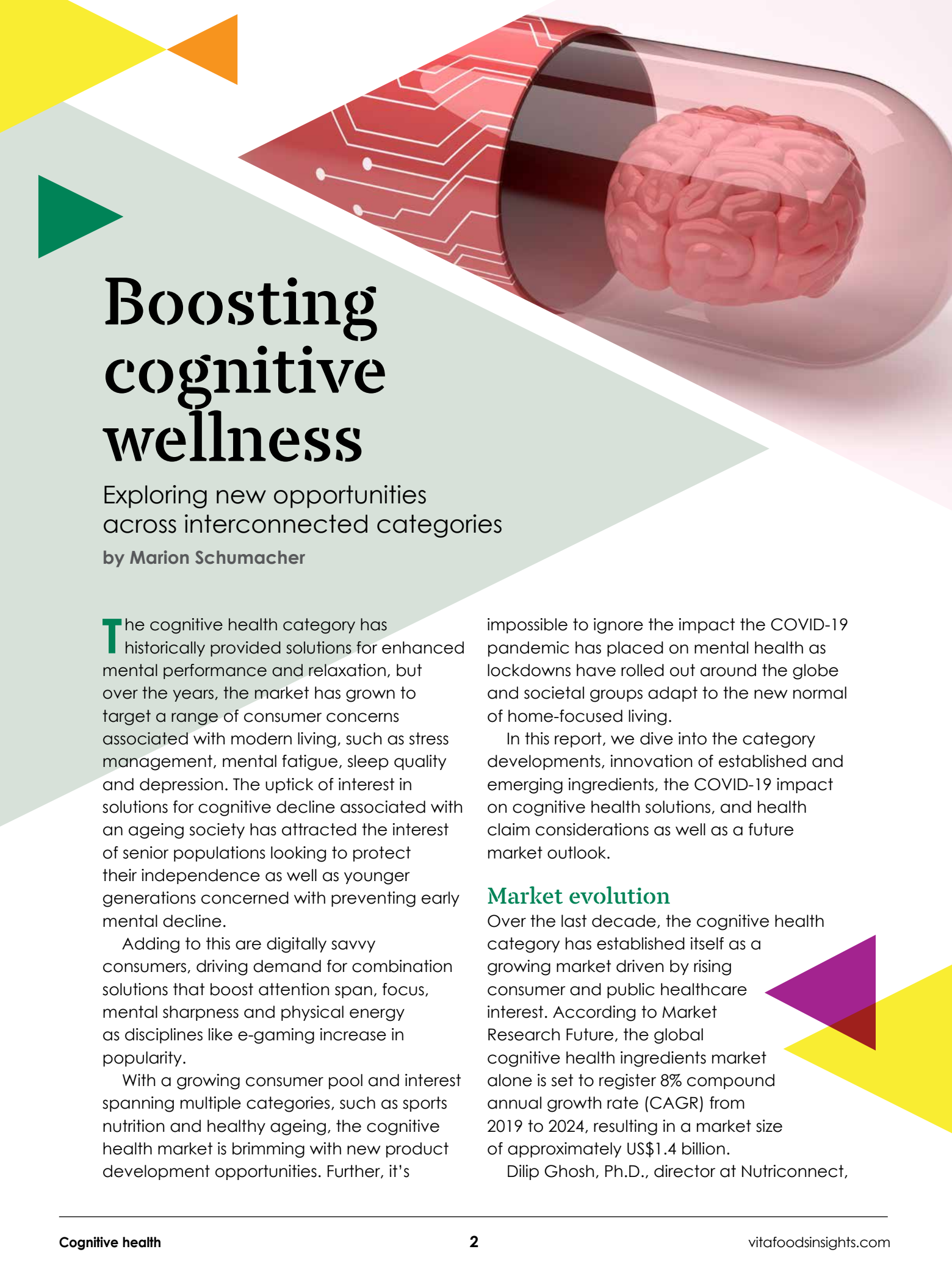




Boosting cognitive wellness

Exploring new
opportunities
across
interconnected
categories



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Exploring new opportunities across interconnected categories

by Marion Schumacher

The cognitive health category has historically provided solutions for enhanced mental performance and relaxation, but over the years, the market has grown to target a range of consumer concerns associated with modern living, such as stress management, mental fatigue, sleep quality and depression. The uptick of interest in solutions for cognitive decline associated with an ageing society has attracted the interest of senior populations looking to protect their independence as well as younger generations concerned with preventing early mental decline.

Adding to this are digitally savvy consumers, driving demand for combination solutions that boost attention span, focus, mental sharpness and physical energy as disciplines like e-gaming increase in popularity.

With a growing consumer pool and interest spanning multiple categories, such as sports nutrition and healthy ageing, the cognitive health market is brimming with new product development opportunities. Further, it's

impossible to ignore the impact the COVID-19 pandemic has placed on mental health as lockdowns have rolled out around the globe and societal groups adapt to the new normal of home-focused living.

In this report, we dive into the category developments, innovation of established and emerging ingredients, the COVID-19 impact on cognitive health solutions, and health claim considerations as well as a future market outlook.

