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# Nutritional<sup>®</sup> OUTLOOK

The industry resource for dietary supplements  
and healthy foods & beverages

November 2021  
Vol. 24, No. 9

## Greatest *of* Care

Studying infant and children's supplements is serious business

**PLUS**

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A Win for GRAS

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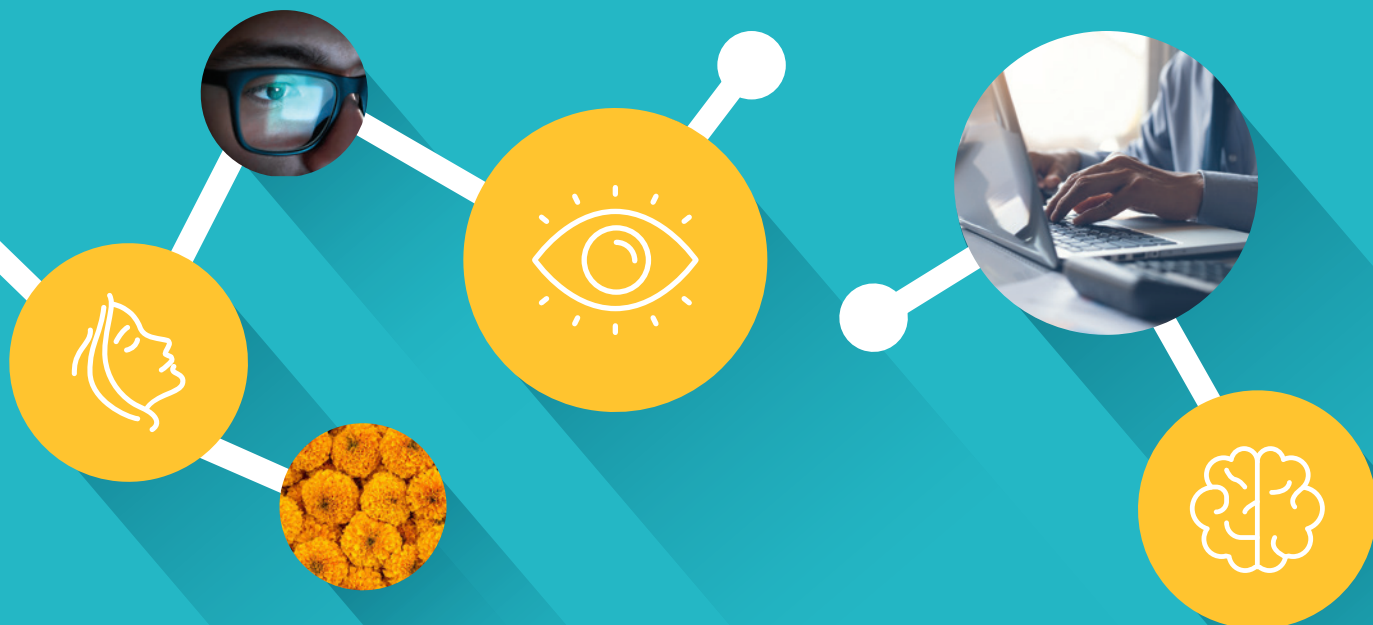
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leading trends, ingredients, evolving science,  
business strategies, and more!



## CHAIRMAN'S LETTER

### Five to Watch

Predictions are rolling in for which ingredients and health categories will track in the coming year. (Note: Look out for *Nutritional Outlook's* annual Ingredients to Watch forecast in our January/February issue.) Market researcher Mintel gave us a look at five major health categories it's keeping an eye on. It presented this snapshot in October during the Vitafoods Europe trade show.

Immune health, unsurprisingly, came in at number one. Will immune health purchases trail off once the pandemic is over? According to research Mintel did in Europe in March 2021—at a time when the pandemic was subsiding—results showed 28% of French and 32% of German consumers said they were consuming *more* food and drink products that support the immune system, said Mintel speaker Emma Schofield, associate director, global food science. With this in mind, she said, “Immune health has a potential to become more relevant to consumers even after the pandemic finally does subside.” This bodes well for ingredients like vitamin C, echinacea, medicinal mushrooms, probiotics—and even postbiotics, which Schofield said “have potential to really emerge and grow in the immune health space.”

Other categories to watch include eye health, whose audience will expand beyond those concerned with age-related eye disease to those concerned about the impact of staring at digital screens; mental wellbeing, which has gotten a lot of attention during the pandemic and is increasingly prioritized as a health determinant; weight management—again, with the pandemic highlighting a link between COVID-19 and weight-related conditions; and, finally, healthy aging, which everyone is more mindful of especially two years into a global health crisis.

While none of these health concerns is new, data like Mintel's emphasize how consumers globally are pursuing wellness and preventive health, and how industries like ours can serve their purpose.



**Mike Hennessy, Sr**  
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# More Than Just Sex



When a scientist involved in landmark nutrition studies says there's a problem with clinical trials, you sit up and you listen.

The trouble has to do with how we factor in sex differences when designing clinical trials and interpreting their results, said Howard D. Sesso, ScD, MPH. Sesso speaks from experience. As the associate director of the Division of Preventive Medicine at Brigham and Women's Hospital, and associate professor of medicine at Harvard Medical School, he's been part of such pivotal nutrition studies as the Physicians' Health Study I and II and the Women's Health Study. Sesso shared his thoughts about clinical trial design on October 19 during the Council for Responsible Nutrition's Science in Session conference.

"When we think about dietary supplements and a lot of the large-scale and smaller-scale clinical trials that have been done," said Sesso, "the notion of how sex factors into those results, I would actually say, has been lost, unfortunately."

First, there's the problem of restricting studies to a single sex population, Sesso said. While studies like the Physicians' Health Study and Women's Health Study—which still stand as well-designed, well-conducted clinical trials—focused on one sex only, you lose the chance to study the same outcome in the other sex. Why does this matter? "By limiting the results to predominantly men, or just men, or just women, we lose the value of subgroup analysis," Sesso explained.

Subgroup analysis matters because it gives us a window into how the intervention performed in other populations. And it extends beyond gender, Sesso said. The same goes for differences in age, race and ethnicity, nutrition status, diet, body weight, and many other factors that help us richly contextualize results. By not diversifying and building adequate subgroups into a study, "the problem is you wind up with results that are pertaining to one group but not the other, or [just] a certain age range," he said.

There's also the practical drawbacks of limiting a study—including wasted time and money surely to get decision-makers' attention. Say a study done in men shows promising results that researchers realize should also then be explored in females. Researchers have to initiate an entirely new study, which they could have avoided by including both sexes from the get-go. Sesso said this happened in the case of the Physicians' Health Study, which was conducted in men but then ultimately extended to women. This was "not the most efficient way to do it," he said. "It should have really been done all at once in some capacity."

Then there's the problem of not digging deeply enough into data to show how study results applied to different subgroups, such as how interventions might have impacted men and women differently. This is especially the case with meta-analyses, Sesso said. "Where is the separation by men versus women, by age, things like that? Those are things that are just not emphasized enough in these meta-analyses."

He lamented: "We focus on the overall picture and not the specifics." And these specifics matter. They matter in terms of how we understand and apply study results. They matter in how we make public health recommendations for the broad population.

They also matter when comparing results of different clinical trials in order to make broadscale conclusions—and, indeed, to move nutrition science forward. If more studies were designed more similarly and to include more subgroups, their results could be more easily stacked against each other. "Whether we're looking at large-scale trials or small-scale trials, they need to complement each other in much more direct, functional ways," Sesso said. "There's just too much heterogeneity...across these trials over the course of time that have made it difficult to put together a really sound recommendation."

"In the past, what we've done with our trials is we've been too limiting, frankly. We've focused on intervention and clinical outcomes and didn't build in the mechanisms simultaneously so we could roll a number of different trials together," he concluded.

The good news is we're learning to avoid these obstacles. Sesso pointed to VITAL (the VITamin D and Omega-3 Trial) and COSMOS (the Cocoa Supplement and Multivitamin Outcomes Study). Here, researchers purposefully embraced more subgroups. "Our more recent trials that we've done have included both men and women so we can actually look directly at effect modification by sex, by age, and other important components," he said, "so that when you do a trial, you can actually test the same intervention in a wider swath of people."

Sesso's hope is that we can "start to flip the script a bit" and factor in these considerations when designing studies. "We've been doing it backward," he said. By designing studies more holistically, we may find promising results in some, but not all, of the subjects—and then we can follow up with those likely to see benefits. But if we're not looking at those subjects in the first place? It's likely we're missing a valuable piece of the puzzle.

**Jennifer Grebow**  
Editor-in-Chief



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## ON-DEMAND WEBCAST

Aired: Tuesday, March 16, 2021

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### Webcast Overview

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- Learn about the various challenges growers face in meeting current regulations
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- How to control THC limits and achieve repeatable outcomes in your plants

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- Product Development
- Marketing / Creative
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- Cultivators/Growers

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# A Win for GRAS

A new court decision sides with the Generally Recognized as Safe process.

BY SEBASTIAN KRAWIEC, EDITOR



A recent decision by the United States District Court of the Southern District of New York upholds the legality of FDA's GRAS (Generally Recognized as Safe) process. In a lawsuit against the Department of Health and Human Services (HHS), and FDA, originally filed in 2017, the Center for Food Safety, Breast Cancer Prevention Partners, the Center for Science in the Public Interest, the Environmental Defense Fund, and the Environmental Working Group moved for a summary judgment on the grounds that "the GRAS Rule (1) unlawfully subdelegates FDA's duty to ensure food safety in violation of the United States Constitution (the "Constitution"), the Administrative Procedure Act ("APA"), and the Federal Food, Drug, and Cosmetic Act ("FDCA"); (2) exceeds FDA's statutory authority and constitutes arbitrary and capricious agency action in violation of the FDCA and APA; and (3) conflicts with the FDCA."

The defendants—Xavier Becerra, secretary of HHS, and Janet Woodcock, acting commissioner of FDA—made a cross-motion for summary judgment arguing that "the GRAS Rule is a lawful exercise of FDA's authority under the FDCA, and is not unconstitutional."

One of the main criticisms of the GRAS rule is that independent conclusions of GRAS lack transparency and are inherently a conflict of interest. Prior to the GRAS final rule, FDA instituted a voluntary GRAS affirmation process in which manufacturers would ask the agency to affirm an ingredient's GRAS status. This was a resource

intensive process. In 1997, FDA replaced this process with a notification procedure whereby FDA could be notified of a conclusion that a particular use of a substance was GRAS. In 2010, the Government Accountability Office (GAO) published a report urging FDA to "(1) strengthen its oversight over GRAS substances by finalizing the 1997 proposed rule; (2) minimize conflicts of interest in GRAS assessments performed by third parties; and (3) require any company that conducts a GRAS determination to provide FDA with basic information about this determination, such as the substance's identity and intended uses."

In 2016, the final GRAS rule codified the voluntary notification process mentioned previously. Consequently, the initial action filed by the plaintiffs on May 22, 2017, sought a declaratory judgment that the GRAS rule, "(1) violates fundamental principles of separation of powers; (2) exceeds FDA's statutory authority; (3) does not accord with the law; (4) is arbitrary and capricious; and (5) is an abuse of discretion."

Ultimately, U.S. District Judge Vernon S. Broderick agreed with the defendants and denied the plaintiffs' motion, upholding the current GRAS framework. In his opinion, Broderick acknowledges some of the plaintiffs' concerns but writes that FDA's GRAS rule does not conflict with the FDCA, and represents a reasonable interpretation of the law. "Certain portions of the Record cited by Plaintiffs raise an issue inherent in this case—the increase in processed foods and food additives...I am cognizant of this

reality, and of the fact that circumstances have changed since the enactment of the Food Additives Amendment. Still, as was recognized by both FDA and GAO, it remains unclear under the statute whether FDA even has the authority to make GRAS notifications mandatory. I decline Plaintiffs' invitation to rewrite the statute. The remedy Plaintiffs seek lies with Congress, not me, and Congress has chosen not to act despite the increase in the number of food additives over the last five decades."

What happens now? While there was a recent bill (H.R. 3699) introduced to the U.S. House of Representatives that would significantly alter the GRAS process, it is unlikely to receive the necessary support to pass. The plaintiffs will likely appeal the decision, but FDA will then appeal that decision, dragging the legal process out even more.

"The court delivered a powerful message by reinforcing the legality of the self-affirmed GRAS process," says Ashish Talati, partner at Amin Talati Wasserman LLP. "The court's ruling will be useful to companies that have invested substantial resources to establish the safety of their ingredients through self-affirmation of GRAS."

Michael McGuffin, president of the American Herbal Products Association (AHPA; Silver Spring, MD), echoed this sentiment. "This is an important decision that protects a regulatory option that many responsible suppliers use to bring safe ingredients to the U.S. market," he said. ■

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# Greatest *of* Care

The bar for studying infant and children's supplements is high—and so are the challenges.

BY JUDY BLATMAN

**T**he pandemic changed everything in our lives, but especially the way we view our health. Immune concerns took center stage, and the dietary supplement and functional food industry experienced big bumps in sales for ingredients and finished products believed to address those concerns. But what did the heightened awareness of immunity mean for parents? Did the sales trend translate to infants' and children's products?

For many companies in the industry, that answer is a resounding “yes.”

According to Sam Michini, vice president of marketing and strategy, Deerland Probiotics & Enzymes (Kennesaw, GA), “The undeniable rise in cases of COVID in children and the fear in parents that their kids may contract it has driven sales of any and all immune products for kids through the roof. And this is never really a bad thing—all parents want their children to have sufficient immune strength.”

It's also a “yes” from John Quilter, the vice president of global portfolio, proactive health, Kerry (Beloit, WI). He cites the numbers to back it up. A recent global consumer survey from

Kerry found that immune support is the number one reason why parents purchase healthier foods and beverages and nutritional supplements.<sup>1</sup>

For example, he notes that in the 12 months leading up to the end of November 2020, sales of children's multivitamins in the U.S. mainstream supplements market increased by 37.2% to \$306 million.<sup>2</sup> As Michini reminds us, “The largest-selling children's supplement is the multivitamin, according to *Nutrition Business Journal*.”

But it's not just the multivitamin that is experiencing growth in the children's market.

