

# Brain POWER

Ingredients and  
innovation for  
cognitive health



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Poor modern lifestyles have given rise to sleep, stress and cognitive concerns. Over the years, there have been positive strides and discoveries that provide hope to the consumer and allow the industry to provide benefits and commercialise opportunities. **David Foreman** reveals statistics driving the interest in cognitive products, as well as emerging ingredients and formulation recommendations for market success.

### 7 Are we being smart about ingredient sourcing?

Functional ingredients targeting cognitive health are showing a resurgence in innovation interest, especially in light of the growing understanding of the gut-brain axis. However, manufacturers are challenged by a market fraught with false, misleading and even illegal claims. **Thomas Hayes** advises businesses on how to avoid pitfalls when sourcing ingredients for the cognitive market.

### 10 Innovation for insomnia

The rise in sleep disturbances amongst the general population has driven significant growth for natural sleeping aids. With sleep products expected to be one of the fastest growing categories in dietary supplements in the coming years, businesses interested in this space will want to capitalise on product opportunities as soon as possible. **Aurore Chemineau** investigates the particular issue of insomnia and identifies how businesses can innovate to drive new solutions.

### 13 Takeaways



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# Peace of mind

**These days**, the number of people who can say that they are truly satisfied with their sleep health and mental performance are few and far between. It's unsurprising given the realities of modern lifestyle. Career demands are huge drivers of stress, screen time is at an all-time high, depression cases are rising globally, and many people struggle to shut down in the evening and get a good night's sleep. I know I'm not alone in saying that a bad night's sleep can quickly impact our mood the next day, our work performance and our ability to retain information.

On the tail of that, cognitive health has conventionally targeted the ageing brain, but today's market has grown to include new areas. High stress, lack of concentration and low energy levels are driving consumers to take action. While synthetic drugs treating cognitive concerns have been on the market for decades, consumers are aware of the negative side effects of long-term use, which has deepened the search for natural alternatives.

Botanical ingredients have made huge strides in the cognitive health market, and manufacturers are increasingly interested in unlocking their further potential. David Foreman highlights new and emerging botanicals and formulation recommendations on [page 4](#).

As irregular sleep patterns continue to develop, so too does demand for sleeping aids. However, most people can't access synthetic sleeping pills without a prescription and those who can know the consequences associated with long-term reliance. Although the market for natural sleep aids is large, innovation has gone quiet as manufacturers continue to concentrate on known science. Aurore Chemineau points out the interesting ingredient potential and a clinical study surrounding the stress hormone, cortisol ([page 10](#)).

Lastly, while consumers are concerned about their cognitive health, manufacturers are worried about sourcing reliable ingredients from honest suppliers. The class for nootropic functional ingredients is challenged with products bearing false and sometimes even illegal claims. Thomas Hayes cautions manufacturers to choose their collaborative partnerships carefully and to up their demand for scientifically-validated research.

The nootropic market across the APAC region is attracting some serious attention, so if you're interested in tapping into this sweet spot, be sure to register for Vitafoods Asia – and especially the mental wellbeing conference session.



*Charlotte Bastiaanse*

**Charlotte Bastiaanse**

**Associate editor, Vitafoods Insights**

+44 (0) 20 337 73472

[charlotte.bastiaanse@informa.com](mailto:charlotte.bastiaanse@informa.com)

# Emerging ingredients

## Formulation & delivery formats for sleep, stress and cognitive health

By David Foreman

It's no shock that the areas of consumer interest on the rise are those that impact our mental health. The everyday stresses of life, poor lifestyle decisions, and an ageing population are fueling significant growth. To stand out among the glut of functional foods and supplements, it's critical to be as innovative as possible when designing your finished product. Before diving into the three areas, let's look at the numbers driving this massive interest in 'mind-health' products.