Market evolution

Over the last decade, the cognitive health category has established itself as a growing market driven by rising consumer and public healthcare interest. According to Market Research Future, the global cognitive health ingredients market alone is set to register 8% compound annual growth rate (CAGR) from 2019 to 2024, resulting in a market size of approximately US\$1.4 billion.

Dilip Ghosh, Ph.D., director at Nutriconnect,



notes that while there is active consumer interest in addressing issues closely linked to mental health, such as stress and anxiety, the current state of knowledge regarding promotion and protection of cognitive health solutions is at an immature stage. Ghosh highlights that brands need to identify these knowledge gaps and define the unique role of cognitive health products to public healthcare stakeholders. Together with industry, regional governments could work to support cognitive health with specially formulated, clinically proven products.

“The primary areas of concern for consumers are physical support, including memory, motivation, cognitive function, and concentration,” says Jean-Marie Raymond, founder of Pharmactive Biotech Products, “and on emotional support—mood improvement, stress and anxiety reduction, relaxants, and support for sleep quality.”

In a 2020 Consumer Trends survey concentrating on prominent European markets, Innova Market Insights found that 70% of consumers indicated ‘controlling tension and stress levels’ as top of mind. Across the Baby Boomer, Gen X, Millennial and Gen Z generations, prevention was identified as more important than treatment when referring to dealing with stress management. The survey also investigated the impact of stress on mental and physical health, with 47% of respondents suggesting stress causes bad mood, and 41% stating

“Brands need to identify these knowledge gaps and define the unique role of cognitive health products to public healthcare stakeholders.”

stress causes sleeping disruptions.

Over the last decade, there have been significant changes to what we eat as well as the processing and refining of foods. “As most of the brain is derived from food, this has led to increasing demand for nutritional supplementation for brain health—combined with changing demographics, a rise in ageing populations, and an awareness of healthy ageing,” says Eric Meppam, co-founder and commercial director, Pharmako Biotechnologies. The market is



evolving to meet these growing needs. More recently, he adds, online retailing has become one of the most accepted distribution channels around the world, particularly in emerging markets such as Asia Pacific, Latin America and Eastern Europe. New products in cognitive health have benefited from this new channel possibly more than other segments.

COVID-19 impact on the category

Mental wellbeing has been a rising concern to consumers and public healthcare in years before the COVID-19 outbreak. A 2019 Innova Market Insights survey found that 32% of UK consumers and 39% of U.S. consumers claimed to experience stress at least once a day. But the COVID-19 pandemic has resulted in unprecedented changes that may become permanent fixtures of day-to-day life, especially the way we work, socialise, travel and shop. “People are learning to manage new forms of stress such as unemployment,

uncertainty related to physical health, and balancing work and childcare," says Lisa Riedell, senior director of marketing, Alfasigma. These stressors are likely to continue as we work towards a solution for COVID-19.

"In some ways, life has gone on, but it has been concentrated in the same physical space," says Massimiliano Carreri, chief commercial officer, Linnea. He adds that stress, sleep disorders and anxiety were already prominent global concerns, reflected by the skyrocketing sales of dietary supplements targeting cognitive health.

"The implications of measures designed to control the COVID-19 pandemic are impacting the cognitive health market," Meppem says. "As well as an obvious demand for immune-boosting ingredients and formulations, national lockdowns have led to increased anxiety, low mood, depression and stress in many population groups." He comments that anecdotes from customers in several markets also indicate an increase in nootropic supplements, as e-gaming, which was already increasing dramatically in popularity, has acquired more active users during lockdown and isolation.

Raymond echoes this, saying that the pandemic has strongly affected mental balance and stress, and noting that new products have emerged to manage and prevent anxiety, irregular sleep, bad mood and negative mindset. "Teenagers are one of

the most vulnerable targets for mental unwellness due to the COVID-19 crisis and among the hardest hit from a mental health standpoint," he says. "Parents are seeking natural, holistic solutions for mental health for both their children and themselves."

As awareness for mental health and an emphasis on prevention grows, stress management, relaxation, sleep aids and mental performance will emerge as key trends driving deep changes in consumer behaviours and market shaping, comments Carreri.

Additionally, as there are known links between the brain, gut and immune system, Ghosh foresees the rise of combination solutions that address these three key areas emerge as areas for further scientific exploration.

Ingredients in favour

Fortunately, there are a range of established and up-and-coming ingredients that can positively impact myriad aspects of cognitive performance. "Established ingredients that continue resonating to consumers are more focused on maintaining alertness and making sure the brain gets all the nutrients and antioxidants, such as B vitamins, phospholipids, and omega 3," notes Raymond.

Similarly, research has been done on L-carnitine's positive effects on cognitive performance, as it supports mitochondrial health and production of cellular energy. Acetyl-L-carnitine in particular has been investigated for its ability to cross the blood-brain barrier to directly fight potential oxidative damage in the brain and improve neural capacity. "By helping to increase neurotransmitter production, acetyl-L-carnitine provides the essential tools to help the slowing of cognitive decline while supporting a wide range of functions, including the production of adenosine triphosphate (ATP), increase in antioxidant activity and production of glutathione," says

“The implications of measures designed to control the COVID-19 pandemic are impacting the cognitive health market.”