FrieslandCampina Ingredients (Amersfoort, The Netherlands) recently conducted a global insight study<sup>3</sup> with the support of registered healthcare practitioners in the U.S., China, and the UK, which revealed that 70% of pediatricians have prescribed dietary supplements such as minerals, and pre- and probiotics, to their patients over the past year, according to Sophie Nicolas, the company's marketing manager, early life nutrition.





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## The Pandemic: Just One Factor Pushing Immunity-Support Products

And it wasn't just the pandemic that was responsible for a growing interest in immunity concerns from parents for their children.

Quilter advises that “demand for immune health products for kids is very high, and that this long predates the pandemic. As any parent knows, keeping children healthy means more days spent together as a family, and fewer school days lost.”

As Henna-Maria Kailanto, PhD, senior scientist, IFF Health (New York City), explains it, while the growth in an overall broad concern about children's immunity grew even more during the pandemic, it actually reinforced the preexisting demand for children's immunity products.

Nicolas says FrieslandCampina has certainly seen growing interest in immune health solutions for the child and infant demographic, noting “it's natural for parents to want to protect the health of the ones they love most, and their concern will rise during times of greater risk.”

One of the things her company's recent global consumer research study uncovered<sup>4</sup> was that “in the U.S., 49% of parents of children aged 0-12 months are concerned about their infant's immune health, making this one of their biggest priorities overall.”

But like Quilter and Kailanto, Nicolas sees the pandemic as being only partly responsible for the growing interest in immunity. “This is not only because of heightened interest in immune health as a result of the pandemic, but also because mums and dads have long been seeing immunity-related symptoms in their child's first year of life,” she says.

She adds that “caregivers also have to contend with a huge variety of potential diseases and immune threats as children grow, including respiratory and digestive issues. So, no matter what is going on in the world, immunity will always be a priority.”

Michini raises another important point: “Adults who have felt or perceived success incorporating immune support supplements in their regimens are more easily encouraged to ensure their children follow suit as they believe in the value of immune support supplementation.”

## Scientific Research in Children Presents Challenges

With the increased interest in children's products for immunity comes an even greater responsibility to make sure that products are safe and do what they say they can do.

“Obviously when you're marketing products for children [and] infants, your target audience is the concerned parent who wants the absolute best for their kids,” says Kerry's Quilter, whose company makes Wellmune, a yeast beta-glucan for immune health. “That means that a demonstrable commitment to safety, scientific substantiation, openness, and transparency is of the utmost importance, even more than it is in products for adults.”

Quilter shares that Wellmune is supported by over a dozen published, peer-reviewed clinical studies, many of which have demonstrated benefits for kids specifically.

And while there are always challenges in conducting scientific research, somehow the challenges seem even greater when the research will be used as substantiation for the younger among us.

## Safety Is Top of Mind

For Kyle Krause, product manager, functional fiber and carbohydrates, North America, Beneo Inc. (Parsippany, NJ), “Safety is of the utmost importance.”

According to Krause, “The safety and efficacy of Beneo's prebiotic bioactive substances have been demonstrated for use in infants and small children.” In fact, he adds that these ingredients are some of the most studied on the market, resulting in their being trusted by those companies who are formulating for infants and children.

Safety is one of the reasons why it is important to Beneo to work with trusted academic partners, says Krause, those “who can provide both a safe environment for study and a non-biased view of the scientific study findings, while pushing the science forward in the field of gut microbiota in this age group.” He notes, “These are experts in their field and astute at discovering the most nuanced reactions to food ingredients.”

The safety aspect is not lost on anyone. Morgane Maillard, marketing group manager, Lallemand Health Solutions (Mirabel, Canada), says, “Health and safety are big

concerns when conducting clinical studies with infants and children, as these specific populations require higher standards.”

## Consent, Compliance, and Other Challenges

One of the challenges of conducting scientific research for products intended to be used by children and infants is the necessity to obtain parents' consent, says Maillard, “and then, to make sure there is good follow-through and good compliance during the length of the study.”

Conducting scientific research in the immune health category is always challenging, states Maillard, and is something she's keen to talk about. “Researchers can choose to look at beneficial effects on general health, such as the reduction of incidence of common cold-like symptoms, or to check the enhancement of immune defenses by considering the levels of immune competence and mucosal immunity markers.”

According to John Deaton, PhD, vice president of science and technology, Deerland Probiotics & Enzymes, there are two main challenges unique to research in the infant/children population. Dosage form is the first.

He points out the need to confirm “that your product is in a safe and desirable delivery format to ensure there is no potential for choking. Depending on the target age group, traditional tablets or capsules may not be options.”

In Deerland's clinical trials, Deaton has handled that issue by using highly stable ingredients— (the Deerland branded probiotic ingredient is *Bacillus subtilis* DE111)— which, says Deaton “has allowed us to use delivery formats like quick-dissolve stick-packs or gummies that may not be options for ingredients that are more susceptible to manufacture or storage stress. We've also utilized popular flavoring, like chocolate, to make dosing a desirable experience for children, and as such have seen almost perfect compliance.”

Deaton identifies “sampling” as the second unique challenge in infant and children's research. Whereas in immunity-focused clinicals for adults it is customary to evaluate immune markers (e.g., pro-inflammatory cytokines) in the blood or saliva, he says, it is often not “feasible or possible to get the

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*“As with infants, research into the effects of nutritional solutions on children is still a growing field,” says FrieslandCampina’s Sophie Nicolas.*

amount of blood or saliva necessary [with infants or children] to accurately make these measurements. Clinical trials in these populations often must be designed around other tests, including fecal microbiome analyses, and incidence and duration questionnaires.”

But even stool samples require special analysis considerations when it comes to infants and children. “Depending on what is being measured, it may be necessary to treat stool samples before analyzing to remove inhibitors,” states Deaton. “A healthy adult tends to have a stable and more established microbiome than children, in whom the microbiome is still developing. In these cases, it helps to look at microbiome diversity measurements and not just shifts in genera.”

IFF supplies several branded ingredients for children and immune health under its Howaru line, including Protect Baby, Protect Early Life, and Protect Kids, each featuring different probiotic strains. The company takes a number of steps to ensure safety when it comes to research for children, including following international Good Clinical Practice guidelines provided by the International Conference on Harmonization and ethical principles for medical research as identified by the World Medical

Association’s Declaration of Helsinki policy statement, says Kailanto.

One of the challenges with children’s research is compliance, she points out—making sure infants and children take the probiotic as required in the study. “We take this into consideration and ensure that caregivers are given instructions on proper administration of the study product,” she says.

FrieslandCampina’s Nicolas finds that in the infant category, “one of the biggest overall challenges is finding enough participants for clinical intervention studies, which represent the highest standard of research.” While noting that more women are choosing to breastfeed—something that FrieslandCampina fully supports—her company’s challenge is to “ensure that, when breastfeeding is not an option, the nutrition available to infants is of the highest quality.”

To meet that objective, Nicolas says, “in order to support recruitment for our studies, we are therefore moving towards multicenter trials more often.”

### **The Elephant...**

And perhaps among the biggest elephants in the children’s research room is when and how to use studies in other age populations.

Nicolas doesn’t shy away from that issue. “As with infants, research into the effects of nutritional solutions on children is still a growing field,” she says. “Children have a more varied diet than infants, which makes it more challenging to study the impact of specific health ingredients—they are a much smaller part of the complete nutritional picture.” She adds that therefore, in some cases, “we look into the possibility of extrapolating expected findings by translating scientific data from studies in other age categories. However, when health benefits are expected to differ in young children, we make sure to establish dedicated studies for that age category to confirm the health effects of our products.”

The quality of infant and young child formula is already high, so continuous improvement is a challenge, according to Nicolas. But, she says, FrieslandCampina has passion for that challenge. And excellent science, she adds, drives new thinking across the company’s product portfolio.

“When we study the potential immune health benefits of our ingredients, we ensure that every study group is of sufficient size to provide meaningful results. And we reinforce our own research with an extensive knowledge

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of and collaboration with the global academic community, including the world's leading researchers in the field," shares Nicolas.

## New Studies Added to Scientific Literature

Even with all the challenges involved in conducting research in this age demographic, companies continue to ensure they are investing in scientific research to back their immune support ingredients for infants and children.

A recent IRB-approved, randomized, double-blind, placebo-controlled clinical trial on Deerland's probiotic DE111 resulted in two published studies<sup>6,7</sup> in late 2020 and early 2021 with good news results.

The first showed that daily intake of the probiotic strain *B. subtilis* DE111 was able to introduce subtle but positive changes in the gut microbiome profile in children aged 2-6 years old and attending daycare, without changing the overall microbiome equilibrium.<sup>6,7</sup>

The second published study from the trial suggested that daily consumption of 1 billion CFU of *B. subtilis* DE111 supported a healthy gastrointestinal tract with a reduced duration of vomiting, hard stools, and overall gastrointestinal discomfort. The study was conducted in young children attending daycare. Additionally, it showed the probiotic is well tolerated and safe to use in children 2-6 years old.<sup>8,9</sup>

A new study published in 2021 suggested that supplementation with the probiotic combination *Lactobacillus acidophilus* NCFM and *Bifidobacterium lactis* Bi-07—two branded probiotic strains found in IFF Health's Howaru Protect Kids—can have a significant impact on a simulated viral immune response in blood cells collected from young children taking probiotics. The researchers suggested that further studies are needed to better understand the mechanism by which probiotics ameliorate symptoms in viral upper respiratory (and gastrointestinal) infections. Additionally, the study found that the probiotics product was safe and well tolerated.<sup>10,11</sup>

The study was a collaborative effort between IFF (formerly DuPont Nutrition & Biosciences) and the University of Wisconsin-Madison and was conducted in a population

of 21 children (with two dropping out) over a 30-day time period.<sup>10,11</sup>

The Rosell Institute for Microbiome and Probiotics by Lallemand published a comprehensive review<sup>12</sup> in June 2021 summarizing 28 clinical studies—with all but two covering the efficacy of Probiokid, Lallemand's multistrain probiotic ingredient with Rosell-52 (*Lactobacillus helveticus*), Rosell-33 (*Bifidobacterium infantis*), Rosell-71 (*Bifidobacterium bifidum*), and fructooligosaccharides (FOS). Infants from birth through up to seven years old were included in the trials.<sup>13</sup>

Among the conclusions reached by the authors was this: 12 studies showed that the probiotic ingredient significantly increased the efficacy of standard diarrhea treatment regardless of etiology, reducing the risk of unsolved diarrhea by 69%.<sup>12</sup>

The scientists further reported that in eight studies, the probiotic enhanced immune defenses—assessed by levels of various immune competence and mucosal immunity markers (six studies)—and reduced the incidence of common infections (two studies).<sup>12,13</sup>

The review also included safety data conducted on the three single strains separately.

Beneo expanded its chicory root fiber and rice starch ingredients portfolio in June 2020 with the addition of two new organic branded solutions: Orafit Organic and Remyline O AX DR (an organic waxy rice starch). According to Beneo, in a press release, "Consumers worldwide are increasingly seeking out organic products, with figures showing they have become more important to one in four consumers in the last year and many willing to pay a premium price for them."<sup>14</sup>

Remyline O AX DR was "the first of its kind to be brought to market, opening up new possibilities for product development," Beneo says<sup>14</sup>. Steven Gumeny, product manager, rice ingredients and functional proteins, Beneo, says that "rice is not only clean and natural; it is also incredibly functional. Research shows that parents appreciate seeing rice on the label as it has a natural perception<sup>15</sup>...and in addition, rice is easy to digest..."

Beneo also had good news on the science front. In a press release<sup>16</sup> from April 2021,

Beneo announced that a published study<sup>17</sup> demonstrated that the prebiotic fortification of infant formula milk with Beneo's oligofructose-enriched inulin was shown to reduce the duration of infections in the first year of a baby's life.

The infant formula in the study was either enhanced with 0.8 g/100 ml of Beneo's Orafit Synergy1, a chicory root-derived prebiotic, or an unsupplemented control formula. The findings demonstrated that the babies who consumed the Orafit Synergy1 formula had significantly shorter infection episodes compared to the control group.<sup>16,17</sup>

This study is part of the EARNEST (EARly Nutrition programming-long term follow up of Efficacy and Safety Trials) project, an EU-funded integrated initiative. This is the third study using the same dosage of Orafit Synergy1 showing safety, good tolerance, and health benefits, but it is the first long-duration trial to show these results, the company adds.<sup>16</sup>

FrieslandCampina's Nicolas says, "Nourishing the gut microbiota with oligosaccharides can support the infant immune system." She references a recent study<sup>18</sup> that adds to the body of literature showing that "oligosaccharides such as galacto-oligosaccharides (GOS) and human milk oligosaccharides (HMOs, which include variants such as 2'-FL, LNT, and 3-FL) have been shown to stimulate growth of *Bifidobacteria* by serving as a substrate."<sup>19,20,21</sup>

"This enables the outnumbering of pathogenic bacteria through competitive advantage," says Nicolas—a result demonstrated in another recent study.<sup>22</sup>



These two new studies are important, according to Nicolas, because "these underlying mechanisms of action have been connected with specific infant health outcomes such as showing a reduced incidence of infections in babies nourished with formula containing GOS."

FrieslandCampina's Vivinal GOS ingredient has been on the market for over two decades and comes supported by over 55 clinical studies, says Nicolas. The company also touts its Aequival range of human milk oligosaccharides (HMOs). "A lot of research is in progress investigating how gut healthy ingredients like HMOs and GOS can support infant immunity and more," she says.

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## Room to Grow for Children's Immune Products?

"At a time when consumers are more interested than ever in taking a preventative approach towards their own health and their children's health...it makes sense that the infant immune health category will continue to grow over time, meeting the needs of these consumers even after the pandemic has passed," says Nicolas.

Deerland's Michini sees children's immune support supplements becoming more of a mainstay in parents' care regimens. "The pandemic has taught parents—and young adults who will become parents—about how vulnerable even healthy people can be to a sudden epidemic or pandemic."

And just as the pandemic made us more comfortable with masks, hand hygiene, and other social behaviors driven by the crisis, Michini thinks that "consuming dietary supplements and functional foods/beverages that stimulate appropriate and strong immune functionality is going to become as routine for children as their multivitamins."