### Sleep

- Adults who were short sleepers (less than seven hours of sleep per 24-hour period) were more likely to report being obese, physically inactive, and current smokers compared to people who got enough sleep (seven or more hours per 24-hour period).
- Adults who were short sleepers were more likely to report 10 chronic health conditions compared to those who got enough sleep.
- Adolescents need 8 to 10 hours of sleep per night. But, more than two-thirds of U.S. high school students report getting less than eight hours of sleep on school nights
- 50 million to 70 million Americans have a sleeping disorder.

### Stress

- Clinical anxiety affects 10% of the population in North America, Western Europe and Australia/New Zealand.
- Stress is a top health concern for U.S. teens between grades 9 and 12; psychologists say if they don't learn healthy ways to manage that stress now, it could have serious long-term health implications, according to the American Psychological Association.
- Stress levels in the workplace are rising with six in 10 workers in major global economies experiencing increased workplace stress; workers in China (86%) report the highest rise in workplace stress, according to The Regus Group.
- Approximately 13.7 million working days are lost each year in the U.K. as a result of work-related illness, at the cost of £28.3 billion per year, according to the National Institute for Health and Clinical Excellence.

### Cognitive

- One in nine Americans aged 45 and older say they are experiencing thinking declines.
- Among those aged 45 and older who live alone, 14% said they were suffering from declines in mental function.

### Where does the potential lie?

The numbers above can be a bit frightening. Luckily, there have been positive strides and discoveries that provide hope to the consumer and allow the industry to provide benefits and commercialise opportunities.

When taking a closer look at each area, several botanical extracts are rising to the top due to their sound clinical research, efficacy, and relatively good safety profiles. Without going into too much detail, suffice it to say each one of these ingredients deserves a second look.



### Sleep

Of the three areas, sleep is perhaps the most uninteresting, as there hasn't been as much discovery as in the stress and cognitive categories. Some of the 'old but gold' ingredients continue to prevail with ongoing sound research and should still be considered. Among the top ingredients to consider for sleep are melatonin, magnesium, hemp oil (phytocannabinoids), Lactium®, L-theanine, valerian root, passion flower, 5-HTP and even kava. When considering formulation, the best approach would be to consider a blend of two or more of these ingredients at a therapeutic dose, which can be found in literature.



### “ Several botanical extracts

are rising to the top due to their sound clinical research, efficacy, and relatively good safety profiles

### Stress

The area of stress can and should be the primary focus for consumers and formulators. Stress is at the root of both sleep and cognitive issues. There are some relatively new ingredients that provide clinically-proven benefits related to stress. This list includes: ashwagandha (Sensoril® or KSM-66®), Zembrin®, Rhodiola rosea, hemp oil (phytocannabinoids) and bacopa. Outside of these are established golden ingredients: magnesium, vitamin B-complex, valerian root, passion flower, L-theanine and several others. Formulating products that provide a blend of these ingredients would be best. Finding the ones that offer different and unique benefits together to provide a 'shotgun' approach will achieve the greatest results. An example of such a combination would be Zembrin and rhodiola, plus a B-complex with magnesium.

### Cognitive

Cognitive function is a hot area of interest, within which there are some great ingredients. For this section, formulators need to hone in on more than the ageing brain—more so on focus, concentration and recall. The ingredients that appear to shine in this category are: Sibelius® sage, bacopa, CeraQ®, PQQ, Zembrin, Sensoril, Cereboost, Zynomite®, phosphatidylserine (PS), Alpha-GPC, and even omega-3s. Combine these ingredients with nutrients known to support the nervous system, such as B vitamins or magnesium, and the result will be a blend geared toward supporting cognitive health.



