NOVEL DELIVERY SYSTEMS

How are innovators delivering next-generation options for dietary supplements? p. 18

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Bolstering Botanical Best Practices

This free, hands-on assessment program comprises checklists that those in the herbal industry—everyone from growers and harvesters to processors and manufacturers—can use when working in their area of the field to determine whether or not they are meeting what experts in those fields have defined as best practices. I recently spoke with Jane Wilson, AHPA’s director of program development, about how these standardized best practices tools can be used up and down the botanical supply chain, and about how they hopefully will help bolster quality control and transparency throughout the botanical industry.

First off, Wilson says, the increased public scrutiny around dietary supplements—and around the herbal supplement industry, in particular, as a result of 2015’s New York Attorney General (NY AG) investigation of herbal supplements and retailers—was the impetus that led AHPA to create the assessment tool. Wilson notes that, as a result of the NY AG investigation, many of the major supplement industry trade associations began undertaking self-regulatory initiatives.

AHPA’s assessment tool, she says, is aligned with the association’s area of expertise, the botanical industry. “That was really the big driver, the recognition after the NY AG activity that there was more work that we could do as an industry to police ourselves and hold ourselves to high standards,” she says.

By 2006, she says, AHPA had already developed and released its Good Agricultural and Collection Practices for Botanical Materials document. But by mid-2016 (post NY AG), she said, AHPA decided to further update and translate those standards into actionable checklists for companies to use and make sure the checklists encapsulated new regulatory requirements such as those of the Food Safety Modernization Act.

The association gathered experts specializing in various areas of the botanical industry, and those experts helped to identify and develop the checklists. “We looked at things they were already using and got a sense of what it is that they do on a daily basis in terms of what would help their decision-making processes,” Wilson says. “The result is nine separate checklists covering: 1) botanical identity and quality assessment, 2) cultivation, 3) wild collection, 4) general farm standards, 5) harvest, 6) post-harvest handling, 7) further processing, 8) food facility and farm facility, and 9) a dietary ingredient supplier assessment tool.

Wilson says these checklists can be used in a number of ways. First, those working in the field can use the individual checklists to self-assess their own procedures against expert-defined best practices as they do their work. But those operating farther upstream—for instance, those who purchase botanical ingredients—can also require their suppliers to utilize these checklists to confirm that the suppliers are adhering to best practices. “So, it can kind of be a push-pull,” Wilson says.

“The suppliers can use it and provide it to somebody upstream who’s buying their botanicals, and they can say, ‘Hey, this is what we do, so you can see what our practices are.’ And then the people upstream can send it backward and tell a supplier, ‘Well, we want to buy your material, but we’d like you to fill this out so that we can get a sense of what your practices are and around certain activities and how you produce your botanical material.’” Wilson also points out that the checklists are editable Word docs so that companies can change any portions that they feel don’t apply to their business, etc. “They’re intended to be flexible so that companies can use them to the best advantage,” she says.

If anything, Wilson says, the hope is that these tools will emphasize the need for documentation. Because, she says, “I think the question goes to, ‘Are you doing it, and are you documenting it?’” Because those can be two different things. So, when somebody starts asking you to prove whether you’re doing something, it’s helpful if you have an SOP that you can show them that says this is what our staff is supposed to do, etc.”

“There are probably segments of the botanical industry where a lot of these practices are just generally recognized, but it’s not anything that anyone’s thought, ‘Well, I need to keep a record of the fact that I’m doing that,’ or ‘I need to be able to demonstrate that somebody has been adequately trained on that,” she continues. “So, it’s just formalizing, hopefully, a lot of these activities that have been well-recognized for a long time, but now, because of some of these issues, like attention from the NY AG, that it becomes important to be able to document specifically that you are doing these things and that you’ve been adequately trained to do these things.”

Jennifer Grebow
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A new market data report found that the plant-based food category is expanding rapidly. Compared with data from 2016, plant-based food product sales are up 8.1%, with sales reaching $3.1 billion. The first-of-its-kind report, which was commissioned by The Good Food Institute (GFI; Washington, DC) and the Plant-Based Foods Association (PBFA; San Francisco, CA) with data from Nielsen’s Expanded All Markets Combined Channel, shows that plant-based food products are more popular than ever, while sales for all other foods sold in the same channel were down 0.2%.

The report features data collected from grocery stores, drug stores, mass merchandisers, club stores, dollar stores, military stores, and Whole Foods Markets, collected over a period of 52 weeks ending August 12, 2017. GFI and PBFA noted that the data does not include restaurants or foodservice. Specifically, the data pertains to food items that are meant to replace animal products, including meat, seafood, eggs, and dairy. For data-tracking purposes, the market was segmented into the following categories: tofu and tempeh, meat alternatives, milk alternatives, other dairy alternatives, egg substitutes and mayo, and meals.

Within the broader plant-based food category, the plant-based meat market is up 6% this year, compared with 2016 data. According to the report, refrigerated plant-based meat products are growing particularly quickly, up 20% over last year, while frozen plant-based meat products experienced more modest growth.

Dairy alternative sales are also showing no sign of slowing. The plant-based milk category is up 3.1% over last year. Meanwhile, the report says, sales for cow’s milk are down roughly 5%. Plant-based dairy alternatives (excluding milks but including cheese, yogurt, ice cream and frozen desserts, butter, dips and dressings, iced coffees, and creamers) are up 20% over last year, with $700 million in sales.

“There is a revolution going on in the plant-based meat space,” said Bruce Friedrich, executive director, GFI, in the press release. “Right now, the sector is small, but growing, and we are working hard to create a viable market sector. It is especially impressive to see that all the plant-based companies are working cooperatively because a rising tide will lift all boats.”

**FDA Asks International Trade Commission to Decline Amarin’s Request to Investigate Omega-3 Supplement Makers’ Practices**

Weighing in on a continuing dispute between pharmaceutical firm Amarin Pharma (Bedminster, NJ) and the supplement industry’s leading omega-3 marketers and suppliers, FDA sent a letter to the United States International Trade Commission (ITC) on October 6, 2017, recommending that the Commission decline Amarin’s request to investigate said supplement firms’ practices.

Some background: Amarin Pharma, maker of a synthetic EPA omega-3 drug in an ethyl ester form marketed as Vascepa, filed a complaint with the ITC alleging that omega-3 dietary supplements predominantly comprising EPA in either the ethyl ester (EE) or re-esterified (rTG) form are synthetically produced and therefore should not be considered “dietary ingredients” under Section 201(ff)(1) of the Federal Food Drug and Cosmetic Act (FDCA).

Arguing that such omega-3 products should be classified as “new drugs” and are "falsely labeled, and/or promoted for use as, or in dietary supplements" under the FDCA, Amarin asked in its complaint that the ITC investigate the "unlawful importation or sale in the United States of synthetically produced omega-3 products."

In its own letter to the ITC, FDA “respectfully submits” that the Commission not initiate an investigation for several reasons. Among them, FDA noted that Amarin’s claims that supplement companies engaged in unfair competition based on false advertising can succeed only if the ITC itself finds that the supplement products in question are unapproved “new drugs” rather than “dietary supplements” under the provisions of the FDCA—yet such a determination Congress has delegated solely to FDA to make.

Further, FDA stated that Amarin’s complaint “is predicated on open questions of law and policy on which FDA has not reached final conclusions.” In other words, FDA has several kettles simmering on issues that Amarin raises, and were the ITC to undertake the requested investigation, its findings may conflict with later-finalized FDA guidance on the matters.

FDA also expressed concern that action on the current Amarin request could “create an incentive for other parties to file similar complaints about other FDA-regulated products” ranging from foods and drugs to biologics, medical devices and vaccines, among others. And for good measure, FDA noted that while Congress granted FDA the tools to enforce the FDCA, it prohibited private parties from bringing any such enforcement actions themselves. As the agency states in its letter, “FDA cannot administer and enforce the FDCA effectively if core FDA issues—such as whether a product is a ‘new drug’ or a dietary supplement under the provisions of the FDCA—yet such a determination Congress has delegated solely to FDA to make.

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FDA’s comments follow a public interest statement and non-institution letter that the Council for Responsible Nutrition (CRN; Washington, DC) filed in response to the ITC’s Notice of Complaint and non-institution letter that the Council for Responsible Nutrition (CRN; Washington, DC) filed in response to the ITC’s Notice of Complaint and non-institution letter that the Council for Responsible Nutrition (CRN; Washington, DC) filed in response to the ITC’s Notice of Complaint and non-institution letter that the Council for Responsible Nutrition (CRN; Washington, DC) filed in response to the ITC’s Notice of Complaint and non-institution letter that the Council for Responsible Nutrition (CRN; Washington, DC) filed in response to the ITC’s Notice of Complaint and non-institution letter that the Council for Responsible Nutrition (CRN; Washington, DC) filed in response to the ITC’s Notice of Complaint and non-institution letter that the Council for Responsible Nutrition (CRN; Washington, DC) filed in response to the ITC’s Notice of Complaint and non-institution letter that the Council for Responsible Nutrition (CRN; Washington, DC) filed in response to the ITC’s Notice of Complaint and non-institution letter that the Council for Responsible Nutrition (CRN; Washington, DC) filed in response to the ITC’s Notice of Complaint and non-institution letter that the Council for Responsible Nutrition (CRN; Washington, DC) filed in response to the ITC’s Notice of Complaint and non-institution letter that the Council for Responsible Nutrition (CRN; Washington, DC) filed in response to the ITC’s Notice of Complaint and
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Setting the Bar High

Interest in portable, tasty nutrition reaches new heights.