Kerry's Quilter advises, "The trend to watch is the growing consumer need for scientific substantiation, and the ingredients to watch are those that meet it. However," he adds, "it's not enough to rely on scientific evidence supporting a broad category; you have to be able to demonstrate the benefits of the specific ingredient."

IFF Health's Kailanto sees two trends that will make a difference in category growth: combination products and enticing kids to consume new products, taste, and texture.

"Overall," she says, "We see early-life immune health as a very promising segment since it is the first years of life that offer a window of opportunity to support immune system development and programming for future health."

Beneo's Krause agrees, stating that nutrition in early life is crucial for development, with implications throughout one's lifespan. "The focus on both infant and children's nutrition has a very promising future," he says, adding that "research available on clinically proven ingredients that can contribute to infant and children's nutrition is key." ■

**Judy Blatman Communications LLC specializes in strategic counsel, media training, writing, and talent solutions. Blatman is looking forward to resuming her volunteer work as a puppy socializer for the nonprofit Hero Dogs once the pandemic subsides.**

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# Diving DEEP

Omega-3 exploration unlocks a new world of benefits.

BY KIMBERLY J. DECKER

If any historians are already drafting their accounts of the pandemic's effect on supplement sales, it's unlikely they'll give omega-3 fatty acids the same coverage they will higher-profile immune boosters like vitamins C, D, and E, and zinc.

So it's probably a good thing that historians *aren't* yet writing that final analysis, as unfolding evidence continues to paint omega-3s as potentially powerful mediators of inflammation and the immune response in their own right.

In fact, the entire omega-3 space is bubbling with ferment as investigations into unanticipated health effects, "new" omega-3s, and a widening role for plant-based sources proceed—reminding consumers and industry alike that these fatty acids deserve a spot in the history books.

## Roller Coaster

Ellen Schutt, executive director, Global Organization for EPA and DHA Omega-3s (GOED; Salt Lake City, UT), describes omega-3 sales at the height of 2020's pandemonium as "a roller coaster," with the ride stabilizing only by

the year's fourth quarter and the category's overall take benefiting mightily from online purchases—a trend that "we expect to continue," she says.

Fortunately, the omega-3 market entered lockdown in a position of strength, adds Nena Dockery, scientific and regulatory affairs manager, Stratum Nutrition (Carthage, MO), and remained there throughout its progress, thanks to growing awareness that nutritional interventions "might either help prevent infection with the SARS-CoV-2 virus or offset some of the devastating symptoms of the disease," she says.

## Countering COVID

And while omega-3s haven't historically played a large part in such immune-support interventions, "Multiple research studies have investigated their role, either alone or in conjunction with other ingredients, on inflammation's link to immunity," Dockery says.

But that's not their only possible role relative to COVID. Limited research suggests that omega-3s might fight viruses by inhibiting their replication, or by changing the





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fatty-acid composition of the cell's lipid-bilayer membrane to prevent viral entry into cells, Dockery says.<sup>1</sup>

And in January, scientists at Cedars Sinai Medical Center in Los Angeles gained fast-track publication of research showing that patients with an omega-3 index (O3I)—a measure of the amount of EPA and DHA in the blood—above 5.7% were as much as four times less likely to die of the disease than were patients in the lowest quartile.<sup>2</sup>

"These studies set a good starting place for conducting more extensive research to determine a potential clinical benefit from supplementation," Dockery says. "In the meantime, research, along with accompanying marketing, has helped sell products—*lots of them*—despite production and shipping being hampered. As a result, the omega-3 market is expected to grow at a CAGR of 6.6% from 2020 to 2027."<sup>3</sup>

## Long Way to Go

Yet analyses of NHANES data show that American adults still consume roughly 100 mg of combined EPA plus DHA per day<sup>4</sup>—well below the daily 250 to 500 mg that the 2010 Dietary Guidelines for Americans recommend. Toddler and teenage consumption appears even lower.<sup>5</sup>

Blame lies with the typical Western diet, which Dockery describes as "greatly deficient in omega-3s and critically imbalanced in the ratio of omega-3 to omega-6 fatty acids—mainly because of heavy consumption of short-chain linoleic acid, or LA."

To wit, while a healthy diet might comprise an omega-3-to-omega-6 ratio somewhere between 1:2 and 1:4, "most Westerners consume ratios of 1:10 up to 1:50 through overconsumption of highly processed foods," Dockery says. "And though omega-3 supplements can improve this ratio, we still have a long way to go."

## Playing the Long Game

Supplement formulations usually carry their payload in the form of long-chain EPA and DHA, often from marine sources.

Why? As Dockery explains, "It's been 50 years since publication of a landmark population study uncovering the link between fish consumption and reduced risk for cardiovascular disease set in motion

concentrated research on EPA and DHA and the subsequent intense marketing of these two omega-3s. As a result, EPA and DHA became *the* omega-3s that consumers associate with health benefits."

And not without reason. "EPA and DHA omega-3s are in every cell of the body and are known to be good for the heart, brain, and eyes and during pregnancy," Schutt says. Thus, we see them in prenatal and infant formulas to help prevent preterm births and promote neonatal brain development, in cardiovascular-support supplements for healthy blood lipid levels, in eye-health formulations—even in products for mental and mood wellness.

Indeed, says Greg Lindsey, CEO, Wiley's Finest (Coshocton, OH), "The pandemic helped increase awareness of the mental-health need for EPA and DHA. Clinical work on omega-3s and mental-health issues like depression has emerged as more important than ever. Many people aren't aware that the American Psychiatric Association recommends fish and fish oil to support mental health."

## Something Special

But among the buzziest fields of omega-3 research right now involves not EPA and DHA themselves, but products of their metabolism known as special pro-resolving mediators (SPMs).

SPMs appear to actively target and help resolve inflammation, producing downstream effects that may touch on conditions ranging from COVID, lung injury, and sepsis to cancer, cardiovascular disease, and pain.<sup>6</sup>

SPMs are also opening a window onto how the body heals after injury. "Or said another way," Lindsey states, "they're helping us understand how homeostasis—that is, returning to health and recovery—works in the body. And that's exciting."

## Beyond EPA+DHA

Just as exciting is what scientists are learning about omega-3s beyond EPA and DHA. As Greg Cumberford, vice president, science and regulatory, Nature's Crops International (Winston-Salem, NC), explains, "Emerging science is showing how lesser-studied omega-3s support cell membranes, signaling functions, and anti-inflammatory activities in their own right, and that taking in

high preformed DHA alone may inhibit or short-circuit metabolic activity from these precursor omega-3s."

In fact, supplementing solely with EPA and DHA bypasses several intermediate fatty acids with health benefits, including SDA (stearidonic acid), ETA (eicosatetraenoic acid), and DPA (docosapentaenoic acid). And though our bodies can construct these intermediates via ALA metabolism, the first step in that construction requires an enzyme in which many of us are deficient, Dockery says, thanks to factors ranging from smoking, pharmaceuticals, and chronic diseases to plain-old aging.

As for benefits, SDA is "gaining recognition for anti-inflammatory and cell-signaling functions similar to DHA," Cumberford says. "And along with ALA and ETA, it may help drive better fluid intelligence and structural brain integrity in healthy seniors." Meanwhile, ETA, which readily metabolizes from SDA, yields anti-inflammatory metabolites similar to those associated with EPA and DHA, he says.

Derek Tobin, business development and clinical science manager, Epax (Norway), notes that the company received a Norwegian Research Council grant worth more than \$900,000 to study the potential of newly discovered fatty acids on health. "The aim is to help conduct further studies in manufacturing processes and biological research into the benefits of these new very-long-chain fatty acids in areas such as brain, eye, and skin health, and fertility," he explains. "We've already begun collaborations with universities and research institutions, and that's providing test materials for preclinical research, with clinical studies to take place at a later stage."

## Efficacy Without Fish

Oddly, fish oil contains no SDA and only low levels of ETA. "And though DPA is naturally present," Dockery notes, "it's often destroyed in the purification process that removes heavy metals and other contaminants."

So consumers hoping to build up a reserve of these intermediaries might be wise to consider non-marine sources. But the challenge with non-marine sources, Dockery says—and particularly plant-based ones like flax, chia, and soybean—"has always been research support. Fish oil and its EPA and



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DPA content have been heavily marketed for years, and plant sources—with the exception of algae—don't contain these long-chain fatty acids.”

But Cumberland and colleagues see things differently. “While literal reams of studies have looked at the relative bio-availability and efficacy of omega-3s, we’re coming from a more fundamental place: We’re challenging the accepted claim that dietary plant-based omega-3 ALA and SDA are somehow ‘inefficiently’ converted into the circulating long-chain DHA that the body and brain use in the first place,” he says.

After all, he argues, humans largely evolved eating plant-based diets, which gave them “far more balanced” omega-3-to-omega-6 intakes than we get now.

Moreover, while the conversion of ALA to DHA appears not to boost circulating DHA levels significantly, Cumberland cites new carbon-isotope ratio mass spectrometry data showing that dietary ALA and SDA actually *do* readily “turn over” to DHA. And this new data comes atop research showing that EPA naturally synthesized from plant-based omega-3s like ALA accounts for “significant amounts” of brain-tissue DHA, too, he says.

“So in our view,” Cumberland concludes, “not all omega-3s are created equal: EPA and DHA both have well-studied metabolites and important science linking increased consumption to health and longevity. But they’re not physiologically ‘essential.’ We can readily and efficiently synthesize them as and when needed from truly ‘essential’ plant-based ALA and from more-advanced SDA.”

## The New Plant-Source in Town

It’s a mildly revolutionary notion that’s already influencing formulations.

For example, when Wiley’s Finest was designing its non-marine CatchFree Omega line, Lindsey recalls, the company settled on a formulation combining algal DHA with ahiflower oil, a plant source of multiple omega fatty acids—including plenty of SDA—partly because the body more readily converts ahiflower’s SDA to EPA than it does ALA.

“We call it a shortcut to more EPA, giving the body the most EPA it can get from a plant source,” Lindsey says.

And ahiflower oil isn’t just about omega-3s. “Ahiflower oil is an excellent standalone omega-3-6-9 supplement,” says Andrew Hebard, Nature’s Crops’ CEO. “It’s the most complete and balanced ‘multi-omega’ while also offering a clean taste and aroma rare in the omega category.”

No wonder the company expects to see ahiflower oil appearing in a number of foods and beverages in the coming years, “providing a plant-based, full-spectrum omega boost in meal-replacement powders, vegan milk alternatives, and spreads,” Hebard says.

## Truly Sustainable

Even better, plant-based omega sources like ahiflower boast the impressive sustainability credentials that consumers, especially younger ones, care about.

Those younger consumers “are more prone to weighing their eco-social opinions when making purchases,” Lindsey claims—giving brands that formulate with plant-based omega-3 sources “the ability to appeal to these new consumers and meet their demand in the omega-3 market.”

And sustainability goes beyond pleasing consumers. “Let’s remember,” Cumberland says, “that the vast majority of dietary EPA/DHA used in human nutrition comes from around 20 million metric tons of wild-harvested forage fish extracted from the oceans each year. If recommended EPA/DHA dietary intakes were met globally and predominantly through wild-harvested fishery catches, it would spell ecological disaster.”

Regeneratively farmed sources like ahiflower offer an alternative. “Each acre of ahiflower produces as much omega-rich oil as 320,000 anchovies,” Hebard says, “and provides growers opportunities to cultivate a profitable crop that uses minimal inputs, adds vital biodiversity to their rotations, and provides an enticing environment for pollinators.”

Marine sourcing can be mindful, too. According to Crawford Currie, head of medical R&D, Hofseth BioCare ASA (Alesund, Norway), pressures on wild fish stocks are

putting the spotlight on sustainably farmed fish—like the salmon that Hofseth uses for its omega-3 products.

“We have total traceability from egg to fish,” Currie says, adding that Hofseth’s products bear a QR code to prove it. And while heavy-metal exposure is an inevitability with wild-caught fish, “the levels in our fish are many times below the maximum that Norwegian regulations allow,” he says, “and Norway has amongst the most stringent regulations globally.”

So there’s room for a variety of sources. And, as Dockery says, “There’s plenty of room for growth, too, particularly as the plant-based arena opens up. The main challenges will be consumer education surrounding the benefits of all omega-3s—not just EPA and DHA—and how best to supplement for optimal health benefits.”

**Kimberly J. Decker** writes for the food and nutrition industries from her base in the San Francisco area where she enjoys eating food as much as she does writing about it.

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# Something for *Everyone*

Plant-based dosage forms take on the giant: gelatin.

BY KIMBERLY J. DECKER



**A**s in every other CPG category, plant-based products in the dietary supplements space are receiving a warm welcome. So warm is that welcome that Future Market Insights forecasts a CAGR of 10.9% for the global vegan—that's *vegan*, not just vegetarian—supplement market from 2020 to 2028.<sup>1</sup>

Yet while growing plant-based demand raises the profit prospects for makers of botanical blends, phytonutrient-driven antioxidant formulas, and non-marine omega-3s, those profits will materialize only if manufacturers see plant-based in the big picture.

Namely, says Lindsey Toth, associate director, global marketing, Lonza Capsules & Health Ingredients (Basel, Switzerland), "What's most important for brands developing new plant-based supplements is to think and plan holistically—*inside and out*. Yes, your ingredients are critical components

of the formula, but what's often forgotten is dosage form."

As plant-based options continuously improve, though, dosage forms will remain forgotten no longer.

## Good to Grow

Consumer interest in plant-based dietary supplements—and all the health and eco virtues they embody—won't likely surprise industry insiders.

It certainly doesn't surprise Toth, who's witnessed rising demand not only for supplements with plant-based pedigrees but for products that address a whole constellation of trending positions—from vegan and organic to GMO-free and just-plain "clean." In fact, she says, "Today, 79% of consumers value products made from natural, clean sources."

All of which leads Michael Baumann, global strategic marketing manager, IFF

(New York City), to conclude that "whether they're being more eco-conscious or going plant-based, consumers are becoming more selective in choosing products that fit their lifestyles and dietary restrictions. Manufacturers must adapt."

## Form Factors In

That means adapting supplement dosage forms, as well.

Proprietary Lonza research found that 70% of U.S. consumers say that dosage form factors into their supplement choices, Toth says.<sup>3</sup>

And many of those consumers are looking for plant-based options "across multiple supplement categories," adds Dan Peizer, vice president, global strategy and marketing, consumer health, Catalent Inc. (Somerset, NJ).