Lisa Riedell, senior director of marketing, Alfasigma—producers of MitoCarn™ Brain acetyl-L-carnitine.

There are also botanicals with a long history of use such as *Ginkgo biloba* and *Bacopa monnieri* and others that have the historical context alone with unique formulations and robust research portfolios.

“There are many adaptogenic herbs with a long history of traditional use now backed by solid scientific studies showing benefits supporting capacity for mental work and physical performance,” says Holly Johnson, Ph.D., chief science officer at the American Herbal Products Association (AHPA). “I think the real innovation will be in consumers integrating and adopting of a variety of traditional health paradigms into modern life, including the use of botanicals known to have properties that aid in response to the stress.”

Ghosh concurs about the move toward these powerful ingredients: “Since consumers are increasingly inclined toward botanicals, two of the most existing and established Indian Ayurveda-derived cognitive ingredients, bacopa and ashwagandha, are gaining huge popularity. In the last decade, companies with patented formulations such as CDRI08 (bacopa) and KSM-66 (ashwagandha) have invested significant resources in clinical trials around the world on different population groups. This gives confidence to global consumers from a personalisation perspective.”

“The real innovation will be in consumers integrating and adopting of a variety of traditional health paradigms into modern life.”

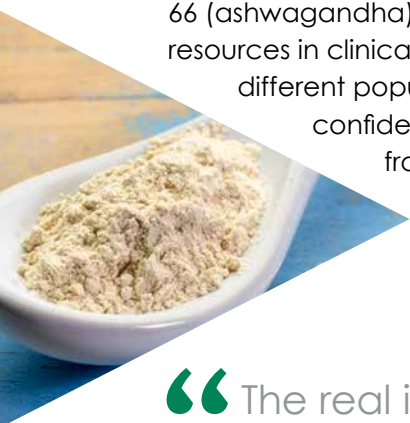
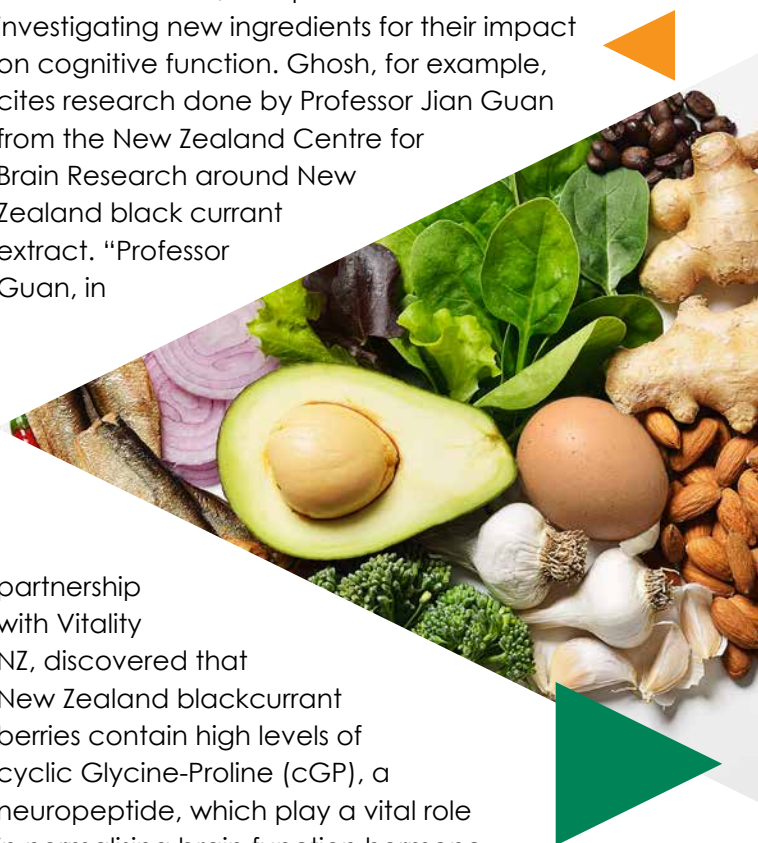
Emerging ingredients

At the same time, companies are investigating new ingredients for their impact on cognitive function. Ghosh, for example, cites research done by Professor Jian Guan from the New Zealand Centre for Brain Research around New Zealand black currant extract. “Professor Guan, in

partnership with Vitality NZ, discovered that New Zealand blackcurrant berries contain high levels of cyclic Glycine-Proline (cGP), a neuropeptide, which play a vital role in normalising brain function hormone Insulin like Growth-Factor-1 (IGF-1). IGF-1 is essential for cognitive health, neurological development, improving the brain signalling pathways and healing recovery.”

Another unique offering is found in saffron; PharmActive's affron® is a saffron extract standardised to specific bioactives that address relaxation, mental and physical balance, and maintain a positive mood. Raymond comments, “As new ingredients emerge to help cope with stressful situations in a more tailored way, one of the most interesting is affron, which was recently awarded as Ingredient of the Year for Cognitive Function at NutraIngredients USA Awards.”