BY INNOVA MARKET INSIGHTS

The cereal bars market is maturing after years of strong growth, particularly in the United States, which is the largest market in the world. Global and U.S. launches of cereal and energy bars recorded by Innova Market Insights fell slightly in the 12 months to the end of June 2017, although numbers were still well above totals for the previous five years. The mature U.S. market saw just over a 50% rise in launch numbers over the previous five-year period (June 2012–2017). Meanwhile, the less well-developed regions of the world saw even more dynamic growth with a surge of more than 90% globally over the same period.

As interest in cereal bars has grown, the category has broadened to encompass a wide range of products, including granola/muesli, breakfast, nutrition, and energy and performance bars. With increased competition in this market, however, many product makers seek to highlight points of differentiation by combining features and blurring definitions, often carrying a range of ingredients and product claims designed to appeal to the widest possible audience seeking nutritious, tasty, and portable snacks in a highly competitive environment.

Market Differentiation: What’s In and What’s Out

The nutrition bars sub-category focuses specifically on health, but most products launched in the cereal bar market also use health claims. More than 83% of global launches recorded by Innova Market Insights in the 12 months to the end of June 2017 used at least one kind of health positioning; in the United States, nearly 95% of cereal bars launched in the same period had some kind of health positioning.

Whole-food nutrition and natural ingredients are key areas of interest, with clean labeling and “free from” continuing to be areas of focus. Nearly half of U.S. launches featured one or more claims relating to naturalness, no additives/preservatives, or organic certification. This figure rises to nearly two-thirds when GMO-free claims are also included.

The growing use of GMO-free positionings has been apparent in the global food and drinks market in recent years, but has been especially prevalent in the United States and for cereals. Innova Market Insights estimates that 48% of newly launched products use this type of claim, up from around 10% five years previously.

Cereal bar launches with “free-from” positionings are not far behind clean labelling in the United States, with 64% featuring allergen-free, gluten-free, lactose-free, vegan, and vegetarian claims. Gluten-free is the leading health positioning for cereal bars as a whole.

Recently launched Pure Organic bars—with quinoa, brown rice, amaranth, flaxseed, and hemp seed—illustrate the trend of bars with healthy grains.

This positioning is used for more than 60% of all new product introductions.

Other key areas of interest include the use of whole grains, fiber, and, more recently, protein. Protein is now the most significant of the three, with “high/source of protein” claims used for 47% of launches in the 12 months to the end of June 2017, compared with 34% for fiber and 17% for whole grains.

Gains with Grains

Interest in whole grains has been key to the growth of the cereal bars market for many years, but more specific types of grains are increasingly being featured. For instance, ancient grains and seeds have seen rising levels of new product activity in the food and drinks market over the past few years, with their reappearance in modern diets reflecting increased interest in products such as quinoa, chia, millet, buckwheat, sorghum, spelt, amaranth, teff, and kamut. Such grains and seeds are being positioned as traditional, natural, and nutritious. Cereals, perhaps not
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surprisingly, have seen especially high levels of activity, with nearly one-fifth of launches featuring ancient grains, rising to nearly 24% for cereal and energy bars.

Some launches profile the inclusion of ancient grains very specifically, with recent introductions including Thrive Ancient Seeds Superfood Nut Bars from GoMacro (Viola, WI) and Ancient Grains Triple Berry Nut Crispy Bar from Pure Organic (Solana Beach, CA). The latter product features an organic ancient grains blend of quinoa, brown rice, amaranth, flaxseed, and hemp seed.

Another on-trend ingredient popular in the cereal bars category is hemp, with the United States again leading developments. Its success is attributed to several factors; in addition to being a source of high-quality plant-based protein, it is also high in polyunsaturated fatty acids, rich in B vitamins and minerals, and contains high levels of both soluble and insoluble dietary fiber.

Taste, convenience, and novelty are important if the products are to compete with other snacks and meal replacements.

More than one-quarter of U.S. food and drinks launches featuring hemp in the 12 months to June 2017 were cereals, with cereal bars alone accounting for more than 21%. Recent launches with a strong focus on hemp include Everbar Hemp Powered Bar from Livity Foods LLC (Rockville, MD) and the Evo Hemp Organic Raw from Hemp Healthy (Boulder, CO). The Evo bars also focus on other key trends, being organic, raw and cold-pressed.

Taste, Convenience, and Novelty Remain King

While health and nutrition concerns appear to be driving product development, it must not be forgotten that taste, convenience, and novelty are also very important if the products are to compete successfully with other snacks and meal replacements. Increasingly indulgent ingredient blends and flavors are also featuring strongly, including more savory options and sweet–savory combos, along with the development of new formats such as miniature and bite-size options in resealable pouches or sharing bags.
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BRAVE NEW FORMATS

Novel supplement delivery systems push boundaries.

BY KIMBERLY J. DECKER
In the beginning, there were tablets. And, they were good...for the most part. But for users who found them unpalatable, difficult to swallow, or just plain boring, they left a lot to be desired. So, dietary supplement developers said, “Let there be better delivery systems.” And, then there were capsules, gel caps, and soft gels, which considerably improved upon the basic tablet.

Then developers said, “Let there be shots, sprinkles, chews, and gummies,” and these options were even more convenient, appealing, and innovative than what came before. So now that everything from nutrient nanoeumusions to liposomal blends is emerging from R&D labs, we may be witnessing the most exciting delivery advancement the dietary supplement space has ever seen.

But: Are they truly supplements?

That’s the question facing industry and regulators as new nutrition platforms push the edges of science, creativity—and the law. How far do those borders reach? Vincent Tricarico, vice president of contract manufacturing, NutraScience Labs (Farmingdale, NY), believes, “We’re still in the very early stages of determining where these new formats end up in terms of regulation.”

And while FDA might counter that we know exactly where the regulations stand, thank you very much, we can all agree that the goal, as Tricarico says, “is to keep the public safe.” So, as we chart this brave new world of supplement delivery systems, caution may be the first commandment.

Challenging Tradition

Despite all the innovations in delivery-system design, formats such as classic capsules, powders, softgels, and tablets—as well as gummies, liquids, and chewables—remain the most popular supplement delivery systems by far, Tricarico says.

Missy Lowery, MSc, senior manager of marketing, Capsugel (Morristown, NJ), concurs, noting that all generations—“Millennials, GenXers, Boomers, matures”—still gravitate toward traditional delivery formats. More specifically, she says, 42% of supplement users prefer capsules, while 41% prefer tablets, according to the most recent 2015 Supplement Over-the-Counter Rx Data (SORD) study from NMI.

But, Mona Liu, brand supervisor of marketing, Sirio Pharma Co., Ltd. (Shanghai, China), says, “While these delivery systems have been successful in the past, they’re facing challenges from innovative delivery systems of the future.”

Why We Innovate

Such challenges are understandable. “Innovation in delivery systems is critical to helping certain individuals meet their needs, preferences, and limitations,” says Douglas “Dufy” MacKay, ND, senior vice president of scientific and regulatory affairs, Council for Responsible Nutrition (CRN; Washington, DC). Older users can have difficulty swallowing pills; children simply may not like them. Consumers can tire of the same-old supplement vehicles. Even psychology plays a part, as “the traditional tablet and softgel can remind people of medicines or drugs,” Liu adds.

Innovation does more than satisfy consumers, however. It also feeds supplement industry growth. Of course, discovery and development of new supplement ingredients—and new uses for them—account for the bulk of that growth. Differentiating a product via novel delivery is a reasonable means of ending off competition, at least for a while.

Says MacKay, “There are all sorts of reasons to explore different formulas and ingredients in everything from a gummy to a tablet to a capsule to a liquid to a chewable to a wafer”—all of which, he adds, are “well within our regulatory areas.” It’s when exploration starts moving outside those areas that alarms may sound.

No Direction Home

To an industry as captivated by scientific progress as ours, limiting the scope of delivery-system invention can feel a bit like taking away the punchbowl. “There’s the desire to be creative and innovative and to think outside the box, which is such an exciting thing to be part of,” MacKay states. But the flipside of that excitement, he says, is “the tension between the category and the limitations it presents based on the regulations.”

And the “number-one limitation” that the Dietary Supplement Health and Education Act of 1994 imposes is its narrow definition of a dietary supplement: a substance administered orally, swallowed and absorbed through the gastrointestinal tract. “You start getting into inhalables, transdermal patches, nasal sprays, vapes,” MacKay says, “and these just don’t have a home inside of dietary supplements. They can’t change the supplement laws. These just are not dietary supplements.”

Crossing the Line

Consider sublingual products. Vitamin B₁₂ is a prime example of a nutrient for which sublingual administration—wherein drops of the vitamin placed under the tongue are absorbed through blood vessels—is “convenient and important,” MacKay say.

Many of the enzymes that help us absorb B₁₂ through the gut weaken and diminish with age. And though “you can still deliver B₁₂ in a dropper bottle, make it with dietary supplement GMPs, and label it as a supplement,” MacKay continues, “you cannot tell the customer that it’s intended to be absorbed through the blood vessels under the tongue” as opposed to the gut. Only doctors can do that—say, as a treatment for megaloblastic anemia. “So, the question for FDA becomes, ‘Is that appropriate for supplementation, or is that more of a clinical use?’” MacKay says. “And their answer would be clinical. It makes sense from a public health/public policy balance.”

Even wildly popular functional foods can tread into dicey regulatory territory. Several times recently, FDA has warned marketers of melatonin-containing brownies, beverages, and other foods that because their products are conventional foods rather than supplements, the presence of melatonin—an unapproved additive without GRAS status for food use—in their formulations renders...
them adulterated. Here, too, MacKay thinks “if you peel back the layers of that onion,” FDA’s move “does make some sense.” While an ingredient like melatonin may be “appropriate to put into a dietary supplement labeled, ‘Take one capsule before bedtime, it’s not appropriate just to throw it into some chocolate milk.”