Take botanicals, which are a key focus "because of their alignment with the



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plant-based message,” Peizer claims, while the entry into the market of plant-based omega-3s like ahiflower also promises to stoke demand for plant-based delivery.

## Setting the Standard

Alas, supplement platforms like hard capsules, softgels, and gummies have traditionally been the domain of gelatin-based dosage forms—and still are.

“There is, without doubt, increasing demand for non-animal varieties,” admits Angie Rimel, marketing communications manager, Gelita USA (Sioux City, IA). “But the gelatin market remains both buoyant, and dominant.”

Per Innova Market Insights’ database, roughly 90% of the softgel and hard-cap universe relies on gelatin as a dosage form, she notes, with approximately 90% of the latest supplement launches in the gelatin category comprising products like hard-caps, softgels, and gummies.

And as far as Liz Clarke is concerned, there’s “good reason” for gelatin’s ubiquity: “Its physical properties, including thermoreversibility and pH-independent gelling, are simply unmatched by current plant-based ingredients,” says the technical marketing manager for North America at Nitta Gelatin NA (Morrisville, NC).

Gelatin’s performance and operational benefits begin with its economy and simplicity relative to plant-based options. Case in point: Rimel notes that gelatin-capsule production requires 40% less raw material than does capsule production using hydroxypropyl methylcellulose (HPMC), gelatin’s chief plant-based counterpart.

“Gelatin capsules also gain the upper hand when machineability and efficacy are the performance standards,” Rimel continues. Capsule shells must form “very thin and precisely cast films,” she explains, and both gelatin and even carrageenan accomplish this easily; the process with starch-based ingredients like HPMC, by contrast, “can be slow and more complex.”

Gelatin capsules permit less oxygen entry than does HPMC, which is a boon when delivering oxidation-sensitive formulations. To supply the same protection, Rimel says, HPMC capsules would either have to incorporate an antioxidant or use airtight blister-and-foil packaging.

And pharma-grade gelatins generally dissolve readily for quick payload release, Rimel says, disintegrating within three minutes once digested. Meantime, “The dissolution and disintegration times for standard HPMC hard-caps are longer, and issues have been reported with inconsistent and unreliable release.”

Clarke reminds brands to consider ingredient availability when moving beyond gelatin.

*Nitta Gelatin’s  
Liz Clarke  
reminds brands  
to consider  
ingredient availability  
when moving  
beyond gelatin.*

“There’s no denying that supply chains everywhere are still experiencing COVID-induced stress,” she says, “and the complexity of manufacturing inputs for some plant-based gelatin alternative can raise additional hurdles.”

So whereas a hard gelatin capsule requires one ingredient for production—hint: *it’s gelatin*—an HPMC capsule “requires many other chemical inputs,” Clarke says, “including ethylene and propylene oxide—two ingredients that have seen critical availability disruptions and wild price swings over the past year.”

Finally, “Gelatin is a natural, single-ingredient product that’s been used in home kitchens for more than 80 years,” Clarke declares. “Many plant-based offerings, including HPMC, are highly processed, synthetic ingredients considered food additives.” And ultimately, she believes, even an animal-origin ingredient “that’s natural and not genetically modified may be more

attractive than a highly processed plant-based ingredient that is.”

## Gelatin’s Downsides

So gelatin’s got a lot going for it. But it also has drawbacks.

“Many consumers know what it’s like to leave gelatin-based gummies in the car on a sunny day,” Baumann points out. “The gummies lose their shape and form a big lump.” And while that drawback is obvious to consumers, others are all too apparent to manufacturers.

Among them are potential ingredient interactions, and subsequent stability issues, as well as the high moisture content (roughly 12% to 14%) of gelatin capsule shells. By contrast, Baumann says, the 4% to 6% moisture of HPMC-based capsules “better protects hygroscopic and moisture-sensitive ingredients while providing chemical stability against crosslinking.”

Thus, observes Udo Losehand, head of global technical developers, Roquette (Geneva, IL), “Despite gelatin’s numerous plus points, manufacturers are exploring alternative materials to overcome these challenges and meet consumer preferences for plant-based.”

## Come a Long Way

Initially, those alternatives shrank in gelatin’s shadow, often failing to live up to the latter’s performance and quality characteristics.

Fortunately, “Plant-based delivery has undoubtedly come a long way over the last decade,” Peizer insists. Following HPMC’s development in the 1950s, he claims, “Additional plant-based technologies have been introduced that provide robust non-gelatin options to meet consumer needs and technical flexibility to allow for a greater range of formulation and fill options.”

## Pleasing Both Sides

When choosing amongst the technologies, he advises focusing on those that provide “all the functional and aesthetic benefits consumers have come to expect from traditional materials while adding benefits that appeal to both consumers and brands.”

For example, Peizer’s noticed “a lot of interest” in Catalent’s Vegicaps softgels, which he says exhibit all the experiential benefits of

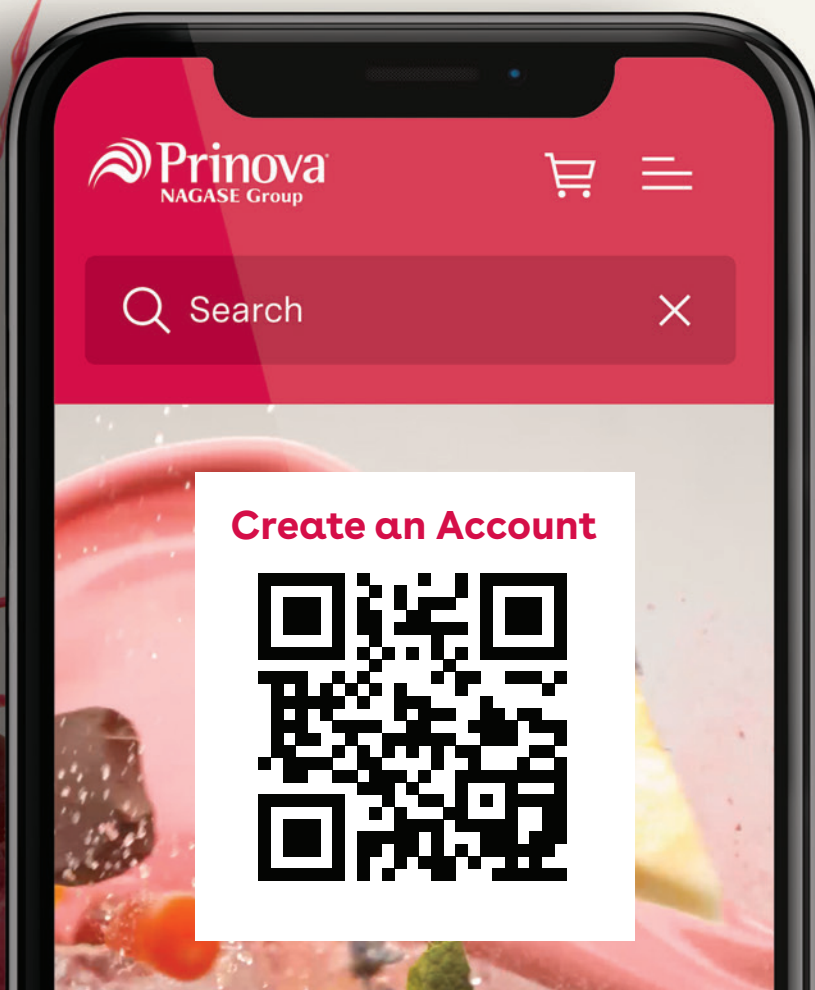
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gelatin-based products—including perceptions of improved swallowability—while offering formulators a wider formulation range and the potential for use in certified-veg-an products, too.

## Fit for Function

Adds Toth, “Make sure the form suits the ingredients you’re working with. Some may be light- or moisture-sensitive, while others need protection from stomach acid, for example. And consider the full process—from target consumer needs through filling and machinability.”

Research led Lonza to tried-and-true HPMC for its Capsugel Vcaps and Vcaps Plus capsules, which Toth calls “ideal” for protecting moisture-labile ingredients like herbs and minerals, and for offering an immediate-release profile. “We can add gelling technology to our base HPMC polymer to modify a capsule’s release profile further—useful when working with acid-sensitive ingredients.”

And for the company’s Plantcaps capsules, pullulan—an ingredient produced via tapioca fermentation—was the choice. It protects oxygen-sensitive ingredients, releases actives rapidly, and enables organic labeling in the U.S., Toth says, making Plantcaps “the ultimate dosage form for clean-label formulations.”

## Solutions from the Sea

Baumann advocates alginate-based coatings for delayed-release tablets and capsules, wherein actives need protection from the stomach’s acid as they travel toward absorption in the intestines. Made from brown seaweed, alginates maintain the supplement’s integrity throughout digestion, Baumann says; but even when immediate release is required, “cellulose-based super-disintegrants can create fast action in tablets, capsules, granules, orally disintegrating tablets, and chewables.”

And while Baumann says that plant-based softgels have historically lacked gelatin’s “great sealing properties” and high fill capacities—achieving only 50% to 70% capacity even with simple fills compared to gelatin’s typical fill of 85% to 100% of a soft-gel’s volume—IFF developed its “optimized shell-forming” SeaGel system specifically to

meet such standards and replicate gelatin’s flexibility in size, shape, and fill options.

## Peas and Qs

Losehand notes that Roquette put the pea-starch dosage forms in its Lycagel line through their paces in capsule applications and found that—among other benefits—the ingredients yielded dry times of four to five days, which compare well to the three to four days that gelatin softgels typically require.

“In terms of capsule performance,” Losehand continues, “one of the best characteristics of high-performance pea starch is its strength relative to gelatin and ability to maintain structural integrity during production and storage.” Tests even showed that the products maintained a hardness of 19.1 N after six months at 25°C and 60% relative humidity, and 17.3 N after 12 months at 20°C.

Pea starch’s absence of crosslinking also means no significant increase in capsule disintegration during storage, Losehand adds. In tests, the product demonstrated a disintegration time of less than eight minutes after both 12 months at 20°C and six months at 40°C and 75% relative humidity, he says. “Further tests revealed that our pea-starch capsules showed no leakage or sticking, and do not exceed 8% moisture at 25°C and 60% relative humidity, and at 20°C,” he adds.

## Going for Gummy

But while plant-based dosage forms have largely tamed capsules and softgels, gummies have proven tougher to subdue.

That’s because gelatin creates a “unique melt-in-the-mouth experience and texture” that consumers have grown accustomed to, Baumann says. That standard has historically laid outside plant-based ingredients’ reach, but technologies involving carrageenan, starch, agar, and pectin are improving.

Pectin in particular is “an exceptional gummy gel former,” Baumann says, lending a “soft, tender mouthfeel and much cleaner, shorter bite.” Its uniform gelling properties make for what he calls “a clean-cut, shiny appearance” with superior taste and flavor release, to boot. Baumann also praises pectin’s “effective setting time and stability during storage and shipment.”

“But not all pectin is created equal,” Bauman cautions. “Pectin tailored for gummy

supplements—like Grindsted Pectin CF Premium grades—allow label claims, easy implementation, and efficient processing.”

Scott Bergeron, director of sales, coatings, Americas, Mantrose-Haeuser Company, Inc./NatureSeal Inc. (Westport, CT), notes that Mantrose-Haeuser has expanded its range of plant-based Certicoat anti-sticking polishes for gummy vitamins. Made with plant-based waxes and oils, the clean-label coatings not only make gummies look better in the package—enabling matte or high-gloss finishes, he says—but extend shelf life while providing good surface lubricity and flowability.

Several certified-organic options are also available, Bergeron adds. “Sustainability and environmental impact are important in consumers’ decisions,” he says. “By offering high-quality plant-based products with superior processing benefits and a wide range of finishes, we’re empowering manufacturers to offer customized delivery systems to their customers.”

Clarke notes that gummy formulators will even turn to blends of animal- and plant-based gelling agents both to optimize workability and to create “unique new textures,” as she calls them. “This is an exciting space to be in, because it allows product developers to go from short to bouncy to chewy and anything between.”

But perhaps best of all, it proves that “there’s room in the delivery-systems world for all kinds of ingredients,” Clarke says, “and much to consider beyond simply plant- or animal-based.” ■

**Kimberly J. Decker** writes for the food and nutrition industries from her base in the San Francisco area where she enjoys eating food as much as she does writing about it.

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# Creative CONFECTIONS

"Candyceuticals" are advancing as a delivery system.



BY MIKE STRAUS

Who can take a sunrise and sprinkle it with dew? According to the 1971 film "Willy Wonka & the Chocolate Factory," the Candy Man can. While most manufacturers will find sunrise and dewdrops challenging ingredients to work with, emerging trends in delivery systems are giving rise to a new class of good-for-you confectionery items that deliver functional ingredients in the form of a sweet treat.

As interest in "candyceuticals" grows, confectionery is offering more flexibility as a delivery system, growing beyond gummies and into chocolate, candy, chewing gum, and more. Here are some of the ways the confectionery space is transforming nutraceutical delivery systems.

### Functional Chocolate Combines Decadence and Nutrition

Fortified chocolate is a relatively new invention but one that's taking off. Nicole Smith, CEO and cofounder of The Functional Chocolate Company (Evergreen, CO), says dark chocolate, in

particular, is an ideal delivery system for functional ingredients. Smith contends that dark chocolate is already a functional food due to its high concentration of antioxidants, flavanols, and minerals. Not only that, but its high fat concentration improves the bioavailability of added nutraceuticals, she says.

Perhaps most importantly, chocolate performs well where several other delivery systems fall down: in the taste department. "Our approach to making our products both functional and delicious involves pairing the right flavors to complement the active ingredients rather than trying to hide or fight the botanical flavors," Smith explains. "For example, our Rhythm Bar for PMS includes ginger as an active ingredient. Instead of trying to cover up that strong ginger flavor, the bar is ginger snap flavored."

The Functional Chocolate Company's Rhythm Bar is formulated with the branded and trademarked PurGinger, a powdered ginger (*Zingiber officinale*) ingredient manufactured by Applied Food Sciences (Austin,

TX). PurGinger is formulated to be highly water soluble and shelf stable for two years.