### Consumer pill fatigue

Regardless of the new and older ingredients, consumers are developing pill fatigue, which is driving innovation. Of all these, liquids and lozenges were some of the first formats the industry went to as it was something different to offer consumers within the pharmaceutical market. Since then, gummies and chews have taken off with great interest and impressive growth. While these formats are still popular, taking innovation to a whole new level is required to make products more appealing and stand out amongst the competition. Of these, thin films, packets, sachets, countertop liquid dispensers (Tespo for example), and effervescent may be the future formats of choice. However, each one of these selections as well as ones that have been around for years pose limitations. Dosing, stability, packaging, and shipping will all need to be considered when determining optimal delivery method.



There is great hope for providing new and clinically proven functional foods and supplements that address some of the most popular health concerns of this and the next decade. Consumer awareness and education is driving innovation in product formulation while pill fatigue is driving the innovation in how these ingredients are delivered; it's an exciting time to be in this industry! ●

*David Foreman, RPh, ND is a pharmacist, author, television commentator, radio host and practitioner of natural living and holistic approaches to better health. His focus is to use all forms of media to educate on the benefits of herbs, vitamins, healthy lifestyle choices and the role they play in health. David is currently a part of the Scientific Advisory Board for Organic & Natural Health Association.*

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## Drawing the line

### Are we being smart about sourcing ingredients for cognitive health?

By Thomas Hayes



**Functional ingredients targeting** cognitive health (nootropics) are becoming top of mind in today's growing market. Lux Research's Tech Signal tends to agree, showing a resurgence in innovation interest within the space after a lull around 2011:



Figure 1: Innovation interest over time for ingredients targeting cognitive health as measured by the Lux Tech Signal.

### Market growth areas

Lux sees three main drivers helping propel this resurgence:

#### Isolation and formulation of plant extracts

Phytonutrients, some with ties back to traditional Chinese and Ayurvedic medicine, are finding their way onto the ingredient lists of packaged goods. These extracts are typically blended with others, along with vitamins, amino acids, and/or other small molecules. This is precisely

what companies like Senescence Life Sciences, AlphaGen NZ (Ārepa), Brain Forza, and Neuro-hacker Collective are doing.

## Growing understanding of the gut-brain axis

Although most of the focus has been on improvement of mood rather than cognitive performance, the work being done by the likes of University College Cork, the Catholic University of Leuven, and Bened Biomedical is paving the way to understanding the relationship between the gut microbiome and mental health more broadly.

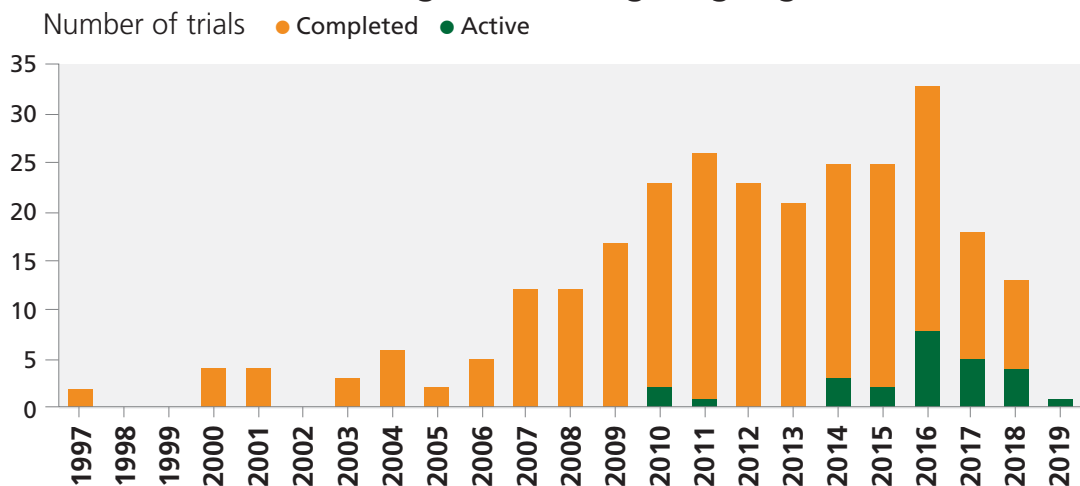
## Development of on-the-go delivery formats

Though most nootropics remain in powder or pill form, beverages are becoming more popular, particularly in small-volume 'shot' form. Nerv is a prime example of this, targeting college students with busy lifestyles. ZBiotics also employs the same beverage form factor, in a product that attempts to indirectly improve cognition by preventing hangovers.

