consumers are still catching up. GPA has taken a leadership position with the establishment of a synbiotics working group to help manage the maturation of this product development opportunity.

There is no consistent global definition of a prebiotic, especially one that recognizes emerging science and the scope of ingredients now known to have prebiotic activity. It is especially this latter term, 'prebiotic activity' where GPA has focused, as that is the area where GPA has attempted to convey how prebiotics work and establish the pathway under which ingredients can move towards accepted prebiotic status. A consensus group formed by GPA defines a prebiotic effect as 'a health or performance benefit that arises from alteration of the composition and/or activity of the microbiota, as a direct or indirect result of the utilization of a specific and well-defined product or ingredient by microorganisms.' GPA's working definition of a prebiotic is "a product or ingredient that is utilized in the microbiota producing a health or performance benefit'. (GPA is working on a manuscript for discussion, peer-review, and publication later this year.)

While probiotics are generally familiar and somewhat understood, the same cannot be said for prebiotics, even with, (maybe even better expressed) industry and health care practitioners, let alone consumers. GPA started its stakeholder education programs at its inception and these activities continue with regular webinars, education at conferences such as the Food & Nutrition Conference (FNCE – US dietitians) and other programs. A set of curricula for each group is in development.

## CONSUMER AWARENESS IS GROWING

GPA is able to provide its members with information about supplement users worldwide. This includes what they look for on a prebiotic label and what influences the purchasing decision including dosage. While the early understanding of prebiotics may have been that they were synonymous with fiber, new research continues to show that not all prebiotics are fiber, and conversely not all fibers are prebiotics. Consumers increasingly understand this fact and the reasons they choose a prebiotic typically rank 'source of fiber' well down the list, after other health-related benefits such as digestion, immunity, regularity and even the term 'microbiome health'.

This shows increasing discernment on the part of users, as does the fact that increasingly, they are seeking out specific prebiotic types. Overall, it is gratifying to see that 85% of supplement users are aware of prebiotics, as the category approaches the awareness level of probiotics and omega-3s.

It is becoming clear that prebiotics are poised to be one of the biggest ingredient categories to provide health and nutrition solutions for several health benefit areas, beyond gut health and digestion. This is borne out by the list of health benefits with which users increasingly associate prebiotics, certainly their role in overall microbiome health, but also emerging science in inflammation, resilience and immunity and mental wellness.

While the interest is there, the need for education has become even more important. In addition to an active communications program and committee, GPA has enlisted influencers around the world from global academia (as an external advisory group), health care practitioners (regular dialogue with US dietitians) and is in the process of developing an education committee that will take charge of these activities. At the same time, the GPA Technical Committee has already authored several white papers and resources – on Prebiotics 101, Prebiotic Types, Prebiotics, and Immunity, Synbiotics as well as a recent series educating type by type. All such resources are on the website.

For its members, in addition to consumer insights, GPA has consolidated burgeoning prebiotic research into a database, and has deployed a member regulatory map of the world, depicting status by region and country and governance (food, natural health product etc.), to allow members to better plan global regulatory strategy.

Some other key initiatives underway include:

- In support of young and emerging researchers in the field, GPA offers annual Young Researcher grants for both Foundational and Applied Science
- Ongoing awareness building on the emerging science supporting prebiotics and their role in overall microbiome health

GPA is a category specific global organization committed to stewarding the prebiotic category. As such, it is committed to representing regionally, focusing on any and all category specific issues and nuance. As a member of the broader supplement community, GPA will continue to ensure this exciting category grows responsibly and sustainably.