While some ingredients like ginger can enhance the taste of chocolate, other ingredients, like valerian root, don't work so well. The Functional Chocolate Company uses natural bitter blockers to mask unpalatable flavors when working with bitter ingredients. Smith says her company is very conscious of consumer concerns around sugar, and its formulations aim to make the product as widely accessible as possible without compromising on taste. The company's initial formulations contain 5 grams per serving of non-GMO, fair-trade cane sugar, and The Functional Chocolate Company is currently working to develop new formulations that use alternative sweeteners.

### Confectionery Delivery Systems Parallel the Cannabis Market

Smith says that while there are endless delivery system options for nutraceutical ingredients, several of these options have stalled and

remain novelties. This trend, she says, mirrors one in the legal cannabis market. Cannabis brands have added tetrahydrocannabinol (THC) to all sorts of products, from hot sauce to ice cream, but the majority of these options haven't achieved mass-market appeal and remain little more than interesting novelties.

"The top categories in edible cannabis are gummies followed by chocolate, which mirrors the vitamin and supplement space," she explains. "Powders, drink mixes, and other traditional delivery methods will remain the top categories, and other novelties will pop up. But we anticipate chocolate will be the next big disruptor, following the path of the gummy supplement market."

### Balancing Nutritional Load and Price Considerations

While some confectionery products like chocolate and gummies are rapidly growing in popularity, challenges remain. Peter Losee, senior manager of business development for Corbion (Lenexa, KS), says creating an effective confectionery nutraceutical demands that formulators consider not only functionality and taste but also nutritional load and price.

"It comes down to the amount of [a nutrient] that can be included in the product without affecting other attributes like taste, texture, and stability," Losee explains. "Once that balance is determined, the supplement may require a consumer to take two or three pieces to equal the nutrition in another format like tablets. Given the taste of confectionery, however, most consumers seem to be very comfortable with the increased number of pieces to gain the necessary nutrition value."

Corbion's internal data show that mineral-fortified gummies grew by 35% in the last 12 months, with North America accounting for 65% of the global market. Losee says many of the fastest-growing applications in nutraceutical confectionery revolve around immunity. In light of the COVID-19 pandemic, nutraceutical confectionery consumers are driving a significant sales jump in vitamin and mineral confectionery products. Ingredients like vitamin C, vitamin D, zinc, calcium, and magnesium are among those experiencing the most significant growth. Other emerging areas of focus in candyceuticals, Losee notes, include sleep, vision, and hair growth.

### Confectioneries of Tomorrow

Candyceuticals continue to expand into new applications and delivery formats. While gummies have dominated the headlines as the next big thing in delivery systems, innovative brands are discovering that confectionery has much to offer. Nutraceutical chocolate, candy, and gum are on the rise, and their growth will

open up new opportunities for formulators who are willing to experiment. ■

*Mike Straus is a freelance writer living in Kelowna, Canada. He writes for trade publications like Hoist, Canadian Chiropractor, Grow Opportunity, and Massage Therapy Canada.*

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# *From* **STRENGTH** *to* **STRENGTH**

Maintaining motivation in the protein market

BY KIMBERLY J. DECKER

**T**here's something unimpeachable about protein. While other nutrition superstars may rise and fall, protein stands unique among macronutrients in "maintaining a positive image even as carbohydrates and fats have experienced negative attacks and backlash," observes Max Maxwell, manager, market intelligence, Glanbia Nutritionals (Chicago).

Yet if protein's popularity appears to defy gravity, it's not maintaining that buoyancy all on its own. After all, the protein sector runs on the combined forces of ingredient suppliers and CPG brands, both of which keep delivering the nutrient's power—and appeal—to loyal consumers.

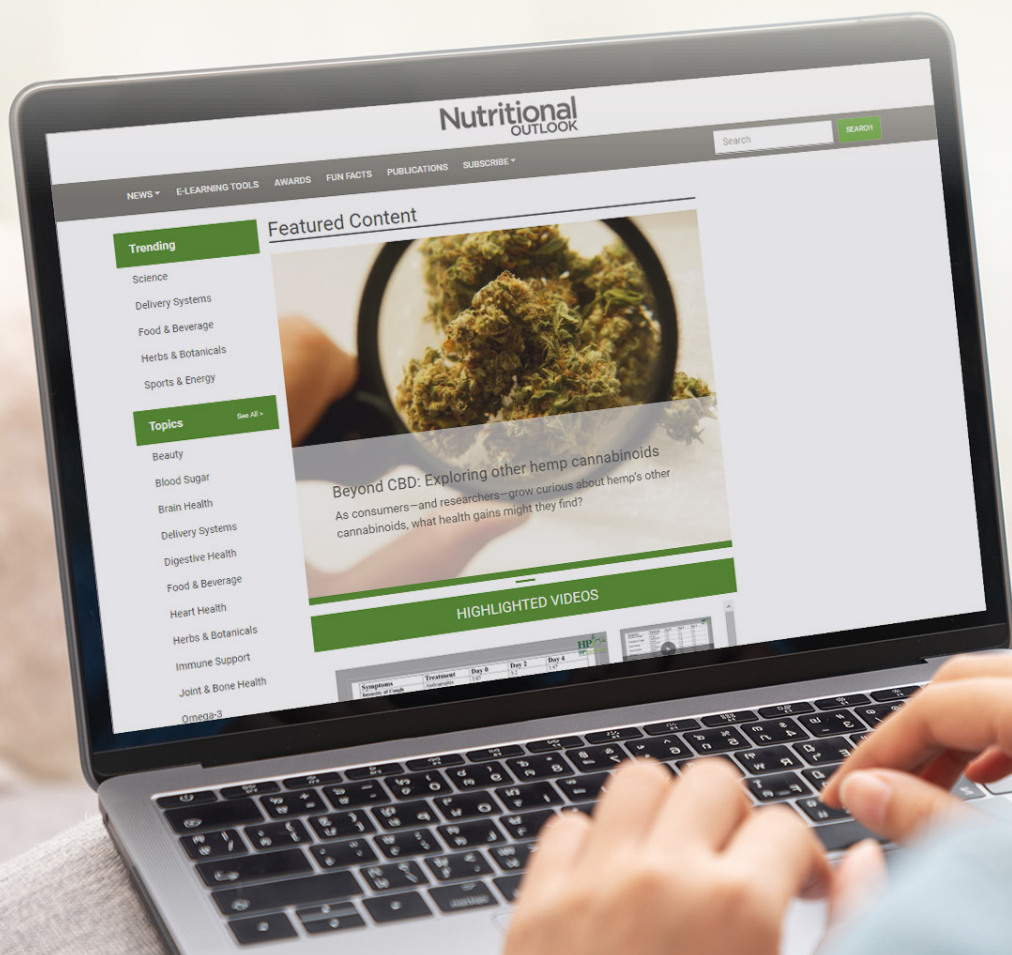
## **Broadening Base**

Ramon Mommersteeg, marketing manager, performance and active nutrition, FrieslandCampina Ingredients (Amersfoort, The Netherlands), sees "several factors at play" in keeping protein in the good-for-you spotlight—not least of which is the increasing appeal of all things "good-for-you."

"Consumers are more health-conscious than ever," he says, "and that's something that COVID-19 accelerated." In response, they're stepping up their diet and fitness routines, he continues, which, in turn, "has led to a boom in the search for nutritional solutions, with protein being front and center as consumers recognize that protein plays a role in being strong and physically active, and that those qualities are essential to good health."



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*“Mainstream brands have made protein very accessible as they’ve expanded into the space,” says Glanbia’s Max Maxwell.*

There was a time when that recognition registered principally with fitness enthusiasts—protein’s core consumers. But its benefits are now all but officially established within the mainstream.

No wonder, then, that “we see demand remaining strong because we keep seeing more consumers incorporating protein into their diets,” says Catherine Armstrong, vice president, corporate communications, Comax Flavors (Melville, NY). “And no, not all of those consumers are athletes looking to build muscle.” Nor are they necessarily following lifestyle diets like paleo or keto, she adds. “Rather, they’re using protein powders and other applications—bars; even cookies—as meal replacements.”

## The New Snack

And as guilt-free snacks.

FMCG Gurus data from this year show that only 3% of global consumers claim *not* to snack, notes Mommersteeg, “and of this majority, more than two-thirds say they regularly snack on protein bars.”

Moreover, FMCG Gurus found that more than half of these snackers chose their protein-packed products because such options “offer healthy indulgence,” Mommersteeg adds. “To me, that proves that not only is protein absolutely still on the menu for consumers; they’re even looking for it in new, more convenient products that fit their everyday lifestyles.”

## Make It Easy

Maxwell couldn’t agree more. “Mainstream brands have made protein very accessible as they’ve expanded into the space,” he says. And they’ve done so in no small part by emphasizing convenience.

We see this in the growth of ready-to-drink (RTD) over ready-to-mix (RTM) protein beverages, Maxwell points out, as well as in the pervasive adoption of those aforementioned

protein bars “so that consumers haven’t needed to alter their behavior to get protein’s added benefits,” he says.

And though protein bars “slumped” during the pandemic as consumers were hunkering at home, “once work and travel return to a new normal,” Maxwell wagers, “bars will remain the format of choice for on-the-go convenience”—and for increasingly appealing flavor profiles, fun mini formats, and refrigerated options that, literally, “keep the sector fresh,” he adds.

But why stop at bars? Maxwell’s confident that protein’s migration into categories like cookies, chips, baking mixes, breads, popcorn, and extruded breakfast cereals offers brands the opportunity to reach yet more consumers and generate further “explosive growth,” he says.

## Minding the Details

A new take on snacking isn’t all consumers want from their protein products, though. “Consumers are also concerned about sourcing, sustainability, climate impact, and products with a backstory and mission,” Maxwell says.

Moreover, Armstrong adds, consumers are especially looking for “clean” proteins and products with “simple” ingredient statements. “And protein quality is important, too,” she says, “with more consumers reading labels to make sure that’s what they’re getting.”

How closely consumers monitor such nutritional details “depends on who they are and what their level of sophistication is,” Maxwell believes. For although protein’s historical base of athletes and bodybuilders focuses intensely on performance benefits and specific protein types—for instance, whey protein isolate versus concentrates or hydrolyzed whey—newer, more mainstream entrants to the category, in many cases, “just want protein,” Maxwell says.



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## Finding Common Cause

Yet even though “different protein consumers have different needs and wants,” Mommersteeg affirms, there’s often considerable overlap between different demographics’ goals and preferences.

“For example,” he says, “for some older adults, remaining active is a key driver for maintaining muscle strength as they age—which becomes a key driver for protein consumption. But this driver isn’t too dissimilar from why the active consumer wants to proactively maintain strength and fitness as they age, too. And then *this* consumer also overlaps with the traditional sports-performance consumer, who’s also interested in protein for improving performance.” The upshot: By formulating with one of these consumers in mind, brands get that much closer to formulating for the others.

## Dairy Dominates?

And though plant-based proteins are making headlines for their health and sustainability benefits—and not just with vegans and vegetarians,” Mommersteeg is quick to note—he’s convinced that “dairy proteins remain a top choice for high-quality protein.”

Why? For one, dairy’s complete amino acid profile scores points with active and older consumers, he says. Meantime, innovations in dairy ingredients open doors to formulating the proteins into, for example, clear beverages.

“Last year we even launched a clean-tasting, clear RTD water concept that used dairy-derived whey protein to create a hydrating drink that supports muscle recovery post-exercise,” Mommersteeg says. “So while plant-based dairy is one of many elements of the protein picture, the dairy-ingredients sector is also clearly rising to the challenge of contemporary protein needs.”

## All in Good Taste—and Texture

Another way all protein sources are rising to those challenges is by upping their taste and texture games.

As Mommersteeg points out, “For traditional protein users, like performance athletes, quality nutrition was always much more important than taste and texture. But as more people show interest in protein,

taste and texture have become increasingly important, as well.”

And here again, consumers of all types have improved protein ingredients to thank. The effect of those ingredients “has been a revolution in innovation and new functional-product development,” Mommersteeg says, with examples including not just the clean-tasting hydration drink mentioned above but also protein bars that don’t petrify on the shelf.

*“I see a lot of protein products being promoted through social media,” says Comax Flavors’ Catherine Armstrong.*

“High-protein bars—with 30% protein and higher—are notorious for hardening over time,” Mommersteeg explains, “which makes them unpalatable.” He offers FrieslandCampina’s Excellion Textpro ingredient as not just an “excellent protein source” for these applications, he says; it’s also a targeted texture solution expressly developed to contribute a softer mouthfeel and reduce hardening over a bar’s shelf life.

From her perch at a flavor house, Armstrong has also seen the shift among protein consumers toward demanding indulgence as much as they do nutrition. “So brands are positioning their products as indulgent—but healthy—treats,” she says. Flavor profiles that fit the bill “run the gamut from salted-caramel pretzel to banana bread,” she says. “We’re also seeing more bite-sized and mini options that are portable and convenient as snacks, too.”

Adds Kirsten Karlsson, director of marketing, Ascent Protein (Denver), “We’re seeing a lot of success and sales boosts with limited-time-only flavors throughout the

year to keep things fresh and exciting. Consumers enjoy the variety.”

And that’s no accident for Ascent as a CPG protein brand that’s putting these principles of healthy indulgence into practice.

“Better taste and texture have always been key priorities and differentiators for us,” Karlsson says, “because we know how much they inform repeat purchase and drive word-of-mouth marketing.” So before any new launch, the company conducts “extensive” consumer research to solicit feedback on taste and texture, she says. “The reality now is that there are a number of high-quality proteins on the market, and better taste and texture go a long way toward satisfying consumers and keeping them coming back to the brand.”

## Progressing Protein

As for what else will keep consumers coming back to protein in general, Maxwell is bullish on the prospects for individualized nutrition. “It’s likely that as we gain the capability to personalize products for individual dietary needs,” he predicts, “there will be even more specialization in the proteins that people want.”

And as is the case everywhere, social media is making its mark on protein, too. “Interestingly,” Armstrong says, “I see a lot of protein products being promoted through social media. More influencers are promoting bars, powders, and other products via channels like Instagram. So they’ll promote special limited-time offerings and announce when a new flavor is ‘dropping.’”