## Legitimacy challenges

Unfortunately for earnest developers, this class of functional ingredients (among others) is fraught with false, misleading, and even illegal claims. In 2019, this was highlighted by a \$26 million settlement between the U.S. Federal Trade Commission and a group of corporate entities for unsubstantiated claims. Many of these developers lean on semipseudoscience, relying mainly (or completely) on marketing tactics to gain sales. To add to the challenge in gaining legitimacy, the number of clinical trials to provide sound, science-driven claims is extremely limited and looks to be waning:

### Clinical trials around ingredients targeting cognitive health



**Figure 2: Active or completed clinical trials around ingredients targeting cognitive health. The years on the horizontal axis are the start years of the trials.**

## Coming out on top

So, how can your organisation succeed? First, simply ignore startups that make exaggerated and borderline-fraudulent (if not entirely fraudulent) claims. Second, engage with industry members that have built out clinical evidence. Third, collaborate with leading research



universities. There's no point in making any move where risk greatly outweighs reward, so there's no need to engage with flashy startups that are clearly exaggerating the science. Instead, by looking to leaders in both the industry and research communities, companies can source credible ingredients at scale today while allowing for development of a pipeline with a long-term view. In terms of industry, DSM, Unilever and Bayer are front-runners, with six, five, and four relevant trials, respectively (all other companies have two or fewer). DSM is especially making a push into this space, forming a partnership in June 2019 with SLS Nutraceuticals, a subsidiary of the aforementioned Senescence Life Sciences. With regard to academia, Northumbria University in the UK is a go-to, sitting atop the leaderboard with 32 studies (all others have 10 studies or fewer). Not only is the university generating the most clinical evidence, but it is conducting research reflective of all the drivers spurring innovation interest in this area.

### Future expectations

Going forward, we expect pseudoscience startups offering 'nice-to-have' products to diminish, succeeded by those providing credible products with more concrete value propositions and more legitimate claims. Look to large ingredient companies, working either alone or in tandem with reputable partners, to provide these credible products.

With respect to value propositions, the focus will shift from optimisation to prevention. In other words, instead of aiming to give someone an extra mental edge, products will target clinical endpoints around curbing cognitive decline. This will be driven by the need to create solutions for the 'superageing' demographic, particularly relevant to APAC consumers. Organisations should make moves that align with this future science-based direction and not get entangled in the hype that surrounds the space today. ●

*Thomas Hayes is an analyst at Lux Research. His focus lies within the health and nutrition space, delivering market insights and propelling growth and product development for businesses.*



# Innovation for insomnia

## The potential for cortisol in the sleep aid market

By Aurore Chemineau



**The health and wellness** trend that is taking root across the world. Today, it's not just a matter of diet or exercise, it's also taking care of targeted areas of concern—and mental health has become an integral area of consideration.

### Market growth

Dietary supplements with mental wellbeing claims have shown growth and offer further potential. In 2018, 24-30% of European dietary supplement consumers bought capsules or pills to help boost their mental health.<sup>1</sup> Mood, stress and sleep products rank highly among the most growing segments in the European dietary supplements market.<sup>2</sup>



“**Sleep aids** are expected to be one of the fastest growing categories in dietary supplements in the coming years.

Western and Asian consumers are further seeking natural sleeping aids as sleep disturbances increase. The market of traditional sleep aids reached \$1.3B in 2018 with 51% of the market in Europe; it is expected to reach \$1.5B by 2022. New product developments have seen significant growth with an increase of 47% from 2016. Sleep aids are expected to be one of the fastest growing categories in dietary supplements in the coming years.