GLOBAL  
**PREBIOTIC**  
ASSOCIATION



Rikke Bekker Henriksen,  
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Federation

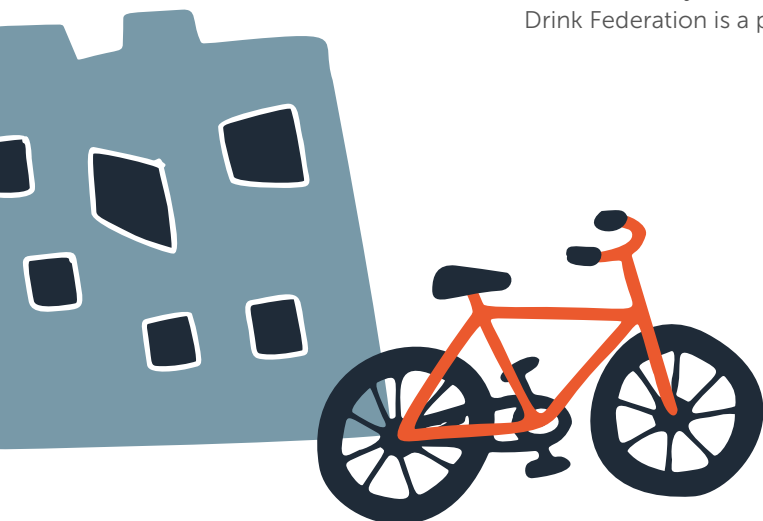
## HOST NATION: DENMARK PREPARES TO WELCOME GLOBAL SUPPLEMENT SECTOR TO COPENHAGEN

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Ahead of IADSA's World Supplement Forum in Copenhagen, Connect spoke with Rikke Bekker Henriksen, Senior Advisor at Danish Food and Drink Federation.

Danish Food and Drink Federation, the association for the Danish supplement sector, is gearing up to host IADSA's World Supplement Forum and Annual Week. It takes place from 13-15 June in Copenhagen, Denmark's capital city, at the headquarters of the Confederation of Danish Industry, which Danish Food and Drink Federation is a part of.

As a 'home' event, it will be a busy few days for Danish Food and Drink Federation. But Rikke Bekker Henriksen, Senior Advisor with responsibility for the supplement sector, says there is great excitement and pride at the prospect of welcoming IADSA members and other industry stakeholders to the Forum. She believes it represents an excellent opportunity to showcase Denmark's strengths – especially its world-leading approach to sustainability, a topic that will dominate the Forum's afternoon session.





In Copenhagen every effort is made to do things as sustainably as possible. Symbolic of this is the city's favourite mode of transport. "When our guests arrive, they will see the tradition of using bicycles to get everywhere," says Henriksen. "Even in the basement of the Confederation of Danish Industry we have about 20 bikes – and helmets, of course – which our staff can use to travel to and from meetings."

Henriksen has been with Danish Food and Drink Federation since April 2021, having previously worked for several food and beverage businesses across more than two decades, in areas such as quality, safety, regulation and CSR. She says Denmark's supplement sector presents unique challenges. In particular, it is very tightly regulated, with domestic laws that in some cases go beyond those prescribed by European Union Directives. As an example, ashwagandha is banned from sale in Denmark, despite being widely sold elsewhere.

"Whenever there is new EU regulation, the Danish authorities are the first to implement it, and they often use the strictest interpretation possible," she says. She admits there is a positive flipside to this: Danish supplement companies operate under such stringent rules that they are known globally for their exceptionally high safety standards. In large part, this explains why as many as 60% of sales are generated by exports, with Asia a major customer.

But Denmark also remains one of Europe's smaller markets for supplements, which Henriksen says might be connected to the way they are perceived by regulators. "Traditionally, the official line from the authorities has been that we eat so healthily in Denmark that we can get all the vitamins and minerals we need from food, and we don't need supplements."

Nevertheless, there are positive signs of progress, with data from Danish Food and Drink Federation showing that sales are growing at about 6% per year, having been given a boost in the years following the Covid-19 pandemic.

In spite of any differences of opinion, Henriksen says that Danish Food and Drink Federation has good relations with regulators. "We have dialogue groups with officials from the Danish authorities to discuss the impact of regulation. Within that, there's a specific group for food supplements. We meet once or twice a year and our discussions are quite open, which is something that I, as representative of our members, really appreciate."

The key aim for Danish Food and Drink Federation, she says, is to build the reputation of the Danish supplement sector as trustworthy in the eyes of the country's decision-makers. For three days in June, those eyes will be on IADSA's World Supplement Forum in Copenhagen, offering the perfect opportunity for Danish Food and Drink Federation to show that while Denmark isn't Europe's biggest supplement market, it still has a lot to offer.