All of which attracts even more attention and excitement to an already-dynamic category. As Mommersteeg says, “There’s absolutely more to come for the protein trend. We’re at a turning point in the way that consumers think about their health and wellness, and as a result, I believe we’ll be seeing a lot more from protein in our day-to-day lives, and in places where maybe we hadn’t before.” ■

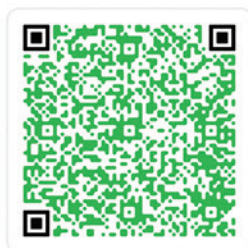
*Kimberly J. Decker writes for the food and nutrition industries from her base in the San Francisco area where she enjoys eating food as much as she does writing about it.*



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# Plant Protein's New Players

New entrants are raising the bar for creativity and even nutrition. But can they go commercial?

BY MIKE STRAUS



**P**lant proteins have come a long way. Newer ingredients are giving formulators more flexibility while improving texture, flavor, and nutrition. Some ingredient suppliers are even combining various plant proteins into blends offering tailored benefits.

Consumers may still only be mostly familiar with legacy ingredients like soy and almonds. But as the plant protein market matures, newer sources will have an opportunity to take the spotlight. Here are some of the plant protein sources gaining traction—and the measures it'll take to get them to commercial scale.

## First, Pea Protein

Some of the most popular emerging plant proteins are sourced from legumes. In fact, consumers often perceive legumes like nuts, seeds, and beans to be the best-tasting and healthiest plant proteins, says Jacquelyn Schuh, global marketing director of protein nutrition solutions for ADM (Chicago).

And it shows. "The use of pea protein specifically has grown by 297% for meat alternatives and 127% for dairy alternatives over the past five years," Schuh says. "This growth

is likely because brands are looking for plant proteins that can help position products for consumer-friendly labeling."

## R&D Advances Next-Generation Proteins

What comes after pea protein? Formulators are investigating various plant ingredients that currently rank low in consumer awareness but have great potential. Algae, hemp, lupin, amaranth, and sorghum are among the ingredients undergoing technological development, Schuh says.

Suppliers are working hard to create functional isolates or concentrates from these ingredients that brands can then incorporate into formulations with ease. Consumers, however, might take longer to get comfortable with these unfamiliar options.

"Growth in fermented, cell-based, and 3D-printed proteins continues to spur innovation," Schuh says. "However, we anticipate there will be a gap in consumer acceptance, especially by those who are focused on clean labels. Closer on the horizon are processing and formulation advancements to refine plant proteins so that they need fewer complementary ingredients like emulsifiers, maskers, and stabilizers."

*Advanced research is bringing a variety of non-traditional proteins closer to reality.*

Nevertheless, advanced research is bringing a variety of non-traditional proteins closer to reality. ADM recently opened a plant-based innovation lab in Singapore to foster product development. The company also partnered with Marfrig (São Paulo, Brazil) to launch PlantPlus Foods, a new joint venture that will offer a variety of finished-product plant-based foods. Earlier this year, ADM announced that it became an investor in Air Protein (Pleasanton, CA), an alternative-protein manufacturer that creates protein flour from the elements present in air. You heard that right.

## From Concept to Commercial

While these newer plant protein sources are gaining some degree of consumer awareness, they still haven't toppled legacy sources like soy protein. Scaling emerging proteins will require effective marketing to educate consumers and foster brand familiarity.

Ryan Bracken, co-CEO of Merit Functional Foods (Winnipeg, MB, Canada), says consumers are becoming more knowledgeable about the fact that there are different kinds of plant-based proteins. They are now interested in knowing which type of plant protein is in the products they buy.

This phenomenon, he says, is now driving interest in newer sources like canola protein, which his company offers. "We expect this shift will continue as consumers have better taste experiences with different types of protein," Bracken adds. "For instance, if a consumer tries and loves a product that is made with canola protein, we expect they'll start seeking out more canola protein products."

## Dairy Matters

The dairy-alternatives market, in particular, is one where emerging plant proteins could shine. Here, suppliers have an opportunity to get a leg up via nutrition, because most of the plant-based dairy alternatives on the market today, like oat milk and almond milk, have less protein per serving than cow's milk, Bracken says.

"Consumers want dairy-alternative products that are true replacements for dairy products, which includes comparable protein levels," he says. "Most dairy beverages offer protein levels of 8 grams per serving, which is why we sought to produce plant protein ingredients that can deliver a similar result."

## Raising the Bar

Bracken notes that the consumer base for plant proteins has expanded in recent years. Early adopters in the plant-based movement have traditionally been forgiving of poor quality in plant-based products. But now that the plant protein consumer base has expanded beyond vegans and vegetarians to include flexitarians, the flexitarian demographic expects good taste, good texture, and improved nutrition from plant-based foods—which is forcing ingredient suppliers and brands to step it up.

Merit Functional Foods' branded canola protein ingredient, Puratein, works well in a variety of formulations, Bracken says. Canola protein, he adds, is ideal for plant-based ice cream due to the whipping and foaming effect it exhibits during processing, while its gelling characteristics make it a fit for plant-based burgers.

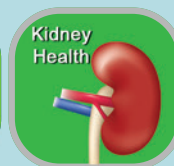
Ingredient suppliers are answering the call for plant proteins with innovation. As flexitarian demand for plant-based food grows, more opportunities will emerge for brands that can reproduce a meat-like or dairy-like experience through plant proteins. Smart marketing campaigns that emphasize taste, experience—and, when possible, nutrition—will be essential in reaching this new demographic. ■

*Mike Straus is a freelance writer living in Kelowna, Canada. He writes for trade publications like Hoist, Canadian Chiropractor, Grow Opportunity, and Massage Therapy Canada.*



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# Collagen on the Cutting Edge

The next generation of collagen ingredients is here.

BY MIKE STRAUS

**A** new age of collagen products is on the way thanks to the innovation of ingredient suppliers. At the end of the day, their significant research and ingredient development will give formulators more flexibility to invent with collagen. This puts the market in position to better meet the increasingly sophisticated needs of educated consumers. Here are some of the doors opening.

### More Applications Than Ever

Emerging studies are unveiling collagen's versatility and utility across a wide variety of applications far beyond just beauty-from-within.

Collagen peptides offer benefits ranging from anabolic body toning to increasing strength and flexibility of ligaments and tendons, says Angie Rimel, marketing communications manager, Gelita USA (Sioux City, IA). "Specific [collagen] peptides stimulate joint cartilage regeneration and support bone health by promoting biosynthesis of the extracellular matrix. The fact that peptides also contribute to immune function is a fairly new discovery."

Evidence that collagen can support the immune system prompted Gelita to launch its new branded ingredient Immupept. Immupept is a bioactive collagen peptide that stimulates keratinocytes and fibroblasts, maintaining the skin's defense barrier and regulating proteins involved in the immune response.

### Collagen on the Brain

Brain health is primed for a collagen breakthrough, says Abdul Alkayali, vice president of sales and marketing, Certified Nutraceuticals (Pauma Valley, CA).

Specifically, Alkayali says, "Collagen peptides from select jellyfish are a superfood for the brain. They are a complete protein containing all 20 essential and nonessential amino acids, plus macronutrients and calcium-binding proteins."

His firm's patented KollaJell collagen peptides come from wild-caught, edible cannonball or barrel jellyfish. KollaJell is rich in neurotransmitters dopamine, glutamate, glycine, tyrosine, GABA, and norepinephrine.

The fact that there exists 28 different types of collagen means there is rich opportunity for research. This also means, however, that it's im-

portant that formulators select the right type of collagen for their application, Alkayali says.

"It's important for formulators to look for collagen peptides with the right molecular size," he advises. "Smaller collagen peptides, resulting from too much hydrolysis, lose naturally occurring mucopolysaccharides, hyaluronic acid, chondroitin, and glucosamine."

### Collagen Goes Clinical

Collagen is emerging in clinical nutrition. In fact, collagen peptides are ideal for use in clinical nutrition formulations, says Liz Clarke, CFS, technical marketing manager for collagen supplier Nitta Gelatin North America (Morrisville, NC). With this in mind, Nitta Gelatin recently added a registered dietician to its North American research and development team. The goal? To capitalize on growing interest from the clinical nutrition segment.

"It's really exciting to see clinicians take note of the studies and begin formulating for very targeted health benefits," Clarke says. "We're seeing more interest from the clinical nutrition segment than ever before, and that seems to be a product of the growing clinical



data supporting specific collagen ingredients' ability to support health concerns like pressure injuries, blood sugar balance, or cardiovascular function."

The clinical nutrition market could be the next major opportunity for collagen ingredients. Nitta Gelatin is conducting ongoing research on the relationship between wound healing and bioactive collagen dipeptides proline-hydroxyproline (PO) and hydroxyproline-glycine (OG). The company also developed a proprietary enzymatic process to concentrate PO-OG to a level 30 times higher than that of standard collagen peptides. The result, Clarke says, is an ability to invoke major physiological responses within skin and joint tissue in human clinical studies.

### How Do You Take Your Collagen?

Brands are bringing to market a variety of new collagen delivery formats. Consumers are more discerning these days, increasing pressure on companies to ensure their products satisfy the target customer, says Jaime Reguant, healthcare director, Bioiberica (Barcelona, Spain).


"Consumers are prioritizing taste and convenience," Reguant says. "They're also seeking solutions that can be easily added to their daily routines as they look to balance the demands of a busy lifestyle. The shift in the market is propelling innovation in collagen-based products, from powders and shots to dairy products, gummies, beverages, snacks, and more."

Part of this change is being driven by the type of consumer now looking for collagen and mobility ingredients, Reguant says. While the previous target market was seniors or athletes, a growing population of 25- to 44-year-old consumers is taking a proactive approach to support their mobility.

Consumers also want results. In 2020, Bioiberica completed a preclinical animal study on a blend of its branded Collavant n2 type 2 collagen, patented Mobilee hyaluronic acid, chondroitin, and glucosamine. It found that the combination product improved cartilage appearance, reduced cartilage degeneration, and resulted in significantly better synovial membrane values on histology.<sup>1</sup>

### Everywhere Collagen

Companies are leveraging new opportunities in collagen to appeal to a wide consumer base. As the toolbox grows, companies will

discover new ways to capture the consumer's imagination. 

*Mike Straus is a freelance writer living in Kelowna, Canada. He writes for trade publications like Hoist, Canadian Chiropractor, Grow Opportunity, and Massage Therapy Canada.*

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# Hope for the HEART

Heart disease is still the biggest health threat. Here's the latest on ingredients to help us care for the heart.

BY JUDY BLATMAN

**C**ardiovascular disease (CVD) remains the world's number one killer, even as COVID-19 and its variant strains dominate front-page news. It's a fact we can't forget.

We can't lose sight of the importance of heart health, even as consumers devote more attention to other health priorities during the pandemic, like immunity. "Truth is, right now," says Annie Eng, CEO of ingredients supplier HP Ingredients (Bradenton, FL), "the key focus is on immune support—and rightfully so."

The good news? The pandemic *has* made consumers increasingly aware of the risks associated with CVD, says Steven Riley, director of marketing and consumer sales for UK-based ingredients supplier OptiBiotix Health PLC. After all, he says, "We now know that clinical outcomes are worse in patients with COVID-19 that have cardiovascular disease risk factors, such as obesity, diabetes, and hypertension."<sup>1</sup>

"Compared to the general population, people with cardiovascular disease were more than twice as likely to contract severe forms of

COVID-19," notes Dominik Mattern, vice president, marketing, Kappa Bioscience (Oslo, Norway). "Thromboembolism and microvascular thrombosis are common in severe COVID-19 cases, and a leading cause of death."<sup>2</sup>

Pandemic or no pandemic, cardiovascular wellness remains very important to adults, especially those in middle-age hoping to stave off potentially devastating cardiac events. "According to the latest information from the World Heart Federation," shares Riley, "there are 520 million people currently living with cardiovascular disease. As such, it remains the world's number one killer, causing 19 million deaths per year, which is mainly from heart attacks and strokes."<sup>3</sup>

Sam Michini, vice president of marketing and strategy, Deerland Probiotics & Enzymes (Kennesaw, GA), raises other reasons why middle-aged adults might focus more on cardiovascular health—such as when they have a parent, grandparent, aunt, or uncle who has experienced a heart attack or has a debilitating heart condition. "It shoots up the priority list when

one suffers a cardiac incident, which tends to be a spontaneous devastating event."

The "prevention mindset" motivates these people especially to seek the health insurance of cardio-support supplements, he says.

Marianne McDonagh, vice president of sales for Bioenergy Life Science (Ham Lake, MN), agrees. "Heart disease is the leading cause of death in the western world, largely due to culture and lifestyle, and conventional medicine has done very little to decrease these chronic illnesses with pharmaceutical applications and assorted procedures. This has created a surge and increased interest in dietary supplements to support and maintain heart health."

The desire to take a more active role in shoring up heart health will only be further spurred by the pandemic, says Jonathan Jones, PhD, chief scientific officer for ingredients supplier Monteloeder (Spain). "There is a rising interest in health as a whole. During the past year and a half, many consumers have been under lockdowns, with some countries still in strict living conditions." He notes that "this lack of mobility, together

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with an increase in stress-induced binge eating and drinking, has had a negative impact on our health. Now that the countries are starting to open up, consumers are looking to get back in shape, fast.”

Jones, for instance, is intrigued by how digital consumer wearables add to the interest in heart health for consumers, advising that products such as Apple Watch and Fitbit trackers “have been working hard in developing the technology to track heart health parameters” such as heart rate, ECG, etc. For Jones, beyond the pandemic, the accessibility of this technology has increased awareness among consumers—which, he says, “has had an impact on their need for heart health solutions.”

## The Heart Health Business: Alive and Ticking

Ingredient suppliers serving the heart health supplements market are also enhancing their own solutions. In the past year, several ingredient companies took notable steps to further their cardiovascular portfolio.

In July of this year, Ingredients by Nature (IBN; Montclair, CA) acquired the Sytrinol brand from Lonza<sup>4</sup>, an ingredient said to provide powerful support for the heart by influencing healthy cholesterol levels, healthy LDL levels, and healthy triglyceride levels.<sup>5</sup> IBN plans to explore the synergistic combination of Sytrinol with its clinically backed lemon flavonoid brand Eriomin, the latter studied for its role in prediabetes management. By coupling the ingredients, “the combo may have even greater potential for prediabetes management and cardiovascular support,” according to a company press release.<sup>6</sup>

Says Rob Brewster, president, IBN, “Sometimes we make the mistake of sticking an ingredient into a box, but by thinking outside that box, we realize the interconnectivity of the different systems that maintain good health.”