### Affected demographic

Sleeping disorders affect nearly 30% of the adult population and 20-30% of children from infancy to 18 years old.

Insomnia, common amongst most with sleeping disorders, is defined as one or more of the following symptoms:

- Difficulty falling asleep;
- Difficulty staying asleep with multiple wake-ups;
- Early awakening;
- Non-restorative sleep; and/or
- Poor quality of sleep.

Insomnia may present decreased sleep efficiency or decreased total hours of sleep with an increase in sleep latency (the time between going to bed and falling asleep). Because sleep requirements vary from person to person, quality of sleep is more important than the total number of hours slept.

Continued sleeplessness can have a negative impact on health, resulting in increasing risk of depression and high blood pressure. It can also lower quality of life, affecting fatigue, emotional weakness, lack of energy and mood swings to name a few.

Insomnia contributes to increasing healthcare costs and has become a public health concern.

There is an increase in people reporting insomnia, which is likely related to modern lifestyle aspects such as increased work stress, family management and high mobile usage. Rising stress levels often lead to the development of sleep disturbances, which further leads to fatigue and decreases the ability to cope with daily stress, creating a vicious circle.



Nothing helps recovery more than a good night's sleep. Consumers battling short sleep cycles, high stress and mood swings due to insufficient rest will seek out natural remedies to improve their quality of sleep. With higher incidences of sleep disturbances, the market has an opportunity to commercialise on natural solutions.

## Delivery format and ingredient development research

Cortisol is one of the stress hormones that influences sleep function. Its secretion is cyclic, reaching a peak in the morning and gradually reducing during the day. For a person battling stress and anxiety, cortisol remains at high level and induces sleep disturbances.

The research into food supplements geared toward sleep looks for a natural ingredient with health benefits, but without side effects. The objective is to improve sleep quality but without drowsiness or habituation of the ingredient compared to synthetic drugs.

To develop a product that targets sleep issues, it's worth taking a closer look at the cortisol release. Reducing the amount of cortisol produced by stress during the day can have an indirect impact on sleep quality. ●

## Case study: Clinical study for sleep management

As an example, Lactium®, a natural ingredient developed by INGREDIA SA, has shown a reduction of cortisol release after a stress event, in several clinical studies, leading to a new clinical study of sleep management.

This clinical study was carried out by NOVAREX involving 48 Korean volunteers between 20 and 60-years-old and suffered from poor sleep quality. Volunteers were recruited by following the Korean Pittsburg Sleep Quality Index (PSQI-K>5 and Insomnia Severity Index (ISI<22).

NOVAREX carried out a double-blind, randomised cross-over trial. The duration of the supplementation was four weeks. Either Lactium (300mg) or placebo capsules were administered during the study. Subjective (i.e. sleep agenda) and objective parameters (i.e. actigraphy and polysomnography) were used to evaluate the ingredient's effect on sleep quality.

After four weeks of supplementation, the volunteers demonstrated an improvement in their sleep quality. Lactium administration appeared to have helped extend the total sleep time by almost 10% compared to placebo.

Both subjective and objective parameters showed improvements of sleep efficiency by 10.5% and 5% respectively. Sleep latency was reduced by 54% and the night awakening by 30% for the Lactium group. This study provides additional evidence of the sleep-promoting effect of cortisol reduction, offering insight and potential for future product development of natural sleep aids.

*Aurore Chemineau is Europe Marketing Manager at INGREDIA SA. She been worked in the food industry among for more than 15 years, 10 of which she spent in B2B marketing.*

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## Takeaways for your business

**The nootropic market** has boomed in recent years – especially across the European and APAC regions. The areas attracting the greatest interest are sleep, stress and cognitive health. Consumers continue to seek out natural alternatives to conventional synthetic drugs. Ingredients like ashwagandha, bacopa, rhodiola and hemp are known for their proven benefits, but while established ingredients have certainly cemented their place in the market, new research is paving the way for new entrants.