**Welcome to Nano-World**

Perhaps the arena with the greatest potential for both revolutionizing supplement delivery and attracting FDA’s attention is that of nanoparticles (i.e., those that are 1–100 nanometers in size). Even toxicologists, whose job is to study and understand the adverse effects of chemicals, find the nano-world “probably the most troubling and not-well-defined area” of new product development, says John R. Endres, ND, chief scientific officer, AIBMR Life Sciences (Seattle, WA).

Or, as MacKay puts it, “This is science-fiction stuff.”

Yet, some brands ballyhoo their nano-credentials, promoting products presumably made all the more powerful by the extreme miniaturization of dietary ingredients. The concern, says Endres, is that nano-sized ingredients could pass through the blood–brain and other barriers our bodies have evolved to control what gets inside and into key organs—and not enough research has been conducted to illuminate what happens once they’re there. “So that’s a big issue, one that even major toxicology groups haven’t figured out yet,” Endres says.

Bioavailability is another black box obscuring nanoparticles’ safety. FDA grants ingredients GRAS status based upon common consumption levels generally recognized as safe. But if nanoparticleization makes ingredients that much more bioavailable—which is kind of the point—we no longer know if the levels previously determined to be GRAS continue to be so. “And if you don’t know,” Endres adds, “you have to test it—but if it’s nano, we don’t yet know how to test it.”

Of course, some products claiming to contain nanoparticles really don’t, which adds a troubling layer of misleading labeling. Endres adds that similar safety questions accompany “virtually every delivery format where the whole purpose is to increase ingredient bioavailability and get more into the system.” So, his message to marketers is, “Do your homework because the main concern is safety. That’s always the main concern.”

**Oldies and Goodies**

MacKay agrees that consumer safety is the top priority: “That’s the bottom line. If you set aside the marketing excitement, these are fairly rational models for public health and public safety.”

And here’s the great part: They don’t have to squelch innovation. In fact, they can pay unexpected dividends. For while developers tread cautiously with respect new delivery formats, they continue improving the formats already in use—and in accordance with FDA regulations.

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Delivery Systems

As MacKay says, "Some of the really cool stuff is the simple stuff."

For example, industry "waited for years" for vegan gel caps that weren't brittle and could protect labile ingredients like fish oil. "There were multiple generations of failures in that area where they were too stiff or leaked or had other drawbacks," MacKay says. "So, innovation had to continue."

He's also bullish on "tablets within tablets and capsules within capsules" as a means of making supplement delivery more convenient and personalized. "Compliance is a big piece of this," he notes. "If you're going to use supplements regularly, how easy is it to do so?"

Lowery's company is already making it easier. "Growing consumer interest in multi-combination and multi-release supplements has opened the market for the elegant delivery forms of beads-in-a-capsule and capsule-in-a-capsule DUOCAPS," she says. "Such platforms play to the 'less-is-more' trend by combining two or more supplements into one capsule that minimizes the number of supplements a consumer takes while also giving them more bang for their delivery-system buck."

Lipid multiparticulate (LMP) technology can also boost ingredient effectiveness by modifying release and enhancing bioavailability. LMPs are microspheres ranging in size from 50 to 300 µm, and each particle is formulated to contain a measured micro-dose of actives—from botanicals and vitamins to amino acids and more. Because of their excellent flow properties, Lowery says, the particles are suitable for a broad range of formats, including textured powder blends for scoop, sachet, or stick delivery; powder-filled capsules; sprinkle capsules and capsules-within-capsules. She states, "The ability to precisely deliver a metered dose of actives combined with the controlled particle size of LMPs can lead to improved gut distribution."

All in Good Taste

The particles' "advanced precision dosing and floating microspheres" also feel smooth on the palate "rather than crunchy to the teeth," Lowery adds. Even better, they "improve the consumer experience by masking the taste of bitter ingredients."

And, that's an important point—for as whiz-bang as supplement delivery systems may get, palatability remains a major requirement for success. Take the ever-popular gummy as an example. "It's difficult to balance both the taste and texture when developing multivitamin gummies—especially for those that contain high levels of minerals," Sirio's Liu says. "Dose uniformity—particularly in gummies containing micronutrients, oil-soluble substances, and minerals—also requires special processing. And with process temperatures exceeding 210 °F, moisture contents above 10% and a pH that hovers around 3, the gummy platform does not promote active-ingredient stability."

But Liu's team has focused on "bringing better flavor to gummies and masking their unpleasant bitterness, metal and fishy notes" even as the gummies include more active ingredient. They've also developed an accelerated stability study method that, in three months' time, can evaluate product performance predictive of 18–24 months of shelf life. With gummy multivitamins generating 7.5% of the $6-billion US multivitamin market in 2016, Liu says, such improvements are money in the bank.

And they're no less exciting than any nanoemulsion, vitamin vape, or mood-altering brownie out there. "Every day, we learn how to make formulations more stable and effective within these 'old' standard delivery systems," Tricarico says. "Consumers are familiar with these systems and remain comfortable using them."

Reference

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Is milk by any other name really milk? Not if the 32 lawmakers who signed a letter to FDA requesting that the agency ban the term "milk" from the labels of non-dairy "milks." In a missive dated December 16, 2016, the House members argued that dairy milk is uniquely nutritious, and that by assuming the name "milk," less-nutritious nondairy alternatives mislead consumers.

Whether you buy their argument or not—and FDA, for its part, has yet to take sides—the mere fact that these busy politicians are making it underscores the influence of the dairy industry and the competition it faces from nondairy products. That competition extends beyond the milk case to the protein category, where nondairy plant-sourced options ranging from pea to hemp are chipping away at the primacy dairy protein has long enjoyed.

The dairy industry isn’t taking the challenges lying down, however. After all, it still has a compelling story to tell. Says Kate Sager, marketing manager—America, Ingredia, Inc. (Wapakoneta, OH), "Dairy proteins have been around for a very long time and are industry standards. We do believe that even with the noise that plant proteins are making, animal proteins—and dairy specifically—will continue to dominate the marketplace into the future."

Dynamic Market
The protein marketplace is a crucible of dynamism, regardless of who is dominant. Citing data from the International Food Information Council Foundation’s (IFIC) 2016 Food & Health Survey, Kara McDonald, vice president of global marketing communications, U.S. Dairy Export Council (USDEC; Arlington, VA), notes that 64% of U.S. adults proactively tried consuming more protein in 2016.

Looking specifically at dairy-derived whey, BCC Research forecasts the global market to hit $13.5 billion in 2020, compared with $9.2 billion in 2015, representing a compound annual growth rate of 6.5% for the period.

Notes Pernille Dorthea Frederiksen, health concept developer, Arla Foods Ingredients (Viby, Denmark), "This is testament to the strength of whey as a protein proposition."

As with most trends, the passion for protein is evolving. McDonald notes, "Consumers are..."
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Dairy Protein

"[Dairy proteins] are easier to formulate into a wider range of palatable products, from snacks to dairy proteins to beverages," says Frederiksen of Arla Foods Ingredients.

’siloing’ protein’s benefits for more personalized nutrition.” Mainstream audiences are also “more knowledgeable than ever” about its health benefits and are “looking for convenient high-protein products to help them manage their weight,” she states; meanwhile, more active fans “are looking for sports nutrition beverages to complement their daily workouts.”

Regardless of what consumers are looking for, Sarah Staley, vice president of performance nutrition, FrieslandCampina Ingredients North America, Inc. (Paramus, NJ), cites a Mintel report when she states, “We can see that it remains the most-searched-for term in the United States when seeking healthy products.”

Building Blocks
Consumer interest in protein remains strong for good reason. Protein is a critical source of dietary energy, supplying the same 4 kcal/gram that carbohydrate does. But, protein also supplies something else: amino acids, the building blocks of individual proteins and the body’s tissues. “Muscle, skin, bones, organs and the brain, as well as hormones and other components involved in how our bodies work,” notes Angela Rowan, general manager nutrition, Fonterra Co-operative Group Limited (Palmerston North, New Zealand).

Nutrition-savvy shoppers—and, increasingly, everyone else—have grown wise to this. Notes Rowan, “Most consumers know that protein is an important nutrient that supports muscle health and strong bones, and some even recognize that it can help keep you feel fuller longer.” But what they may not know, she says, is “how much they should be eating, when throughout the day they should be eating more protein or which are the best dietary sources.”

New Protein on the Shelf
And that’s where the flood of plant proteins on the market complicates things. Observes McDonald, “Plant sources seem to get a lot of attention in the media, partially because of the ‘newness’ element.” And as with plant-based “milks” striving to measure up to cow’s milk—which they cannot do without heavy fortification—”protein alternatives are also striving to be like dairy,” she notes.

Such “imitation might be the sincerest form of flattery,” McDonald says, but companies that are eager to promote plant-based protein “may rely on consumers’ lack of understanding of the complex differences in amino acid makeup and nutritional density that set dairy apart” to hold onto that newfound attention, she contends.

Then again, it would be unfair to ascribe consumers’ interest in plant-based proteins entirely to misunderstanding. Concern for animal rights, support for sustainable sourcing, unease about potential antibiotic residues in milk, and a growing awareness of dairy allergies all stoke plant proteins popularity, notes Staley. “We also see that consumers have the perception that plant proteins may be more natural and perhaps ‘better for you’ than proteins from other sources,” she says. Regardless of whether or not that’s the case, what is true is that “consumers want to make better choices, and there’s widespread understanding that protein is good for them,” says Staley.

Superior Nutrition
In such a pro-protein environment, dairy has every reason to thrive, even with the stiff competition that plant products mount. As Frederiksen says, such competition is “to be expected, and it’s been good for the overall profile of protein as a nutrient.”