He adds, “Heart health ingredients are just like that. Yes, the primary purpose of Sytrinol is to help the heart and cardiovascular system, but in doing so, there are other challenges that can be addressed, too.”

As examples, Brewster points to the possibility of the combined ingredients potentially playing a role in immune health and weight management, two areas that are

intertwined with heart health. “That is why we want to explore how Sytrinol combines with other ingredients, especially flavonoids, and to expand on existing science with new and innovative research,” he says.

According to Brewster, IBN is “still in the ideation process of this.” The company intends to “run some internal studies to make sure that this combo is viable and effective,” he says.

Brewster adds, “We are currently finishing up a very promising SHIME study on Eriomin and may follow up with one on Sytrinol to see how it influences the microbiome as well.” He promises to share more information when available, which he expects to be in 2022 at the earliest.

Meanwhile, HP Ingredients strengthened its bergamot supply chain with its June 2021 announcement that it had purchased a stake in the Italian company Herbal & Antioxidant Derivatives (H&AD). According to the press release, HP Ingredients has been the exclusive North American sales and marketing partner for H&AD’s Bergamonte ingredient, a full-spectrum bergamot extract, since 2008, and a major contributor to H&AD’s revenue. The press release further advised that HP Ingredients has been brought in as a shareholder, with Eng now serving as one of the four directors of H&AD.<sup>7</sup>

Eng is enthusiastic about the current science behind Bergamonte, including 12 published human clinical trials examining the beneficial role for the branded ingredient in heart health. She’s equally enthusiastic about the continuing research and development opportunities.

She envisions opportunities in those areas for other citrus ingredients as well, advising that “we are finding that more consumers and brands are strongly associating citrus with more than immune resilience.” In addition to bergamot, she says they are linking grapefruits, lemons, limes, and oranges with a host of other health benefits, including those for heart health.

On another front, OptiBiotix—and its subsidiary ProBiotix Health—continues its global expansion with several announced extensions of commercial agreements that will enable wider international distribution for several of its heart health-focused ingredients and products. According to company

press releases, these include WellBiome, a functional fiber and mineral blend; and its branded line of finished product, CholBiome, which contains LPLDL, a patented probiotic strain.<sup>8,9</sup> In September 2020, OptiBiotix launched what the company called “an innovative tri-layer tablet” branded as CholBiomeBP and positioned it as a blood pressure support product.<sup>10</sup>

According to Riley, while there are many dual-layered solutions available in the market today, tri-layered solutions remain highly innovative. He explains that the specialized technology used in the range of CholBiome products enables each of the three-to-four ingredients per product to work in synergy and be released at optimal times to increase overall effectiveness. In the case of CholBiomeBP, says Riley, “Thiamine and L-arginine are released immediately; then, approximately two hours after ingestion, our patented probiotic strain LPLDL is released. Between four and six hours after the tablet is consumed, the final layer releases with CoQ10,” ensuring that the active ingredients experience increased stability and survivability after ingestion.

## The State of Science

Even as companies count on business deals to improve the fortunes of the heart health category, there is recognition that at the end of the day, science is the beating heart of what will move the industry forward.

## Probiotics

Kaneka Probiotics (Pasadena, TX) saw positive results from a recent heart health study using its branded ingredient, Floradapt Cardio, a multi-strain probiotic formulation comprising three strains of *Lactobacillus plantarum* (CECT7527, CECT7528, and CECT7529). The 12-week randomized, double-blinded, placebo-controlled clinical trial was designed to evaluate the efficacy of red yeast rice (as 10 mg of monacolin K) combined with the three-strain probiotic. The study population consisted of 39 adults with total cholesterol of  $\geq 200$  mg/dL who were statin-naïve or had recently stopped statin treatment because of intolerance.<sup>11</sup>

The researchers concluded that “this combination of 10 mg of monacolin K and *L. plantarum* strains was well tolerated and achieved a statistically significant greater

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reduction in LDL-C and TC in the intervention group compared to the placebo, once adjusting for recent history of hypercholesterolemia treatment.”

The researchers further advised that this particular combination of *L. plantarum* strains was chosen because it had previously been shown to lower cholesterol in a randomized, placebo-controlled clinical trial<sup>12</sup> as well as shown to have high bile salt hydrolase activity and good safety data.<sup>11</sup>

The significance of bile in the cholesterol equation is “the primary mechanism behind probiotics for heart health,” Shastri believes. He explains that “it’s not commonly known that only about 15%-30% of circulating cholesterol comes from the diet. The rest is synthesized by the liver or recirculated in our bile salts.”

According to Shastri, Floradapt Cardio deconjugates bile salts into bile acids, rendering the bile acids less soluble and thereby increasing the excretion of cholesterol.

AB-Biotics, a Kaneka group company, funded the study<sup>11</sup>, supplied the probiotic strains, and was involved in data analysis.

A clinical study<sup>13</sup>, published in November 2020, demonstrated the efficacy of Deerland Probiotics & Enzymes’ branded probiotic *Bacillus subtilis* DE111 in promoting healthy endothelial function and supporting healthy cholesterol levels, according to the company’s press release.<sup>14</sup>

Specifically, the research team found that *B. subtilis* DE111 supplementation of 1 billion CFU per day resulted in significant reduction in total cholesterol and non-HDL cholesterol relative to baseline measures. The team also observed a strong trend toward reduction in LDL cholesterol as well as improvement in endothelial function. It also saw reactive hyperemia index (RHI), an indicator of blood flow and heart health, increase by 9.14%.<sup>14</sup>

“There are several studies showing the effect of other probiotics on heart health,” says John Deaton, PhD, Deerland’s vice president of science and technology. However, he says, “Our study shows a heart benefit from an inherently stable spore-forming probiotic that is resistant to most manufacturing and storage stressors.”

“Further,” he adds, “the study clarifies a clear ‘beyond digestion’ health benefit that can be conferred by a spore-forming probiotic strain.

This is important in defining the health benefits of *B. subtilis* DE111 to enable consumers to know more about the differences between strains and which to turn to for the specific functional categories they are interested in.”

Kaneka also has consumers in mind. Shastri points out that while “probiotic applications for cardiovascular health are still in the early adopter stage,” he has seen research indicating that there’s a large gap between the number of people searching for probiotics for cardiovascular health and the number of probiotic products available on the market to support heart health. He shares that according to market research from Lumina Intelligence, during the 2017-2020 time frame, there were only 14 probiotic finished products marketed for cardiovascular health in the U.S., despite what he calls a “dramatic 1146% increase” during the same time frame in online searches and product reviews from U.S. consumers for that category.<sup>15</sup>

## D-ribose and Ubiquinol

Published research, funded by the National Institutes of Health, National Institute on Aging, and the Department of Health and Human Services in the U.S., reviewed the role of mitochondrial metabolism as it may relate to HFpEF pathophysiology—and the potential mechanisms by which dietary ingredients ubiquinol and D-ribose may impact mitochondrial function. This news was shared by Bioenergy Life Science, which supplies a branded D-ribose ingredient, Bioenergy Ribose.<sup>16</sup>

In the paper, the researchers stated: “HFpEF is a common and often debilitating disease process that may be difficult to diagnose and has limited targeted therapeutic options. Mitochondrial dysfunction appears to play a significant role in the pathophysiologic processes of this clinical syndrome. Improved methods of diagnosis for HFpEF are needed, as are specific effective therapies. Active ongoing research into the roles of ubiquinol and D-ribose in HFpEF may provide clinicians with additional management opportunities.”<sup>17</sup>

The researchers noted that in their current clinical trial, they “believe supplemental oral D-ribose provides patients with HFpEF the extra substrate to bypass the G6PDH step and potentially increase

the myocardial ATP levels. Though we are unable to measure myocardial ATP levels directly, we are obtaining blood ATP measurements in HFpEF patients receiving 15 g of D-ribose or placebo over 12 weeks. Since this current blinded study is still in progress, we are unable to report these data, but we will have a more in-depth metabolic explanation after study completion.”<sup>17</sup> The study was projected to conclude in March 2021 but results were not shared by the time this article was written.

More cardiovascular science is in the works for Bioenergy Life Science’s ingredients, McDonagh says. “We are currently studying both Bioenergy Ribose and Ria-Gev for new parameters within the heart health category.”

## Vitamins

Kappa Bioscience, known for its pure, all-trans vitamin K2 MK-7 ingredient, faces an interesting challenge. Vitamin K has been around for a very long time, but despite the vitamin’s longevity, Kappa Bioscience’s Mattern says that not only consumers, but even the industry, tend to overlook vitamin K.

But, he says, “What could be seen as a challenge might actually be an opportunity, as many still do not know about the difference between vitamins K1 and K2, their roles, and how this impacts their health benefits.”

From a dietary supplement perspective, for instance, vitamin K2 has been shown to make vitamin D3 products better, safer, and more effective, Mattern says. He adds that “this is new news to many, including [health-care] practitioners. More benefit awareness for K2 will highly influence consumer purchasing behavior. Consequently, investment into communication and education is needed; that is a true and valid recipe for every trailblazer in the ingredient business.”

Part of that recipe also includes an ongoing commitment to science. According to Trygve Bergeland, PhD, vice president, science, Kappa Bioscience, “Two of Kappa Bioscience’s research partners are working on clinical trials in the cardiovascular health area using our K2VITAL pure all-trans vitamin K2 MK-7. Both of the [trials are] assessing arterial calcification reduction and

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## FIRST-EVER CACAOFRUIT JUICE NUTRACEUTICAL, FOR CIRCULATORY HEALTH

By Jennifer Grebow  
Editor-in-Chief

**COCOA AND CHOCOLATE** ingredients supplier Barry Callebaut (Amsterdam, The Netherlands; Zurich, Switzerland) unveiled in October what it calls the first cacaofruit juice nutraceutical ever launched. The cacaofruit elixir, brand name Elix, is a functional beverage that not only supports circulatory health, in addition to blood pressure, brain, and skin health, but can also leverage Barry Callebaut's official health claim linking cocoa flavanols to circulatory health.

In 2013, the European Commission approved Barry Callebaut's health claim for cocoa flavanols and healthy blood flow. The claim states that "cocoa flavanols help maintain the elasticity of blood vessels, which contributes to normal blood flow." The health claim applies to dark chocolate products providing a minimum of 200 mg of cocoa flavanols per daily intake, or to cocoa powder beverages delivering 200 mg of cocoa flavanols per daily intake. A similar health claim pending FDA approval is expected in spring 2022, the firm says.

Made from 100% pure cacaofruit, the new Elix drink contains 350 mg of cocoa flavanols per bottle, with the advice that consumers drink one bottle per day to support circulatory health. In addition, the beverage maintains blood pressure, brain health, and skin health, the company says. It is a good source of iron, magnesium, and potassium. Barry Callebaut says its customers can easily combine Elix with other herb and fruit ingredients and added nutrients. Elix itself is described as having a "zesty fruity taste."

Consumer research already indicates high interest in the new nutraceutical fruit drink category, Barry Callebaut says. The research was conducted by independent global research agency MMR in the UK and the U.S.

Barry Callebaut has researched and developed products maximizing the health benefits of cacaofruit for more than 15 years.

More than 100 human clinical studies have explored the health effects of cacaofruit flavanols, it says. Among other benefits, the firm says in a press release, "Cacaofruit flavanols help maintain the elasticity of blood vessels, which benefits the blood flow to, for example, organs such as the heart, muscles, brain, and skin."

In an interview with *Nutritional Outlook*, Pablo Perversi, chief innovation, sustainability, and quality officer and global head of gourmet at Barry Callebaut, said Elix is just one of many milestones for Barry Callebaut in its efforts to bring the health benefits of cocoa flavanols to market. In years past, the company has introduced its high-flavanol cocoa and chocolate line Acticoa, proposed a "fourth" chocolate category with its introduction of Ruby chocolate from the ruby cocoa bean, and introduced WholeFruit Chocolate, a chocolate upcycled from cacaofruit pulp. These "different breakthroughs" are the result of the company's work over the years in "understanding better the science of the cacaofruit as a whole," Perversi said.

What makes Elix and other Barry Callebaut functional products stand out in the market is that they can leverage the official health claim for circulatory health.

"In terms of fruit juice nutraceuticals, we haven't found any others that are actually deserving of a claim that has been already approved by [the European Food Safety Authority] or FDA, which has any equivalence to what we actually have," said Perversi. "And the claim we actually have allows us to position it as a nutraceutical because it actually has a tested effect on human beings that has actually been corroborated for the claim...And not many claims, as you well know, are actually allowed into this type of market, so this is obviously something that has good scientific background."



Perversi said the company expects to see Elix embraced as "food as medicine" especially in areas of the world where consumer health education and purchasing power is higher, such as in the U.S. and Europe. There is, he said, lots of opportunity for the functional beverage to grow globally, however, considering that the worldwide health and food market currently stands at approximately US\$240 billion and is projected to grow another \$80 billion. "We believe that is a big enough market for us to be able to strive in all over the world," he said.

Barry Callebaut's journey to further "squeeze the goodness coming out of the cacaofruit," as Perversi calls it, continues. "It's not today that we started doing these things, and it's not yesterday; we are on a journey of 15 years to extract value out of the cacaofruit," he said. "If there's a breakthrough, suddenly a lot of things come together, and basically this is a breakthrough for us in being able to do it this way and bring it together."

He continued, "The people we have at Barry Callebaut just make these great things happen over and over and over again, and being in the lead and being able to announce a new product almost every year in an industry that hasn't really had these types of things happening for many, many years is actually something that we feel very proud of."



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potential cardiovascular parameters improvement thanks to supplementation.”

More specifically, Bergeland advises, “In the AVADEC trial, supervised by a research team from the Odense University Hospital, in Denmark, the last participant finalized the study in early 2021, and now an extensive analysis is ongoing.” He notes that the study population consisted of 400 patients diagnosed with aortic valve calcification.