Nektium's Zynamite®, a patented extract from *Mangifera indica*, has strong science and clinical trial data backing its improved concentration, memory and everyday



cognitive health benefits. Dr Nigel Gericke, director of science at Nektium Pharma, said the company's latest clinical study highlights the five-year discovery and R&D programme the company has performed to establish Zynamite as a premium natural alternative to caffeine. "Our quest involved a global ethnobotanical research programme, the exclusion of botanicals with caffeine-similar compounds, or compounds acting on the molecular targets of caffeine, and innovative screening using brain electrical (EEG) studies," he explains.

There are other more traditional ingredients that are being investigated for their applicability to today's health needs. Meppam calls out lavender as one such botanical, as Pharmako has actively integrated compressible powdered oil technology, allowing conversion into powder and multiple applications as a result. "Lavender is traditionally recognized having a variety

of therapeutic and curative properties, ranging from inducing relaxation, mild headache relief to helping induce sleep and reducing stress or anxiety," he says. "Essential oil of lavender is purported to be antibacterial, analgesic antifungal, anxiolytic, antidepressant, carminative (smooth-muscle relaxant), as well as to have beneficial immunomodulatory effects on wound healing. Use of lavender oil has extended from topical to oral use in recent years. There are many European studies on the use of lavender oil for stress, GAD (general anxiety disorder) and insomnia."

Clinical research

In addition to sourcing high-quality ingredients with cognitive health benefits, there is an essential need to scientifically substantiate efficacy and use through clinical trials. Clinical support is increasingly important also in the health ingredients space as consumer awareness is duly growing. This is a need that industry stakeholders cannot ignore.

In the botanicals space, Johnson says, "There is a compelling body of evidence from clinical studies on various adaptogenic and cognitive support herbs, but many trials focused on therapies for disease states. Innovative study design based on improvements in stress related biomarkers or cognitive performance endpoints in healthy subjects is the trend for supplement claims."

The importance of clinical research in cognition is huge, Raymond says, because everything that involves the mind is more susceptible to placebo effects. Hence proof of evidence is needed. "The design of the study is very important for the ethical committee—carrying out human clinical studies is not only important to ensure the efficacy and safety of the ingredient, but also to determine the doses that ensure its beneficial effects without associated side effects," he adds.

When discussing clinical research for dietary supplements, these trials are quite different from those for pharmaceutical drugs. Carreri notes that each trial should be designed with the desired claim in mind, staying focused on typical dietary supplement features, including those such as oral administration and palatability.

Before embarking on a product trial, Ghosh recommends experts first conduct a systematic literature review on presumed risk factors and related interventions for relationships with cognitive health, harms, gaps and efficacy. "If the outcome is positive, then conduct a well-designed clinical



trial, with statistical power, to determine your primary and secondary outcomes. Pharmacokinetics data is not available for most products, but it is the information most healthcare professionals will look for. So, it's advised to run a pharmacokinetics study on your product if there is a goal to target the mainstream health system" he explains.

Health claims and regulation

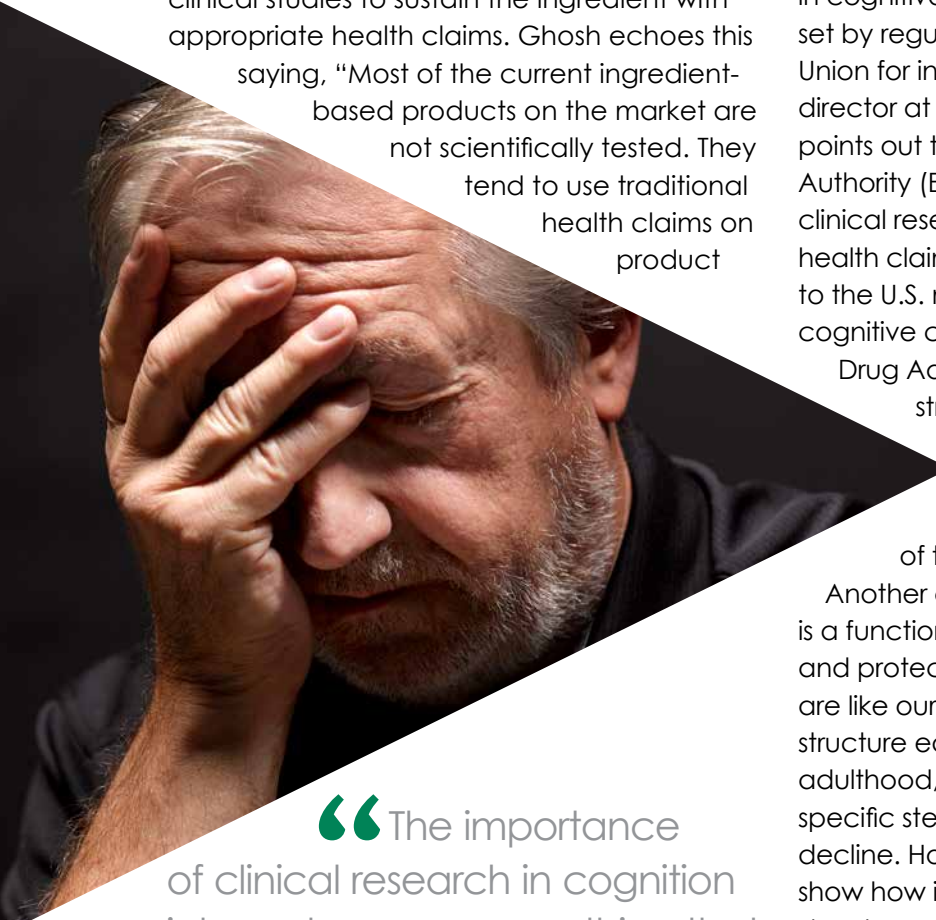
When it comes to cognitive health supplements, brands must be cautious of regulatory compliance and the health claim status of certain products. Many newer ingredients have little science to support their claims, and Raymond notes there is a necessity to endorse the ingredient with sufficiently and ethically designed clinical studies to sustain the ingredient with appropriate health claims. Ghosh echoes this saying, "Most of the current ingredient-based products on the market are not scientifically tested. They tend to use traditional health claims on product