It’s as a nutrient, in fact, that dairy proteins most markedly stands out. “High-quality protein,” McDonald says, “is dairy’s strength.” While all proteins comprise amino acids, dairy contains all the essential amino acids (EAAs) that our bodies need for growth and recovery. What’s more, dairy’s amino acids are
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"of high bioavailability," Rowan says. "So they're readily digested and absorbed to be used."

Dairy protein also outperforms as a source of the branched-chain amino acids (BCAAs) leucine, isoleucine, and valine. BCAAs, and leucine in particular, play "an important role in stimulating muscle growth," Rowan continues. This helps explain why dairy protein is a sports-nutrition must—but Rowan points out that one does not to be training for an athletic event to benefit. "As our muscles are continuously turning over, consuming rich sources of these amino acids can be a valuable strategy for all ages and lifestyle, from athletes and body builders to the healthy aging and those looking to maintain muscle mass for optimal wellbeing."

No wonder a recent study in the British Journal of Nutrition comparing the digestible indispensable amino acid scores (DIAASs) of whey protein concentrate, whey protein isolate, milk protein concentrate, skimmed milk powder, pea protein concentrate, soy protein isolate, soy flour, and whole-grain wheat ranked all dairy proteins "excellent/high" in quality for people ages six months and older, soy isolate and flour as "good," and pea and wheat significantly lower. "The lesson: "You'd simply have to consume a lot more plant protein to get the same nutrition you'd get from non-plant sources such as dairy," Staley says.

Smart Ingredients
New processing technologies are letting suppliers enhance dairy proteins' nutritional profile even further, with micellar casein concentrate (MCC) a prime example of what the innovations can achieve. Staley's company uses a gentle cold-process filtration to produce a micellar casein ingredient that "retains a native-state micellar structure similar to fresh milk," she explains. "This unique ingredient is proven to be the slowest-releasing protein source, resulting in a positive amino acid net balance and, thus, improved muscle recovery."

Indeed, as a recovery aid, slow-digesting micellar casein "sits apart from all other dairy and plant proteins," Sager adds. Because it bathes post-exertion muscles in a prolonged supply of amino acids for growth and repair, she says, athletes who use it "are ready for their next training session." Even better, its long arc of digestion adds to its weight-management appeal, as it both makes people feel fuller—like all proteins—and extends that feeling over time.

MCC is a handy ingredient for processors, too. McDonald points to functional benefits like wetting, dispersability, heat stability at neutral pH, and solubility. Sager notes that her company's powdered form of the ingredient dissolves readily and tolerates heat up to ultra-high temperatures (290 °F). "In comparison," she says, "plant proteins don't always dissolve, can denature with high heat and can produce a very gritty texture."

All in Good Taste
Another plant protein disadvantage: They don’t always taste so great. Consumers often label their taste as "beany," "brothy," "strong," "earthy," and "bitter." Although masking systems somewhat overcome plant's characteristic off notes, they rarely do the whole trick and can muck up the "clean" labeling that drives so many consumers to plant proteins in the first place.

Dairy proteins, on the other hand, call to mind terms like "mild," "neutral," "clean-tasting," and—obviously "dairy-like," which "makes them acceptable to most consumers" and "easier to formulate into a wider range of palatable products, from snacks to dairy proteins to beverages," Frederiksen says. This versatility "is a real benefit if you're looking to target as many shoppers as possible," she notes.

Keep It Clean
So, with a flavor that's complementary rather than overpowering—plus superior nutrition, novel ingredient options, and functional properties ranging from emulsification and foaming to water binding and gelation—what could dairy proteins possibly still be missing?

If you're thinking, "a clean and green narrative," you're wrong: they've got that, too. Says Frederiksen, "Dairy proteins like whey have a great story to tell." McDonald agrees, adding that "the sustainability element is probably the most misunderstood element that seems unnecessarily to sell dairy short."

Dairy proteins receive criticism for the heavy resource input their production entails. But, says McDonald, "Food systems are complex. Not only should the resources needed to make a food be considered, but the unique nutritional value it delivers should be weighed, too."

On top of that, "If you haven't visited a local dairy farm since elementary school," she adds, "you might not realize the intense management to ensure the cows' health and comfort. After all, dairy farmers gain no margin mistreating their key asset."

What's more, US dairy farmers continually meet food safety standards and remain committed to sustainability. McDonald says. Fully 90% less land, 65% less water and a 63% smaller carbon footprint go into producing a gallon of milk than were needed in 1944, she notes. "And dairy production only accounts for approximately 2% of total U.S. greenhouse gas emissions."

As for dairy proteins themselves, Rowan argues that consumers should see them "as highly natural. In fact, dairy protein comes in formats that are far less processed than plant-derived protein ingredients. So to compare dairy and plant proteins for nutrition, taste, functionality, color, extent of processing and impact on the environment, dairy compares well."
**Getting the Story Out**

The challenge may be convincing consumers of this. “It’s very positive that there’s widespread awareness that protein is good for you,” Staley says. “Now we need to concentrate on the clarity of message and robust substantiation to give the consumer a positive ‘reason to believe.’”

McDonald contends that domestic dairies already are. “The U.S. dairy industry is coming together to remind U.S. consumers why dairy has been a traditional staple in their diets with the new campaign, Undeniably Dairy,” she says. The effort, she insists, is already paying dividends: “As more of these health-and-wellness benefits are explored, the more dairy will find a valuable place in consumers’ diets and food and beverage formulations.”

And if there’s room for plant proteins, too, the more the merrier. As Frederiksen says, “We do not view the market for proteins as a battlefield where victory resides with one side only. We believe that the proliferation of proteins is generally a positive thing because it raises the awareness of protein’s benefits in general.” When that happens, dairy can only benefit.

**References**


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Protein enjoys wide popularity as a nutritional supplement, particularly among fitness enthusiasts. However, its popularity means that it’s easy for false notions about protein to proliferate. There’s no shortage of incorrect beliefs regarding protein and protein supplements, both in consumer and industry circles.

A proper understanding of how protein works is essential. Unfortunately, bad science, over-hyped conjecture, and the advent of the Internet have made it easy for profiteers to spin false narratives about protein, which can be a danger both to the nutritional supplement industry and to the end user.

What myths have invaded the nutritional supplement space? Let’s review 10 of the most common protein myths that consumers and industry insiders alike encounter.

**Myth 1: A High-Protein Diet Is Bad for Your Kidneys**

Jose Antonio, PhD, is the editor-in-chief of the *Journal of the International Society of Sports Nutrition* and serves as associate professor of exercise and sport science at the Nova Southeastern University College of Health Care Sciences. Antonio says that he has come across a variety of protein myths in his work, but the one that he opposes most vehemently is the myth that a high-protein diet causes kidney damage.

“Tere are a lot of dumb myths about protein out there, but this the dumbest of them all,” he says. “I’ve heard dieticians claim that when you eat a high-protein diet, it shuts down your kidneys. But there’s no possible mechanism by which that might happen.”

A 2015 literature review found no connection between high protein intake and kidney disease, damage, or impairment in healthy participants. An earlier 2005 literature review also concluded that “protein-induced changes in renal function are likely a normal adaptive mechanism well within the functional limits of a healthy kidney.”

**Myth 2: People Who Consume High-Protein Diets Risk Bone Demineralization**

Antonio points to the claim that high-protein diets put consumers at risk of bone demineralization and eventual osteoporosis as another example of a common protein myth. There’s absolutely no evidence that bone mineral density drops with higher protein intake, he says. He also notes that just as in the case of the kidney-damage myth, there’s no workable theory as to what kind of protein-related
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Changing the Way you see Nutrition
Protein

According to one myth, the maximum amount of protein the human body can absorb in one sitting is 30 g, and any protein consumed above 30 g is simply wasted.

Antonio says that evolutionary biology also refutes this myth. “If you’re a hunter-gatherer, most of your calories come from animals. If you haven’t eaten anything for a day and then you kill an animal, are you going to say, ‘I can’t eat more than 30 g or else my body won’t use the rest of the protein?’ No, of course not. Your body will use what it needs.”

But it seems there is a kernel of truth amid the false claims. At least one randomized clinical trial has demonstrated that protein doses above 30 g do not stimulate further muscle protein synthesis beyond what would be achieved with a 30-g dose. However, this is very different from claiming that any protein consumed above the 30-g threshold is wasted or that the body does not absorb protein above the 30-g threshold. Neither of those statements has been proven through research.

Research doesn’t necessarily support the view that protein from whole foods is more valuable than protein from dietary supplements. Says Antonio: “If I were to ask all of my scientifically minded friends, they’d say that this myth makes sense.” However, he points out, “all of the studies on protein are on protein supplements [and not whole foods] because it’s just easier to use supplements.”

Antonio says that evolutionary biology could cause bone demineralization. A variety of clinical studies conducted over the course of the last several decades confirm this, as does Antonio’s own research.

Says Antonio: “I’m doing a study right now on bone mineral density in female athletes who consume a lot of protein. There’s zero evidence that bone mineral density drops when you eat a lot of protein. The claim that high-protein diets cause bone demineralization makes no sense.”

**MYTH 3: The Body Can’t Absorb More Than 30 Grams of Protein Per Meal**

This myth seems to have originated on Internet bodybuilding forums, where consumers tend to misinterpret nutritional research. According to the myth, the maximum amount of protein the human body can absorb in one sitting is 30 g, and that any protein consumed above 30 g is simply wasted.

But the research indicates otherwise. While literature reviews have concluded that 25-35 g of high-quality protein per meal is a sufficient amount to trigger protein synthesis, these studies don’t prove that any protein consumed above a certain threshold is wasted.