The InterVitaminK trial, planned by the Frederiksberg Hospital, also in Denmark, has similar objectives, but is looking at a healthy population of 450. Inclusion is about to start, and the trial is expected to take three years. Bergeland says the protocol for this randomized controlled trial was presented in September at the International Vitamin Conference in Copenhagen.

“After being overlooked by scientists for decades,” says Bergeland, “vitamin K2 is coming back under their radar, as many areas are still to be explored.”

### Botanicals

HP Ingredients’ Eng advises that her company’s LJ100 tongkat ali (*Eurycoma longifolia*) was shown in a recently published study to improve cardiorespiratory fitness in men with androgen deficiency (ADAM). In the study, 45 men took either LJ100 or placebo

for six months while concurrently working out. Those taking the supplement experienced an approximately 10% greater reduction in ADAM symptoms than those in the placebo and workout group.<sup>18</sup>

Monteloeder has science news, too. According to a company press release, a randomized, double-blind, placebo-controlled study published in spring 2021 demonstrated that daily consumption of the company’s proprietary Metabolaid branded botanical extract ingredient was able to significantly reduce blood pressure. The most remarkable results were observed in the daytime measurements—particularly in systolic blood pressure, which showed a decrease of 5%. The study was conducted in a population of 80 unmedicated, slightly hypertensive subjects over an 84-day period.<sup>19,20</sup>

There’s more to come, says Jones. “We are currently working on analyzing the effect of combining our branded ingredients with a mobile app that helps manage consumer behavior towards a healthy lifestyle. The most relevant outcomes in this study are weight loss and blood pressure,” he says.

### Why Fund Science?

There’s no question that supporting science through research grants or supplying ingredients or involvement in proper study

design can go a long way for ingredient suppliers and finished product manufacturers. Not to mention consumers.

But what about the critics, those who prefer not to see any involvement from industry?

According to Deerland’s Deaton, “Some would argue that industry funding of scientific studies introduces bias, but this isn’t always the case, and ethical suppliers know how to ensure bias is not introduced. There are ways to prevent bias in supplier-funded research via the introduction of protective check points.”

He refers specifically to the recent cardiovascular health study<sup>13</sup> for which Deerland not only supplied the ingredients and study funding but also collaborated with the university on the study design protocol as an example of how to do things properly.

Deaton says protection from bias was in place via the fact that the university performing the study was independent from his company. The statisticians analyzing the data were also independent, and the study was approved by an independent Institutional Review Board (IRB) that received no financial compensation.

He adds that “the study was also double-blinded to prevent the researchers from knowing who was receiving the placebo or the probiotic treatment. The final checkpoint in place was that the findings of the study were

*“If we look at heart health from a more holistic sense, it may help to improve the situation,” says Deerland’s Sam Michini.*





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Deaton emphasizes that “as long as checkpoints like these are in place, then the quality and validity of industry-funded studies can be on par with those that rely on other sources of funding.”

And, he concludes, as long as companies use protective checkpoints to prevent bias, “it is good and helpful for them to financially support science.” After all, unlike well-funded drug studies, nutraceutical research often needs an additional boost. “This support helps promote applied research directly relating to consumer health needs that may not otherwise occur. It also helps ensure that products available to consumers, and the claims used to market them, are backed by valid science,” he says.

Monteloeder’s Jones is also a proponent of industry support for science. “Funding science is vital in order to advance in the field,” he says. “This is the same situation that exists in clinical research for Alzheimer’s disease, cancer, or any other major disease. Without private funding, we would not have the current knowledge nor available treatments that exist today.”

“In addition,” he says, “an important part of our funding comes from public grants; therefore, these studies have been previously analyzed by scientific experts and validated by public authorities. Furthermore, all our studies are published in peer-reviewed journals, and we ensure to make them available for anyone to read.”

According to Jones, Monteloeder provided the ingredients and participated in the study design and interpretation of the results of the aforementioned study.<sup>19</sup> His company also provided funding, as did several national and international public organizations, including the Horizon 2020 project from the European Union.

“Science is part of our DNA,” he says, “so for us, having a deep knowledge of our botanicals, from the raw materials to extraction process, formulations, mechanisms of actions, and clinical efficiency, are of utmost importance.”

Bioenergy Life Science’s McDonagh also disagrees with the criticism of industry involvement, stating that “we advocate for all

new research, even when funded by independent companies or universities, because research often reveals new awareness and discoveries. Additionally, by funding primary research using our branded ingredients, we can validate the ability of our specific ingredients, versus commodity brands, to deliver scientific benefits.”

Company-funded research also enables a company to demonstrate safety and efficacy for consumers. “Ethically speaking,” she says, “all researchers must disclose their conflicts of interest while drafting the manuscript for publication, and if this is done properly, there is no basis for a Catch-22 situation.”

## Hope for Recovery?

Investing in science will also secure the long-term health and growth of the heart health category. As of now, the category could use it.

Brewster of Ingredients by Nature refers to market research from *Nutrition Business Journal* (NBJ) showing that while 2020 saw slightly better growth in the heart health category than in 2019, the category is expected to experience slower growth in 2021 and 2022—5.9 percent and 3.6%, respectively<sup>21</sup>—because the pandemic caused most attention to shift to immune health.

And Deerland’s Michini paints a similar picture. He says NBJ’s annual Condition Specific Report projects heart health supplements to grow at an estimated rate of only 1.5% in 2023, which, he says, NBJ characterizes as “the worst growth year in the category in recent memory.”

“It’s an interesting challenge,” says Brewster, “because the health risks from the pandemic are made worse for consumers with preexisting cardiovascular challenges, but most consumers are focused more on short-term changes than looking at the big picture. This means it is important to develop products that fit into certain lifestyle scenarios that they can feel comfortable incorporating now that will also benefit them farther down the road.”

“One way to do this,” he advises, “is to figure out how to make heart health ingredients cross over into other areas as well. If we look at heart health from a more holistic sense, it may help to improve the situation. For example, we know that there

is a connection between unhealthy blood glucose levels and unhealthy cholesterol, so by catering to consumers looking for improved blood sugar support, we can also help them with their heart health.”

“There are other categories that heart health ingredients can help with, too,” Brewster adds. “It just takes approaching the category from a new angle.”

Probiotics is one of those. Speaking about probiotics as an emerging heart health ingredient, Deerland’s Michini advises that probiotics are a vastly encompassing supplement category and, as such, require more specificity. “It has more marketable strains than the vitamin/mineral category has; therefore, it is essential to distinguish the powers of each strain and/or species. This would entail thoughtful positioning by brand marketers and, in turn, educated retailers.”

Kaneka’s Shastri advises consumers not to expect that by simply taking a probiotic, or any other nutrient for that matter, that a cardiovascular benefit will result. He believes consumer expectations should be modulated by the published science for that given effect on a particular nutrient.

In the case of probiotics, in order for there to be a benefit, “first the strains have to demonstrate a hypolipidemic effect in a randomized, placebo-controlled setting, and second, the finished product needs to have the identical potency as seen in the clinical trial,” he points out. Shastri says that’s the case with his company’s three-strain probiotic and another reason why Kaneka believes having sound science behind ingredients is vital to the category’s growth.<sup>12</sup>

And then, of course, there is the issue of communicating the benefits to consumers under a regulatory framework for supplements that doesn’t reward results from clinical trials with relevant claims.

Monteloeder’s Jones has some experience with that challenge. He says, “Product labeling is a balancing act to send the right message that resonates with the consumers while complying with the norms defined by the regulatory agencies.”

He understands why that’s important. “While this may seem unfair at first, especially if the claims are backed by solid science, it is important to maintain a strict level of contingency of what can be placed on a label. This

increases consumer trust in the products in the market, as they are ensured that the claim complies with FDA/FTC regulations,” he says.

Jones reminds the industry that “there are many examples in the past where non-based claims have been applied to products that have turned out to be false, losing consumer trust that can ultimately affect the industry as a whole.”

But Jones does have one regulatory wish that results from a marketplace reality.

“On the other hand,” he says, “the nutraceutical landscape is a fast-shifting market strongly based on innovation, focused on consumer needs, in almost real time. Unfortunately, the regulatory bodies do not move at the same speed. Therefore, the industry as a whole would greatly benefit from a more agile regulatory body allowing faster innovations to appear in the market—of course, always considering consumer safety above all else.”

Riley of OptiBiotix agrees that there can be challenges when selling a product that does not have approved health claims. He also points to the challenges of differing country and continent regulations for quality, efficacy, and safety regulations. “Since regulatory frameworks can change from time to time, manufacturers and distributors must keep abreast of the different regulations to market their products effectively,” he states.

But Riley remains optimistic. “By using our collective scientific knowledge and combining it with the advancements in technology, we can make a significant difference in people’s lives, therefore decreasing the burden on global medical establishments and improving quality of life,” he says.

Mattern, of Kappa Bioscience, points to more reasons to be optimistic, citing insights from a recent report published by FMCG Gurus surveying tens of thousands of consumers worldwide. For example, he says, the report shares that “three in four consumers in North America plan to improve their heart health over the next twelve months,” and “56% regularly research about ingredients that can improve their health.”<sup>22</sup>

HP Ingredients’ Eng has an interesting twist on marketing the category. “Find ways to ‘re-invent’ what heart health means,” she says. “Get it out of the ‘for older folks only’ category and reinvigorate it for younger, healthy adults who want to remain physically vivacious.”

“Looking into the future,” says Eng, “as the Millennial generation enters middle-age, we see a great resurgence in focus on cardiovascular wellness but beyond choosing fish oils or CoQ10 for cholesterol management. This generation has been raised with the understanding that a healthy lifestyle can and will pay dividends for their well-being in the future; they self-educate and purchase supplements routinely. Cardiovascular health is integral to overall fitness, and this understanding is very strong with the younger generations.”

“For consumers, it’s not only about finding a dietary supplement that can aid their cardiovascular health,” says Riley. “It’s about discovering one that can effectively reduce their cardiovascular risk, either now or in the future.” ■

**Judy Blatman Communications LLC specializes in strategic counsel, media training, writing, and talent solutions. Blatman spent 16 years as senior vice president of communications at the Council for Responsible Nutrition.**

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# Fiber *Forward*

Where is fiber heading?

BY SEBASTIAN KRAWIEC, EDITOR



Fiber's got a lot going for it. One of the biggest boons is consumer recognition. As an ingredient, fiber's perceived healthfulness is the highest among consumers, according to the 2021 Food and Health Survey from the International Food Information Council (IFIC), with 56% of respondents actively trying to consume fiber. For manufacturers, fiber also boasts a lot of advantages. Fiber ingredients can improve the texture and stability of baked goods and even yogurts, help with sugar reduction, and add valuable digestive and cardiovascular health benefits.

According to the IFIC survey, a majority of consumers (92%) try to get fiber from food, but 1 in 5 still use supplements for fiber. To help consumers achieve their daily recommended fiber intake, offering well-tolerated products is paramount. "It can be difficult to meet the daily recommended value of fiber of 28 g for a typical 2,000-calorie-per-day diet through consumption of foods," explains Sarah Diedrich, marketing director, sweetening solutions & fibers, ADM (Chicago, IL). "To conveniently add more fiber, some consumers look to foods fortified with added fiber, but these products can be associated with gastric distress. Our research finds that nearly 70% of consumers would not purchase a product again if it caused gastrointestinal discomfort."

## Immune Health

Fiber is associated with a number of health benefits as science on the gut microbiome improves. One growing interest area is the connection between digestive health and immunity.

"The early research suggests that prebiotic dietary fibers, such as our Promitor Soluble Fiber, may help support immune health, and research

continues regarding this potential benefit," says Melissa Kaczmarczyk, principal scientist, Global Nutrition, Tate & Lyle (London). "Furthermore, a lack of dietary fiber intake can have negative impacts on the gut barrier and result in increased susceptibility to pathogens."

"Consumers' concern for their immune health has only intensified throughout the pandemic, with 65% of global consumers more conscious of immunity due to COVID-19," says Diedrich, citing research from FMCG Gurus. And they're looking at fiber. "In fact, of the 87% of U.S. consumers interested in products with ingredients that may support immune function, 65% are specifically interested in fiber. We anticipate an increase in the development of fiber ingredients that link to immune function—supporting benefits as consumer demand grows."

## Prebiotic Promise

Prebiotic claims can promote the digestive and immune health benefits of fiber products, but manufacturers should be careful not to confuse consumers.

"The introduction of terms like *prebiotic* may cause confusion without proper explanation, but the use of this term shows a greater interest in trying to understand the complexities of gut health," Kaczmarczyk says. "While consumers today have a greater understanding of gut health, additional education needs to be provided to further explain the differences and benefits that prebiotics, probiotics, and synbiotics can have on the human microbiome. Additionally, not all consumers today know that many types of soluble fibers are prebiotics."

She adds, "Over the past 90 days, social media posts confirm interest in 'fiber' and 'prebiotics,' but the combination of these two

terms does not appear as frequently. This data supports that while prebiotics are being talked about alongside fiber, additional steps need to be taken to educate consumers on the link between fibers and prebiotics."

According to Nicole Redini, category strategy manager, NOAM, Tate & Lyle, not enough manufacturers leverage the fiber content in their products. "From an opportunity standpoint, only around 2%-3% of food and beverage U.S. launches make a high-/added-fiber claim, which may indicate that while several products contain fiber, consumers may not be fully aware of the benefits," says Redini. "In addition, less than 1% of U.S. food and drink launches contain a prebiotic claim. This presents an opportunity for brands to launch products with high-fiber, prebiotic, and gut health claims to ensure consumers are aware of the benefits they are receiving by consuming products containing fiber."

With the development of well-tolerated and versatile fiber ingredients like ADM's Fibersol and Tate & Lyle's Promitor Soluble Fibers, fiber can play in many products. "The category with the greatest share of new product launches containing soluble fiber ingredients remains snack, cereal, and energy bars, according to Mintel GNPD," says Redini. "However, in 2020 and 2021, other categories such as sweet biscuits and cookies, cold cereals, vitamins and dietary supplements, and ice cream saw an increased share in launches containing fiber. There has also been a continued rise in the launch of fiber-based gummy supplements over the past year to support gut health."

The takeaway? Fiber has a lot to look forward to—and so do consumers. **N**

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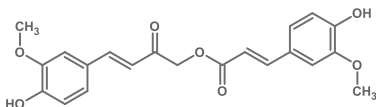
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