labels, even if the products are multi-ingredients based." He adds that although some of these products have been eliminated by regulators, for any specific disease-related claims, appropriate testing through randomised control trials should be carried out. The industry faces a major hurdle, as proper testing often requires large budgets which many SME-size companies simply do not have. However, there can be no compromise when it comes to testing or health claims, as human health and wellbeing should be of the utmost importance to brands developing these kinds of products.

Another challenge, specific to manufacturers, is that it can be quite difficult to measure and substantiate improvements in cognitive function that meet the standards set by regulatory authorities. In the European Union for instance, Tom Druke, marketing director at Balchem Minerals & Nutrients, points out that the European Food Safety Authority (EFSA) has set guidelines for the clinical research required to substantiate health claims for cognition. In comparison to the U.S. market, he states that most cognitive claims fall under the Food and Drug Administration (FDA) category of structure/function claims, which describes the relationship between a nutrient and how it affects either the structure of the body or how it functions.

Another challenge is that optimal cognition is a function of development, maintenance and protection. In many ways, our brains are like our bones; we build a strong structure early in life, we maintain it throughout adulthood, and then we need to take specific steps to slow the onset of age-related decline. However, it can be quite difficult to show how improved nutrition optimises foetal development and contributes to improved memory later in life.

It is also important for brands to consider the medium in which their claims will be

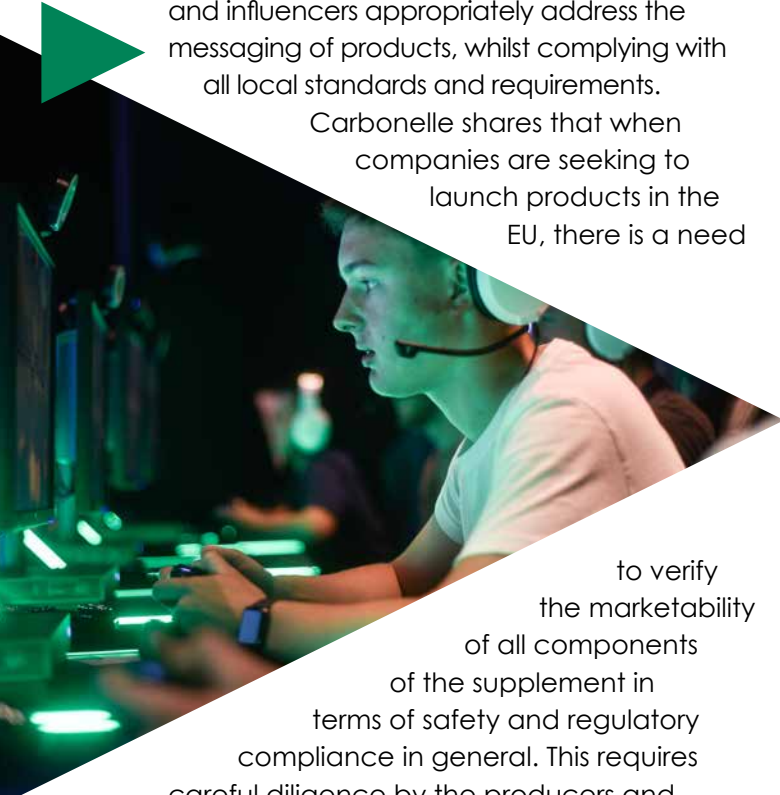


“The importance of clinical research in cognition is huge because everything that involves the mind is more susceptible to placebo effects.”



delivered to consumers. Nicolas Carbonelle, avocat and member of the Brussels Bar, Bird & Bird, reminds companies that all commercial communications about their products must be aligned with the labelling thereof, irrespective of the channels used. He emphasises that this question is of utmost importance because the way a company communicates its product, content of its message, and the way it is presented, can place any given product at risk of being disqualified by a competent authority. He explains that a food supplement may, for instance, never be presented as having disease-preventing properties, such as those reserved for medicinal products. It is also worth noting that national authorities monitor third-party operated channels, such as marketing activities supported by social media influencers. It is important to make sure that the terms of the relationship between companies and influencers appropriately address the messaging of products, whilst complying with all local standards and requirements.