Antonio says that evolutionary biology also refutes this myth. “If you’re a hunter-gatherer, most of your calories come from animals. If you haven’t eaten anything for a day and then you kill an animal, are you going to say, ‘I can’t eat more than 30 g or else my body won’t use the rest of the protein?’ No, of course not. Your body will use what it needs.”

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**MYTH 4: A Higher Dose of Protein Is Always Better**

Antonio says the claim that a higher dose of protein is always better is somewhat true in certain situations, but requires additional context.

“If you’re only getting 50 g of protein per day and your body needs 100 g per day, then yes, 100 g is better,” he explains. “My research also shows that a higher dose of protein is better for athletes—it helps them lose more body fat. But the question we should be asking is, ‘What’s the maximum safe and effective dose of protein?’”

At the 2013 Protein Summit 2.0 in Washington, DC, over 60 nutrition scientists, educators, and experts gathered to discuss the formation of new dietary guidelines for protein intake. The summit’s conclusions included a new recommendation that most adults consume 25–30 g of protein per meal, or 1–1.5 g of protein per kilogram of body mass per day.

However, Antonio cautions that this doesn’t necessarily mean the average adult needs to start consuming more protein. Rather, he says, based on average protein intakes, the typical sedentary American or recreational “weekend warrior” athlete is most likely already getting enough dietary protein. While increasing protein intake is unlikely to cause kidney or bone problems, Antonio says there’s no reason to recommend higher protein intakes for non-athletes.

**MYTH 5: Protein from Whole Foods Is Better than Protein Supplements**

This choice to differentiate whole food protein from whey protein supplements is rather arbitrary,” he adds. “Whey comes from milk, which is a food.”
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Protein

While there may not be enough evidence to prove that whole foods are better protein sources than protein supplements, Antonio notes that those who take protein supplements—particularly plant-derived protein supplements—would do well to also add a lysine supplement to their nutrition regimen. He says that not all protein supplements contain the natural amino acid lysine, despite the fact that lysine is the primary compound that triggers muscle protein synthesis.

**MYTH 6: More Protein Consumed Equals More Muscle Gained**

While the myth that the body can’t absorb more than 30 g of protein per meal isn’t necessarily true, there may be a limit to how much protein should be consumed for the express purpose of muscle building. As Antonio says, “There’s a dosage sweet spot, and any protein you consume beyond that is burned as fuel.”

One Canadian literature review found that 1.8 g per kilogram of body mass per day was sufficient protein intake for most athletes, while another literature review contends that 1.2–1.6 g per kilogram of body mass per day is emerging as the ideal protein dosage for maintaining muscle mass among athletic individuals.

Regardless of the exact number, the research offers a clear consensus that there is indeed a maximum protein intake threshold for muscle building, and any extra protein consumed beyond said threshold is expended as energy.

**MYTH 7: A High Protein Intake Makes You Fat**

Consuming too much of any compound or nutrient can result in fat gain, at least in theory. But Antonio says that in the case of protein, it appears that there may not be such a thing as “too much,” at least not in practical terms. “I’ve done studies on overfeeding people whey protein, and they all lose fat,” he says.

“They also lose more body fat with higher doses of protein. Plus, from a practical perspective, most people can’t overfeed on protein enough to cause problems.”

However, Antonio also mentions an important caveat: One’s level of physical activity may influence whether or not one gains fat from protein. Antonio doesn’t study sedentary people, but he also notes that athletes and fitness enthusiasts are more likely to have a high-protein diet than sedentary individuals.

**MYTH 8: Dairy Protein Is Superior to Plant Protein**

One common misconception in the bodybuilding and wellness enthusiast communities is that dairy protein offers health benefits that plant protein doesn’t. People who promote this line of thinking may also claim that dairy protein is nutritionally denser than plant protein or that protein from dairy sources is easier to metabolize. Antonio says the truth is somewhat more complicated.

**MYTH 9: You Should Always Eat Protein Immediately After a Workout**

The common wisdom in the strength-training community is that during the 30-minute period immediately following a workout, consuming a high concentration of protein and carbohydrates will increase muscle gain by taking advantage of the anabolic window. But scientific support for the anabolic window theory is mixed at best. One 2013 literature review, for instance, states that the anabolic window is “a gray area lacking cohesive data to form concrete recommendations.”

Antonio agrees with this conclusion, but also grants that the anabolic window theory does have a sliver of usefulness. He says, “Total protein intake matters more than timing. But if you’re working out twice a day, then you have to eat right after you work out because otherwise you’ll have a hard time getting enough total protein. The science is equivocal on this issue, but there’s a pragmatic aspect to consider.”

**MYTH 10: Protein Supplements Are Just a Placebo**

This claim is one that often frequents bodybuilding forums and workout enthusiast communities, with some YouTube personalities like Keith and Kevin Hodge espousing this view. One recent article in The Atlantic also made hedged claims regarding the effectiveness of protein supplements, positing that protein powder “is caught up in the same web of ideas and beliefs about masculinity, nutrition, and exercise that can be taken to more disturbing extremes.”

If you’re asking whether dairy protein is more ‘nutritious’ than plant protein, then the answer is no. But on a gram-for-gram basis, milk-based proteins are far superior to plant proteins where protein synthesis is concerned,” he says.

However, he also notes that overall volume of protein consumed can compensate for protein inferiority. “If you’re consuming a lot of protein, [the source] doesn’t really matter. A 40- to 60-g rice protein shake will be about equivalent to 20 g of milk protein. But I’m assuming that you’re also consuming a lot more [dietary] protein throughout the day.”
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Antonio rejects this “protein as placebo” narrative, as it is contradicted by clinical studies that have found increases in exercise performance accompanying higher protein intake. Says Antonio: “For protein to be a placebo, it would have to be inert. But you need protein to live. It’s hardly a placebo. I’m writing a paper right now that outlines all the studies on how protein supplementation improves lean body mass.”

One randomized clinical trial investigating protein supplements found that, relative to a placebo, a whey protein isolate supplement bonded with the amino acid cysteine significantly increased peak power and work capacity in healthy young adults. Another study, a 2015 double-blind, placebo-controlled randomized clinical trial, examined the effect of whey and pea protein and resistance training on muscle thickness and strength and found that pea protein was more effective at promoting muscle thickening than a placebo.13

The Truth about Protein
Protein supplements are effective at improving fitness outcomes; however, many of the claims made about protein (both online and off) exaggerate the research, stretch the truth, or simply promote claims that run contrary to the established facts. In an era of advertising hype and bad science, of fake academic publishers and published facts. In an era of advertising hype and publishing a paper right now that outlines all the studies on how protein supplementation improves lean body mass.”

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The Truth about Protein
Protein supplements are effective at improving fitness outcomes; however, many of the claims made about protein (both online and off) exaggerate the research, stretch the truth, or simply promote claims that run contrary to the established facts. In an era of advertising hype and bad science, of fake academic publishers and short consumer attention spans, the best way to market protein supplements will involve confronting false claims with unassailable data gathered by respectable researchers.

In sum: Effective protein supplement marketing strategies now require brands to replace consumer misconceptions with hard facts. 

Mike Straus is a freelance journalist living in Kelowna, Canada. He has written for publications including Canadian Chiropractor Magazine, UX Booth, and Iconic Concierge Vancouver.

References
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Whey is a protein source isolated from milk whose popularity has risen steadily over the years. Market analysts predict continued growth of the global whey protein market, estimating an average compound annual growth rate greater than 7% over the next five years. The sports nutrition industry is a major driver of this growth. Whey protein–based supplements are mainstays not only for those interested in building muscle mass, but also for those who turn to dietary protein as a means of replacing carbohydrates in the diet for the purpose of weight loss and fat loss.

The versatility of whey protein means it can be used on its own or in combination with other nutrients to benefit a wide range of health needs. Research indicates that these benefits can extend to adults of all ages. As whey protein’s nutritional properties continue drawing interest, recent studies show positive benefits of whey supplementation for the maintenance of lean muscle mass and decreased fat mass, increased muscle strength in young and elderly adults, a reduced risk of sarcopenia (i.e., age-related muscle loss), as well as intriguing cardiovascular effects.

**Increased Lean Body Mass and Strength in Healthy Older Men**

In a recent study, Kirsten Bell and colleagues from McMaster University (Hamilton, Ontario, Canada) investigated the impact of whey protein supplementation in healthy older men with an average age of 73. In the 20-week, two-phase, randomized, controlled trial, 49 men were allocated to consume either a whey protein supplement (30 g whey protein, 2.5 g creatine, 500 IU vitamin D, 400 mg calcium, and 1,500 mg omega-3 fatty acids) or 22 g of maltodextrin, twice daily.

In phase one of the study, participants consumed only the supplements for six weeks, while in phase two, the participants continued the supplementation along with a daily exercise routine for 12 weeks. The primary study outcomes were isotonic strength and changes in lean body mass.

During the first phase, the group consuming the whey protein supplement experienced statistically significant gains in strength and lean body mass, while no such changes were seen in the maltodextrin group. After phase two, both groups saw increases in strength; however, the whey group also had significantly greater upper body...
strength compared to the maltodextrin group, indicating the whey supplement’s ability to support strength and increase lean body mass in healthy older men.

**Countering Sarcopenia in Elderly Men and Women**

Whey protein supports several aspects of health in the elderly, particularly concerning sarcopenia. In an Italian study, Mariangela Rondanelli from Università di Pavia (Pavia, Italy) and colleagues researched the effects of whey protein supplementation along with regular exercise in 130 elderly sarcopenic men and women with an average age of 80.3 years.¹

In the 12-week, double-blind, placebo-controlled trial, participants were assigned a whey protein supplement (22 g whey protein, 10.9 g of essential amino acids, and 100 IU of vitamin D), or a placebo, daily in conjunction with a regular controlled physical-activity program.