Several botanical extracts are floating to the top due to their sound clinical research, efficacy, and relatively good safety profiles. There is untapped potential in complementing older ingredients with newer ones to drive new combinations. While pill fatigue spans the entire dietary supplement market, smart formulation can only accelerate innovation surrounding botanical supplements. Beyond tablets and capsules, liquid shots, lozenges, sachets, thin film and gummies are certainly formats worth considering in order to keep up with the general direction of the industry and consumer demand.

Out of the main target areas, sleep is probably the most uninteresting of the three as innovation over the years has remained relatively cool. That's not to say demand for natural sleep aids hasn't grown with the rise of sleep disturbances, like insomnia, amongst the general population. The market of traditional sleep aids reached \$1.3bn in 2018 with 51% of the market in Europe; it is expected to reach \$1.5bn by 2022. Products offering new development are booming in the otherwise quiet market, showing a growth increase of 47% from 2016. The time to wake up the sleep market is now. An interesting new bit of research surrounding cortisol presents promising findings. Cortisol is one of the stress hormones that influences sleep function. Its secretion is cyclic, reaching a peak in the morning and gradually reducing during the day. For a person battling stress and anxiety, cortisol remains at high level and induces sleep disturbances. To develop a product that targets sleep issues, it's worth taking a closer look at the cortisol release. Businesses broadening their search for solutions – like cortisol – will quickly find themselves at the top of the competition.

Unfortunately for earnest developers, the cognitive health class of functional ingredients is challenged with false, misleading, and even illegal claims. The number of clinical trials providing provide sound, science-driven claims is currently limited. To weed out fraudulent suppliers, brands will have to tighten up their demand for clinical evidence – especially as consumers become stricter about scientifically-backed claims. Collaborating with reputable businesses, partnering with research universities, and looking to industry leaders will help to prevent any dire pitfalls that could seriously harm a business.

It's an exciting time for the cognitive health market as new research and science sheds light on innovative solutions – all geared toward taking care of the population's mental wellbeing. ●



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**Jon Benninger**  
**Vice President & Market Leader,**  
**H&N SupplySide Portfolio**

[jon.benninger@informa.com](mailto:jon.benninger@informa.com)

**Heather Granato**  
**Vice President, Content**

[heather.granato@informa.com](mailto:heather.granato@informa.com)

**Danielle Dunlap**  
**Vice President, Marketing Services**

[danielle.dunlap@informa.com](mailto:danielle.dunlap@informa.com)

**Andrew Rosseau**  
**Art Director**

**Madison Dorn**  
**Program Coordinator**

**Informa Markets**  
**2020 N. Central Ave, Suite 400**  
**Phoenix, AZ 85004**  
**United States**

**Phone: +1 480 990 1101**

[www.naturalproductsinsider.com](http://www.naturalproductsinsider.com)

**Chris Lee**  
**Managing Director, GHNN Europe**

[chris.lee@informa.com](mailto:chris.lee@informa.com)

**Gareth Morris**  
**Head of Sales**

[gareth.morris@informa.com](mailto:gareth.morris@informa.com)

**Maria Sidiropoulou**  
**Client Success Manager**

[maria.sidiropoulou@informa.com](mailto:maria.sidiropoulou@informa.com)

**Stephanie Campos**  
**Client Success Executive**

[stephanie.campos@informa.com](mailto:stephanie.campos@informa.com)

**Charlotte Bastiaanse**  
**Associate Editor**

[charlotte.bastiaanse@informa.com](mailto:charlotte.bastiaanse@informa.com)

**Informa Exhibitions**  
**240 Blackfriars Road**  
**London SE1 8BU**  
**United Kingdom**

**Phone: +44 (0) 20 7921 5000**

[www.vitafoods.eu.com](http://www.vitafoods.eu.com)

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