Carbonelle shares that when companies are seeking to launch products in the EU, there is a need



to verify the marketability of all components of the supplement in terms of safety and regulatory compliance in general. This requires careful diligence by the producers and suppliers of the starting materials. He stresses that particular attention needs to be given to innovative ingredients—the status of which under the Novel Foods regulation is of course a key question to be considered early in the

product development process. Alongside compliance, Carbonelle also states the importance of meeting all legal requirements in accordance to both EU law and the laws of the Member States. “Harmonisation of the requirements applicable to food supplements remains limited beyond the requirements applicable to vitamins and minerals, resulting in a regulatory environment that is not easy to navigate, especially when aiming at commercialising a particular supplement in several Member States.”

Product development opportunities

As the ongoing pandemic continues to alter everyday life, and existing demand for solutions that address mental health and performance spike, the growth projection for the cognitive health market is promising, but how do we separate the winners?

Product manufacturers and marketers should look beyond tradition cognitive health. Ghosh notes that cognitive health appeals to consumers from all strata of life—from senior citizens seeking to stay sharp, to busy office workers looking to overcome mental fatigue, on to school-goers needing focus and mood support. Age has a close relationship with cognitive decline, and industry can't ignore the demand of this wide group especially as life expectancy increases. Ghosh also highlights the positive management of neurodegeneration and neuroplasticity through nutritional intervention, which offers the potential to develop products to increase bioavailability and cross blood-brain barriers. He cites bio-optimised and nano-formulated curcumin as one the best examples in this regard.

Carreri identifies antioxidants, prevention and quality as keywords for the next generation of products. The degenerative processes are at the base of the most common diseases related to cognitive

functions, he says. "The pharmaceutical industry is failing in the management of diseases like Parkinson's and Alzheimer's, and while supplements cannot offer a cure either, adequate lifestyle combined with nutrition can have an preventative effect on cognitive degeneration, reduction, or at least delay, in the development of serious diseases."

The most relevant new products are exploring the relation between immunology and mental balance, Raymond says, as it has been shown that stress is strongly related to immunity weakness. The category is evolving and spreading over different consumer segments—and optimal brain health is no longer solely a focus of the senior and adult population but includes e-gamers and younger generations who are increasingly concerned about their mental health and improving concentration, she outlines. That said, ingredients brands and manufacturers should be mindful of clinical studies demonstrating tolerability and efficacy, transparency in process, and traceability when targeting new population segments.

A leading consumer trend is the requirement for convenience in product use, and novel formats which facilitate convenience for consumers are now emerging, according to Meppem. As a case in point, recently in England Holland & Barrett (UK) launched effervescent tablets for lipophilic ingredients such as palmitoylethanolamide (PEA) and curcumin. "Novel formats are important for the industry—they accelerate segment growth and allow retailers to increase product offerings to attract new consumers without

duplication or cannibalisation," he adds. "The category growth will continue and accelerate as companies invest in science to bring efficacious formulations to market."

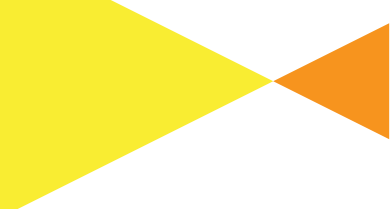
Two prominent opportunities within the market are solutions for e-gaming and cognitive decline, but both tap into very different consumer needs and demand. Brands are entering a very competitive

category, and Meppem cautions that sustainable success needs to be based on efficacy and science. "Low-grade inflammation and endothelial dysfunction are related to cognitive decline and dementia, in a complex interplay with vascular factors and ageing. New studies now measure inflammatory markers, and new products will rely upon this science to demonstrate clinical benefits," he says.

Finally, Riedell foresees continued interest in diversity of application. "New technologies must make the experience of taking cognitive health products more convenient and appealing. More importantly, manufacturers must be able to garner 'trust' in their ingredients to achieve an increase in demand. For industry stakeholders, this translates to a continued effort in supporting our long-standing quality assurance efforts."

“A food supplement may never be presented as having disease-preventing properties, such as those reserved for medicinal products”

**Contributions by Charlotte Bastiaanse,
Fraser Grice & Heather Granato**



Biographies

NICOLAS CARBONNELLE, SENIOR ASSOCIATE, BIRD & BIRD LLP

Carbonelle is a member of the Retail and Consumer sector group, in which he steers the Food & Beverage Regulatory practice group. He advises clients on regulatory law across various sectors, including Food & Beverage, Life Sciences, and the chemicals sector. Across the spectrum of these sectors, Carbonelle assists on borderline products classification and on regulatory path definition and compliance strategies. In the field of Food & Beverage, Carbonelle has built a wealth of expertise in matters relating to general food law and labelling regulations to innovative and highly regulated forms of food products, including novel food and nutraceuticals.