Whey supplementation plus physical activity resulted in several significant improvements compared to the placebo group, including an increase in fat-free mass, gains in relative skeletal muscle mass, and increased handgrip strength. The whey protein supplement led to increases in levels of the anabolic growth hormone, IGF-1, while inflammation decreased as shown by a significant change in C-reactive protein levels (CRP). Quality-of-life measures indicated a significant improvement in physical function, while 68% of those on the whey protein intervention achieved a classification of being non-sarcopenic at the end of the study. By contrast, none of the participants in the placebo group achieved this status. These results suggest important benefits of a whey protein supplement in elderly individuals with sarcopenia.

**Fat Loss and Lean Body Mass Maintenance in Healthy Young Men**

Researchers from the College of Charleston (Charleston, SC) led by Wesley Dudgeon aimed to evaluate the differential effects of administration of a whey protein supplement versus a carbohydrate-rich supplement pre- and post-exercise in resistance-trained men.² Because rapid weight loss regimens often result in a decrease in both lean and fat mass, the researchers wished to assess whether a protein-rich regimen led to retention of lean muscle mass better than a carbohydrate-rich regimen.

In this controlled trial, 16 young, resistance-trained individuals (average age of 24) on a calorie-restricted diet completed a 4-day/week training program for eight weeks. One group consumed a whey protein supplement, while the other group consumed a carbohydrate-rich supplement (both administered as 28 g pre- and post-exercise).

After eight weeks, the results of the study showed that total body mass decreased in both groups. However, those individuals consuming the whey protein maintained significantly more lean body mass than the group consuming the carbohydrate-rich drink. The whey group also lost fat mass, while the carbohydrate group did not, although this result did not reach statistical significance. Furthermore, the whey group showed significant increases in upper body strength compared to the carbohydrate group. This preliminary study supports the potential of whey protein to promote the maintenance of lean body mass as an ad-

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*Nutritional Outlook, November 2017
Whey protein supplements are mainstays not only for those interested in building muscle mass, but also for those who turn to dietary protein for the purpose of weight loss.

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• Lipolytic capabilities to breakdown lipids and fat
• Powerful antioxidant

Whey Protein

Blood Pressure, Lipids, and Endothelial Function
As the prevalence of high blood pressure increases worldwide, effective measures are needed to reduce the cardiovascular complications associated with this condition. Past studies have found a reduced risk of elevated blood pressure associated with milk consumption. Milk’s whey protein content may be a factor in this.

Investigators led by Agnes Fekete from the University of Reading (Reading, UK) sought to study the cardiovascular effects of whey protein supplementation in adults with prehypertension and hypertension. In this double-blind, randomized, crossover trial, 42 healthy non-smokers aged 30–77 were assigned to consume 28 g of whey protein, 28 g of calcium caseinate (another protein found in milk), or 27 g of maltodextrin twice daily for eight weeks, separated by a four-week washout period.

Whey protein consumption led to a significant reduction in 24-hour blood pressure (-3.9 mm Hg systolic and -2.5 mm Hg diastolic) versus control. Peripheral and central systolic blood pressure were also significantly lowered in the whey protein group compared to the maltodextrin control group. Flow-mediated dilation, a measure of endothelial function, also increased significantly in both the whey and casein groups compared to the control group. Total cholesterol decreased in both milk protein groups; however, only whey protein led to a decrease in triglyceride levels, an effect that reached statistical significance compared to the control group. The results from the study indicate whey protein’s potential benefits in the areas of blood pressure, lipids, and endothelial function.
Irfan Qureshi, ND, is executive director, research and regulatory affairs, for Healthy Directions.

References
Heart Health

CoQ10: An Update on an Old Standby
A look at why CoQ10 has remained a go-to heart health ingredient for decades.

BY MAUREEN KINGSLY

In the nutritional-supplements industry, ingredient fads come and go, waxing and waning in popularity and media attention. Some ingredients, however, earn the respect of consumers, physicians, journalists, and scientists alike, and retain their good reputation indefinitely. Coenzyme Q10 (CoQ10) is one such ingredient.

Discovered in 1957 and finding a solid foothold in the supplements market within the last 15–20 years, CoQ10 “is one of the most studied—and more importantly, understood—dietary supplements” on the market today, says Scott Steinford, executive director at large of the CoQ10 Association (Salt Lake City, UT).

He explains that the human body synthesizes CoQ10, but our production of this fat-soluble compound declines as we age. %“CoQ10 is utilized by every cell of the human body and is an intricate contributor to the ATP process,” Steinford continues. “In simplest terms, CoQ10 is responsible for converting food into energy. The effects of CoQ10 deficiency are most noticed in the organs that require the most energy production.” These organs include the liver, kidneys, and, of course, the heart.

“Thousands of studies have demonstrated the activity and importance of CoQ10 in heart health and many other human and veterinary health aspects,” Steinford contends, and demand for the ingredient seems to be in line with that assertion. A 2017 ConsumerLab.com survey of more than 9,500 respondents listed CoQ10 as the third most popular dietary supplement behind vitamin D and fish oil,” Steinford points out.

What’s more, some research has suggested that this ingredient holds promise for other emerging areas such as oral health. “The pharmacology of coenzyme Q10 indicates that it may be an agent for treatment of periodontitis,” says Shobra Prakash and co-researchers in the Indian Journal of Pharmacology, and “coenzyme Q10 may possibly be effective as a topical and/or systemic role or adjunctive treatment for periodontitis either as a stand-alone biological or in combination with other synergistic antioxidants (i.e., vitamins C and E).”

As such, “we are seeing strong sales growth in the natural channel in toothpaste with CoQ10 as an active ingredient,” says Jamie Phillips, director of scientific affairs at SPINS (Chicago, IL). While sales are relatively small, SPINS natural products specialist Kimberly Kawa states, “Sales in the Oral Care category within the Body Care department are up about 7% with Nature’s Answer’s PerioBrite toothpaste (a brightening formula with CoQ10 and folic acid) leading the way.

CoQ10 by the Numbers
In the Vitamin, Mineral, and Supplements category only, total sales of CoQ10 for the 52 weeks ending August 13, 2017 were roughly $164 million, down slightly (about 2%) from the previous year, while sales of ubiquinol (i.e., the fully reduced form of CoQ10) were up 1.3% from the previous year, according to the most recent SPINS data available.

The slight downward trend of conventional CoQ10 (i.e., ubiquinone), says SPINS’ Phillips, is likely due to the fact that “it is an established supplement” with “no new news or marketing messages” in recent months.

As for ubiquinol, “it is more expensive than [ubiquinone], but has been found to be more effective for persons with certain conditions that inhibit the necessary conversion of CoQ10 in the body,” Kawa notes.

CoQ10 Association’s Steinford adds that ubiquinol is gaining popularity with consumers who are concerned with absorption
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and bioavailability; however, "ubiquinone [CoQ10’s fully oxidized form] still commands 90% of the overall CoQ10 market and remains the most recommended form of CoQ10," he says.

Among physicians, CoQ10 has earned trust and confidence, too. A CoQ10 Association study of 100 cardiologists found that CoQ10 was the most-recommended supplement among this group and that 71% of cardiologists recommend the ingredient to "at least some" of their patients.

**Dosing and Delivery**

Demand for CoQ10 is on the rise. "In 2000," Steinford says, "the global demand for CoQ10 was 37 metric tons, while in 2016, the global demand for CoQ10 exceeded 750 metric tons." One reason for this significant uptick, he explains, is that the typical dosage increased from 5 to 30 mg in 2000 to about 120 mg today. He adds that the even higher 200-mg CoQ10 dosage is the fastest-growing one.

Vincent Tricarico, vice president of contract manufacturing at NutraScience Labs (Farmingdale, NY), says he is noticing CoQ10 in a "growing variety of formulations" beyond those for traditional cardiovascular support, including vision-support and antioxidant-specific formulations.

As for delivery systems, Tricarico says an oil-based liquid contained in either softgels or "standard two-piece veggie or gelatin capsules" is best. Steve Holthby, president and CEO of Soft Gel Technologies (Commerce, CA), agrees, specifying that fat-soluble CoQ10 is absorbed more readily when "placed in lipid media such as softgels or when taken with foods containing fat. A softgel delivery system plays a key role in enhancing the effectiveness of CoQ10 getting into the bloodstream," he says.

"CoQ10, being a highly lipophilic and crystalline material, presents specific challenges that require an innovative approach," Holthby continues. "Absorption [by the body] is dependent on the number and size of CoQ10 crystals within the product." (The fewer and smaller the crystals, the better.)

He describes how Soft Gel Technologies’ CoQsol-CF formulation dissolves CoQ10 in solution, resulting in a "completely solubilized CoQ10 that does not require heat or synthetic solvents," and the mixture "fully resists recrystallization at ambient temperature ranges." By improving dissolution, he asserts, absorption is enhanced.

**CoQ10 and Fish Oil**

For those looking to break into the heart-health supplement space, combining CoQ10 with omega-3 fatty acids "can serve as a great starting point" for a heart-health formulation, says NutraScience Labs’ Tricarico.

The CoQ10 Association’s Steinford agrees, citing a July 2017 study investigating the effect of a CoQ10 and omega-3 fatty acid combination on statin therapy in some heart patients, in which the researchers reached the conclusion that "the results of this pilot study suggest the possible beneficial effects of triple combination [statins, omega-3s, CoQ10] on the lipid and non-lipid parameters related to atherogenesis and side effects of statin treatment."

Tricarico adds: "Viewing omega-3 fatty acids and CoQ10 independently, there is ample evidence to suggest the combination of the two ingredients will collectively work to improve heart health."

CoQ10 supplementation is commonly recommended by physicians as an adjunct to statin therapy; the fact that CoQ10 levels in the body are reduced when a patient takes statin medication is widely known. "Given that it’s also common to take an omega-3 supplement with a statin," says Harry Rice, PhD, vice president of regulatory and scientific affairs at the Global Organization for EPA and DHA Omega-3 (GOED; Salt Lake City, UT), "then an omega-3 and CoQ10 combination product makes perfect sense."

One such product is Fish Oil Q from Carlson Labs (Arlington Heights, IL), launched in 2007. "Carlson was the first company to introduce an oil-based CoQ10 way back in the 1980s," says nutritionist and educator Jolie Root of Carlson Labs, "so it was a natural progression to combine omega-3s and CoQ10 in one formula." She echoes GOED’s Rice, stating, "Since fish oils are routinely prescribed as secondary prevention of heart events in persons with known heart disease, who are also likely to be taking statins, the combination just makes perfect sense."

Nordic Naturals (Watsonville, CA) also offers combination omega-3-CoQ10 products, including its Ultimate Omega+CoQ10 softgels, which contain fish oil and the ubiquinone form of CoQ10 and its Omega LDL, which is formulated with concentrated omega-3 fish oil, ubiquinone, and red yeast rice.

Nordic Naturals is now also offering a ubiquinol softgel containing 100 mg of a ubiquinol ingredient from Kaneka Nutrients (Pasadena, TX) in extra-virgin olive oil. "We expect to see ubiquinol implemented in many more formulations, including with omega-3s, for consumers among the baby-boomer generation," says Kaneka North America’s product manager Sid Shastri.

"In many ways, ubiquinol and omega-3s are ideal partners in the battle for cardiovascular health. While ubiquinol is a potent lipid antioxidant that is active in the production of cellular energy necessary for the heart and other energy-intensive organs to function efficiently, omega-3s are valued for their impact on reduction of blood lipids, particularly triglycerides as well as blood-platelet functionality and vasodilation," he states. "By reducing blood lipids and protecting against oxidation of..."
lipids (which then penetrate into vascular arterial intima—an important initiation point in the pathophysiology behind atherosclerosis), there is ample rationale for the combination of these two cardio-protective nutrients."

The Future of CoQ10

While ubiquinone reigns supreme among CoQ10 sales, interest in ubiquinol is building. Shastri of Kaneka North America, notes that "as consumers over 40 years of age become more educated about ubiquinol, as opposed to conventional CoQ10, they have come to appreciate the value of ubiquinol in the production of cellular energy as they age."

He adds, "The knowledge base of manufacturers has greatly increased over the last ten years from ubiquinol’s launch; therefore, we are at the starting point of seeing ubiquinol-anchored formulations proliferate in the market. Brands selling supplements made with Kaneka QH ubiquinol include NOW Foods, Puritan’s Pride, Jarrow Formulas, Doctor’s Best, Life Extension, and Healthy Origins."

References


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Brain health supplements are a growing market segment thanks to several recent research developments and the rise of age-related cognitive decline. One market report by Research and Markets states that the global brain health supplement market was worth $2.3 billion (USD) in 2015, and worldwide sales of brain health supplements are projected to exceed $11 billion (USD) by 2024.

This report points to an aging population of highly educated professionals as the driving force behind the growth in demand. In addition, increased awareness about the benefits of supplements for supporting concentration and memory among college students, scientists, and entrepreneurs has increased sales in this category, according to the firm.

Research and Markets also states that the largest sales channel for brain health products is online stores, which are outpacing drug stores and supermarkets in sales growth due to more variety in price points, more product launches, and a greater availability of private labels.

As demand for brain health ingredients grows, so too does interest in research that demonstrates the value of new and established nutrients for promoting healthy brain function. New studies continue to demonstrate the specialized benefits of various compounds on the brain, particularly for memory and cognition support.

While there are too many brain health ingredients on the market to examine them all in one sitting, what follows is a shortlist of some popular ingredients with new studies that demonstrate their benefits. (Note that this list is by no means exhaustive, and is intended to be a sampling of some compelling recent studies.)

**Omega-3s for Athletes**

Omega-3 fatty acids, the class of polyunsaturated fatty acids typically used as metabolic regulators in dietary supplements, are also useful in cognitive supplement formulations. Gretchen Vannice, RDN, head of Global Nutrition Education, Organic Technologies, the parent company of AlaskOmega (Coshocton, OH), says omega-3 fatty acids are essential to healthy brain function, and that supplements are an ideal delivery form given that most Americans do not consume enough omega-3 fatty acids in their diet.

Says Vannice, “90% of the omega-3 fats in the brain is DHA. In the adult brain, DHA is especially concentrated in gray matter and is enriched in brain cell membranes, where it directly influences functional processes like membrane fluidity, gene expression, myelination, neuroinflammation, neurotransmitter release, and more.”

Vannice says that decades of research have demonstrated that high levels of omega-3 fatty acids are associated with better cognition, slower cognitive decline in older adults, improvements in episodic memory in women, and improvements in working memory in men.

Perhaps the most promising new brain health application of omega-3s is assisting athletes in recovering from traumatic brain injuries (TBIs). One randomized, double-blind, placebo-controlled clinical trial on DHA omega-3 fatty acid supplements followed 81 National Collegiate Athletic Association Division 1 football players for 189 days, the entire duration of the college football season. Participants were given 0, 2, 4, or...
6 grams of DHA per day. The study tracked measures of mild traumatic brain injury, including changes in serum neurofilament light (NFL), which is a biomarker of axonal injury. Elevated serum NFL levels is a telltale sign of mild traumatic brain injury and is common among football players.²

This study found that supplementing with DHA attenuated axonal injury, particularly among starting players, who tend to have more playing time and physical contact, and are therefore more likely to suffer brain injuries.

“This was the first study to examine prophylactic use of omega-3 supplements in football players,” Vannice notes. “While the study used DHA only, based on the literature, I can predict that equal or higher amounts of EPA would provide additional benefits not only for brain health, but also for physical health and recovery.”

### Extending the Shelf Life of Phospholipid Supplements

Phospholipids are naturally occurring lipids present in all cell membranes that contain at least one phosphate group. Phosphatidylserine (PS) is a type of phospholipid that signals phagocytes to begin apoptosis.³

Soft Gel Technologies, Inc. (Commerce, CA) President and CEO Steve Holtby says PS is an essential building block that works to stabilize the membranes of brain cells, thereby protecting brain cell activity and limiting cell deterioration. He also notes the ingredient’s role in stimulating memory and cognition as well as regulating mood.

Says Holtby: “PS supplements have been demonstrated in clinical trials to improve memory, concentration, word recall, and mood in middle-aged and elderly subjects. For older adults with moderate cognitive impairment, PS has produced consistently modest increases in recall of word lists.”

Holtby says that early PS ingredients were extracted from the brains of cows, which presented potential dangers concerning the transfer of infectious diseases such as bovine spongiform encephalopathy. To resolve this risk, manufacturers like Soft Gel Technologies developed a means of extracting PS from soybeans and other plant sources.

However, delivery mechanism optimization presented further challenges. PS tends to degrade when stored in a soft gel, which makes it difficult to produce a PS supplement that appeals to older supplement users who have readily embraced soft gels as a delivery mechanism.

“To overcome this problem,” Holtby explains, “we created a fluid dispersion PS material that has a greater stability. We’ve conducted stability and shelf-life studies, and we’ve found that the soft gel capsules maintain ingredient quality and level for a long period of time. Shelf-life studies performed by an independent laboratory for phospholipid analysis found that even after 24 months, the material showed absolutely no degradation.”
EMERGING NICHES FOR BRAIN HEALTH FORMULATIONS

Several markets could present the largest opportunities for new brain health products in the next 10 years.

Sports Nutrition: Brawn, Meet Brain

In *Nutritional Outlook*, April 2017 feature on sports powders, Kyowa Hakko USA marketing manager Elyse Lovett (New York, NY) said brain health was a growing sports supplement niche for both professional and recreational athletes. However, the brain health sports nutrition market is still in its infancy, as Avner Avisarca, vice president of nutrition, Enzymotec ( Migdal HaErem, Israel) told *Nutritional Outlook* in November 2016.

A young niche with rapidly growing demand is an ideal one for manufacturers and distributors. As studies continue to demonstrate the improvements in athletic performance that brain health supplements provide, expect athletes and coaches in professional and collegiate leagues to start looking to brain health supplements as part of their nutrition programs.

Geriatrics: Keeping Sharp in Old Age

A variety of social and biological factors are making geriatric brain health an increasingly important nutraceutical market segment. In addition to having significantly longer lifespans than Americans did in the past, older adults are at an elevated risk of acquiring mental illnesses and behavioral disorders. As the vast Baby Boomer cohort reaches retirement age, the Centers for Disease Control and Prevention expects cognitive impairment to place “unprecedented demands on our existing health system,” with potentially significant economic ramifications.

The aging Baby Boomer demographic will be one of the strongest driving factors increasing demand for cognitive supplements, making geriatric brain health a promising niche for manufacturers.

Work and Academics: Knowledge Workers, College Students Crave Every Advantage

With the world of work increasingly shifting away from an industrial environment to a knowledge-based one, cognitive performance in the office and the lecture hall are becoming higher and higher priorities for students and working-age people. Changes in work environments over time have created demand for brain health supplements among students and working-age people. In particular, high-pressure work environments with low employment security and highly demanding roles are seeing the highest prevalence in use of cognitive enhancement drugs, while students are seeking out supplements that can promote alertness, improve focus, and enhance memory and cognition.

Some researchers are now calling for public-private partnerships to evaluate the efficacy and safety of cognitive supplements. Such evaluations indicate a growing demand for cognitive supplements among the working-age and student populations, with estimates of use rates ranging up to 20%.