MASSIMILIANO CARRERI, CHIEF COMMERCIAL OFFICER, LINNEA

Now with Linnea, an herbal extract manufacturing company based in Switzerland, Carreri previously worked as head of international sales at Recordati S.p.A and business area manager at Chiesi Farmaceutici S.p.A, both pharmaceutical Italian companies. He graduated from Università degli Studi, Milano, with a degree in pharmaceutical chemistry.

TOM DRUKE, MARKETING DIRECTOR, BALCHEM MINERALS & NUTRIENTS

A consumer packaged goods veteran, Druke has experience with both Reckitt Benckiser and Pfizer Consumer Healthcare, where he worked on the Caltrate and Centrum brands. At Balchem, he currently oversees all strategic marketing initiatives to develop and expand the VitaCholine® and Albion® product lines. He is a frequent contributor to dietary supplement trade magazines and has published several

articles on emerging science and the role of choline in human health.

DILIP GHOSH, PH.D., DIRECTOR, NUTRICONNECT, SYDNEY, AUSTRALIA

Dr Ghosh has a doctorate in biomedical science and post-doctorate from USDA-ARS, HNRCA at Tufts University, Boston. He is an international speaker, facilitator and author and professionally associated with Nutriconnect and Trigonella Labs, Australia. He is also honorary ambassador and adjunct-industry fellow, NICM, Western Sydney University. He is a fellow of American College of Nutrition, professional member of Australian Institute of Food Science & Technology, executive board member of Health Foods and Dietary Supplements Association and The Society for Ethnopharmacology, as well as serving on the editorial board of several journals. Dr Ghosh has published more than 100 papers in peer-reviewed journals, and numerous articles in food and nutrition magazines and books.

HOLLY JOHNSON, PH.D., CHIEF SCIENCE OFFICER, AHPA

Dr Johnson is chief science officer for the American Herbal Products Association, an alliance of over 350 member companies from the natural products industry. She previously served as Laboratory Director for Alkemist Labs, an ISO 17025 accredited natural product testing lab specialising in botanicals. Dr Johnson took a bachelor's in botany and a doctorate in pharmacognosy with specialisation in medical ethnobotany, and was awarded an NIH Fellowship for doctoral training at the University of Illinois-Chicago NIH Center for Botanical Dietary Supplements, before completing a postdoctoral research fellowship at the Institute for Ethnomedicine in Jackson Hole, Wyoming. She is a member of the United

Biographies

States Pharmacopeia's Expert Committee for Botanical Dietary Supplements & Herbal Medicines and their Cannabis Expert Panel, serves on the Editorial Board of the Journal of AOAC International, and also the Advisory Boards of the American Botanical Council and the American Herbal Pharmacopeia.

ERIC MEPPM, CO-FOUNDER AND COMMERCIAL DIRECTOR, PHARMAKO BIOTECHNOLOGIES PTY LTD.

With 20 years' experience in the nutraceuticals industry, Meppem has specialised in bringing to market innovation from both a product and material perspective. A senior sales and marketing executive with a strong commercial background, with extensive experience in businesses with FMCG, wholesale, retail, supply and customer service focus. Pharmako specialises in lipid-based delivery systems, essentially enhancing the body's absorption of fat-soluble nutrients for the nutraceutical, pharmaceutical, functional food and cosmeceutical industries.

JEAN-MARIE RAYMOND, CEO & FOUNDER, PHARMACTIVE BIOTECH PRODUCTS, S.L.

Raymond is the founder of Pharmactive Biotech Products, the pioneer biotechnology company that produces high-quality saffron extract for mood, anxiety, stress, and sleep support. His professional career comprises nearly 20 years in the field of botanical and natural ingredients for food supplements. In 2006, he was awarded the National Top Sales Awards by Actualidad Económica Magazine (Spain).





Q&A



Company Name: Lubrizol Life Science Health

Contact: Teresa Negra
nutraceuticals@lubrizol.com

Title: New Business Development Manager, Nutraceutical Division

<https://www.lipofoods.com/>

1 What innovative ingredients or advancements do you offer that support cognitive health?

Several of our developments are targeting healthy aging which include cognitive health as a key point to maintain an active and independent life.

ASTAGILE™ microcapsules, our most recent development, is based on the powerful antioxidant astaxanthin, which can cross the haemato-encephalic barrier and exert its function in the brain. Other ingredients such as CURCUSHINE™ microcapsules and MAGSHAPE™ microcapsules are reported of interest for cognitive and mental wellbeing.

2 What type of research and scientific studies support the use of these ingredients, and can companies use this to make substantiated claims?

Several in-vivo tests have been conducted with ASTAGILE™

microcapsules to assess its effectiveness on the protection against cognitive alteration, memory enhancement and mental sharpness with positive results. Also, histological analyses of neuronal tissues to see its mechanism of action at the cellular level have been done demonstrating the protection exert in the brain.

Claims regulation is different by country or region, in any case, all the studies of our branded ingredients are designed and executed under a scientific approach and are at the disposal of our customers to support final product positioning and claims.

3 How do you define your company's point of differentiation and advantages in the market?

Lipofoods, the nutraceuticals division of Lubrizol Life Science Health, develops and produces branded ingredients with added value, solving technical issues as well as improving its functionality and health benefits. Our pipeline is constantly updated to meet health industry and customers' needs. Lipofoods market knowledge, core microencapsulation technology, and science-backed products enable our customers to develop premium and market-leading performance functional foods & dietary supplements.

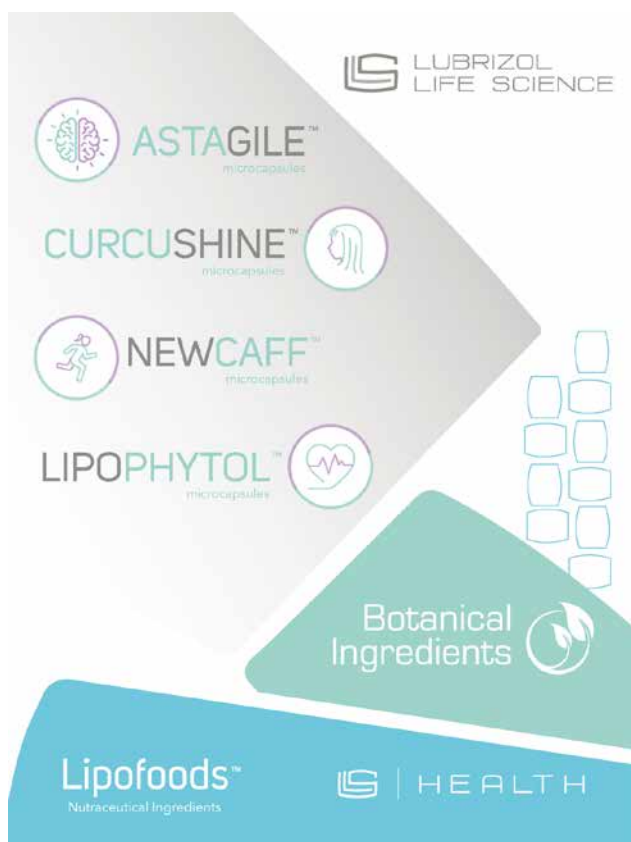
For us, naturalness and environment care are a must in all our developments. An example of that is ASTAGILE™ microcapsules which is based on natural antioxidant bioactive algae ingredients ECO certified.

4 What support do you provide to companies looking to develop new delivery systems or formulations in the cognitive health space?

All our branded ingredients have been tested in different applications and we support our customers in their developments. Some benefits of using Lipofoods microencapsulation technology include controlled interactions with other components, minimized unpleasant taste, enhanced bioavailability and bioactivity, improved stability and dispersibility as well as controlled release of functional ingredients. Consequently, easy enrichment of various types of applications is enabled.

Our ingredients are backed by science and we share all the studies with our customers to support the positioning and reliability of their products by helping them to meet the growing demand for information on products and ingredients from prescribers and end consumers.

Summarizing, we create value for our customers through our fully integrated support on regulatory, formulation, processing issues and health efficiency studies.



About Vitafoods Insights

Vitafoods Insights is a community-powered knowledge platform designed to help the industry connect, develop and progress. Bringing together the best nutraceutical minds, we focus on the trends and market developments that matter. Championing knowledge with purpose, we publish content that drives better business solutions for industry professionals.

CONTENT TEAM

Heather Granato

VP content, Health & Nutrition

heather.granato@informa.com

Charlotte Bastiaanse

Associate editor

charlotte.bastiaanse@informa.com

SALES TEAM

Gareth Morris

Head of sales

gareth.morris@informa.com

SALES MANAGERS

Cem Tuna

cem.tuna@informa.com

David Lewis

david.lewis@informa.com

ACCOUNT MANAGERS

Ash Shirkhan

ash.shirkhan@informa.com

Matthew Pickett

matthew.pickett@informa.com

Misbah Harun-Popat

misbah.harun-popat@informa.com

Pooja Sanghera

pooja.sanghera@informa.com

SALES EXCELLENCE TEAM

Maria Sidiropoulou

Sales excellence manager

maria.sidiropoulou@informa.com

Stephanie Campos

Client success executive

stephanie.campos@informa.com

Aimee Went

Sales operations executive

aimee.went@informa.com

Zeena Kakavand

Sales operations executive

zeena.kakavand@informa.com

MARKETING TEAM

Daniela Elia

Head of marketing

daniela.elia@informa.com

Louise Mather

Marketing manager

louise.mather@informa.com

Tanya Nazarova

Digital marketing manager

tanya.nazarova@informa.com

DESIGN

Katie Dove

Senior content design manager

David Allen

Senior content design specialist

INFORMA MARKETS

Fred Linder

President

Chris Lee

Managing director GHNN Europe

Dan Wu

Brand manager

Danielle Dunlap

VP marketing services

Published by

Informa Markets

240 Blackfriars Road

London SE1 8BU

United Kingdom

Phone: +44 (0) 20 7921 5000

Website: vitafoodsinsights.com

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