References

Citicoline May Hold Promise for Schizophrenia Patients

A naturally occurring cholinergic compound, citicoline promotes normal brain function and supports neuroprotective mechanisms by stimulating the production of phosphatidylcholine and acetylcholine in the brain.

Clinical trials have examined citicoline as a therapy for addressing subject dependence, bipolar disorder, and traumatic brain injuries. Research is expanding into its benefits for schizophrenia patients.

One randomized, placebo-controlled trial followed 43 adult schizophrenia patients for 16 weeks. Before the trial, participants were assessed using the PANSS scale, which measures schizophrenia symptom severity. Individuals were assigned a score correlated to the sum of their ratings for five symptoms on the PANSS negative-symptom subscale. Participants in the experimental group received gradually increasing doses of citicoline, starting at 500 mg/day on the first day of the trial and ending with 2,000 mg/day by the beginning of the second week.

Over the course of the 16 weeks, both the placebo group (n=19) and the experimental groups (n=15) gradually lowered their PANSS scores. However, the experimental group scores decreased by one full standard deviation, whereas the placebo group scores decreased by only one half of a standard deviation.

While a follow-up double-blind clinical trial failed to replicate a statistically significant reduction in the experimental group’s PANSS scores, it did find that citicoline had a significant effect on global functioning scores and free verbal recall.

These studies are significant in that they found a therapeutic effect of citicoline on schizophrenia symptoms. Schizophrenia is a challenging condition to address. The negative symptoms of the disease in particular, such as apathy and avolition, are notoriously resistant to conventional therapies, partly because schizophrenia medications like haloperidol and risperidone tend to induce these symptoms in healthy individuals.

The fact that the first study found a reduction in PANSS scores indicates that citicoline may hold promise in addressing the negative symptoms of schizophrenia.
The study authors caution, however, “further study...is warranted in larger studies that will have greater (statistical) power.”

Arginine Boosts Focus, Mental Acuity, and Problem-Solving Speed

Arginine is a well-studied amino acid frequently used in athletic and heart health supplements, but a silicon-bonded arginine variant is now showing promise for cognitive applications. Double-blind, placebo-controlled human clinical trials have found that arginine silicate is effective at improving mental acuity, cognitive function, and subjective feelings of mental energy.7

Jim Komorowski, chief science officer, Nutrition 21 (Purchase, NY), says a small daily dose of his firm’s branded and patented arginine silicate complex Nitrosigine resulted in significant increases in feelings of energy in two clinical trials involving healthy participants.9

Both studies were double-blind, placebo-controlled crossover trials involving healthy subjects (n=16 and n=11, respectively). Experimental groups received 1.5 grams of Nitrosigine arginine silicate complex per day. Relative to the placebo groups, the experimental groups reported feelings of higher energy and performed better on cognitive tests.

Says Komorowski, “Nitrosigine supplementation also improved response time on a test of cognitive function, and after a single dose. Nitrosigine has been clinically shown to increase mental acuity and focus by 33% within 15 minutes. The impact on mental acuity also continues to build over time...Although studies on other nutrients may have reported some effects on brain function, those effects took weeks or months to develop.”

Resveratrol Supports Memory in Healthy Individuals and Those with Cognitive Decline

A naturally occurring polyphenol commonly found in grapes and berries, resveratrol is most well known as an anti-aging ingredient. Gene Adamski, national sales manager, Evolva (Reinach, Switzerland), and his colleagues Angela Tsetsis and Ernesto Simon say that resveratrol protects grapes from harsh environmental conditions, and that the compound has a similar effect in humans by promoting healthy aging at a cellular level.

Evolva’s team says that resveratrol supports a balanced inflammation response in the brain and improves cerebral blood flow, which results in mood and cognition benefits.

Recent human studies indicate that regular resveratrol intake can support brain function in both patients with Alzheimer’s disease and normal, healthy individuals. One randomized, double-blind, placebo-controlled trial gave varying doses (500 mg/day to 2 grams/day) of resveratrol to 119 patients with Alzheimer’s disease for 52 weeks. This clinical trial found...
Researchers have confirmed through animal studies that bacopa induces dendritic proliferation and promotes neuron communication.

that relative to a placebo, resveratrol resulted in an improvement in Alzheimer's Disease Cooperative Study Activities of Daily Living Scale scores, changed AD biomarker trajectories, modulated neuroinflammation, and induced adaptive immunity.

A second randomized clinical trial found that 75 mg of resveratrol given twice per day for 14 weeks improved performance on verbal learning and semantic memory tasks and boosted blood flow in the brains of 80 healthy postmenopausal women.

The Evolva team says that these studies showcase the mood-boosting and cognitive-enhancing properties of resveratrol and also serve as a jumping-off point for investigations into resveratrol’s long-term health effects: "The same research group is conducting a bigger follow-up study where they investigate the effects of Veri-te resveratrol in cerebrovascular function, cognitive performance, and bone health."

Blueberry Extract Supports Episodic Memory in Older Adults

Wild blueberry extract (Vaccinium corymbosum) is a polyphenol-rich supplement that supports healthy blood pressure levels. In addition, Dan Souza, nutrition and health category manager for the branded blueberry product ThinkBlue by Naturex (Avignon, France), says wild blueberry extract has been clinically shown to improve episodic memory in senior citizens.

One randomized, double-blind, placebo-controlled human trial on the effects of ThinkBlue-branded blueberry extract involved 120 healthy participants between 65 and 80 years of age. This six-month study followed a group of seniors who consumed 111 mg of ThinkBlue per day.

After three months, Souza says, participants in the experimental group saw a 7% improvement in episodic memory. After six months, participants saw a six-point drop in systolic blood pressure. This study is slated for publication at the end of 2017.

Souza says that these findings are significant because they demonstrate a clear opportunity to resolve an ongoing challenge that seniors face: the degradation of episodic memory.

He states, "Episodic memory, the memory of personally experienced events, shows the greatest degree of age-related decline. There's robust and growing literature illustrating the cognitive health benefits of wild blueberries, but until now, there hasn't been a compliance-friendly, clinically substantiated dose of wild blueberry for nutritional supplement applications."

Souza also notes that past studies were conducted using much higher doses (at least 10 grams per day), whereas the ThinkBlue study showed a statistically significant improvement in episodic memory with a much smaller dose of just 111 mg per day.

Data also suggests that blueberry supplement can improve verbal learning skills, and that the ingredient’s effects on memory apply both to short- and long-term memory.

Cécile Frémont, the communications manager, Activ’Inside (Libourne, France), says blueberry’s high concentration of polyphenols, anthocyanins, flavonoids, and phenolic acids make it an ideal brain supplement, particularly for older adults with memory issues.

In one randomized, double-blind, placebo-controlled clinical trial, 215 healthy adults between the ages of 60 and 70 received 300 mg of Activ’Inside’s branded Memophenol grape/blueberry extract or a matching placebo twice per day for six months. According to Frémont, participants were assessed on the Verbal Recall Memory (VRM) test and the Paired Associates Learning (PAL) test, which evaluate short-term working memory and long-term episodic memory, respectively.

Relative to the placebo group, subjects who received Memophenol recalled 60% more words on the VRM test and had significantly fewer errors on the PAL test. Study authors concluded that Memophenol supplementation reversed eight years of cognitive degradation, Frémont explains.

Frémont says this and other studies show that some brain health ingredients are more effective in blends: "Ten studies have been performed with a scientific R&D approach using this same framework, and they’ve revealed that grape and blueberry compounds are better absorbed when consumed in a specific
ratio that boosts the cognitive properties of each single ingredient.”

**Botanicals Promote Dendritic Growth**

Botanical brain health supplements, whether single-ingredient products or blends, have a variety of beneficial effects on the brain.

Deanne Dolnick, science director, TR Nutrionals (Alpharetta, GA), says botanical products like Gingko biloba extract and Bacopa monnieri extract are among the most popular brain health botanicals on the market, and for good reason.

“Gingko biloba extract has been the gold standard in brain health botanicals for a very long time,” says Dolnick. “It’s still popular for supporting memory and cognitive function, as well as increasing blood flow and reducing inflammation.”

Dolnick says bacopa is also an important brain health supplement due to its ability to repair damaged neurons and restore degraded synaptic activity.

Until a few years ago, it was unknown whether the dendrites of neurons could repair themselves. Now, researchers have confirmed through animal studies that bacopa induces dendritic proliferation and promotes neuron communication.

Bacopa also has anti-inflammatory properties that may have applications for a variety of central nervous system disorders, as demonstrated in a recent *in vitro* study involving microglial cells grown from mice.

This study examined the effects of bacopa infusions, teas, and alkaloid extracts (made from 10 grams of powdered bacopa extract) on cell cultures, specifically the neurotoxic M1 microglia and the neuroprotective M2 microglia. After administration, the infusion and a high-concentration alkaloid extract significantly inhibited the release of TNF-alpha and had an anti-inflammatory effect.

Dolnick says this study is significant because it demonstrates that Bacopa monnieri “inhibits the release of inflammatory cytokines from microglial cells and inhibits enzymes associated with inflammation in the brain.”

Evidence suggests that blueberry supplementation can improve verbal learning skills, and the ingredient’s effects on memory apply both to short- and long-term memory.

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Brain Health

Spearmint a Popular Brain Supplement for Athletes

Spearmint (*Mentha spicata*/*Mentha viridis*) has been shown to support memory, attention, planning, and reasoning when administered in high doses. Kim Colletti, global cognition product manager, Kemin (Des Moines, IA), says that spearmint strains bred to be high in polyphenols have several beneficial effects on focus as well as working memory, which processes new stimuli and uses recent memories to solve problems. Colletti says polyphenols like those in spearmint have been found in studies to reduce oxidative stress, boost acetylcholine levels, promote neurogenesis, and have neuroprotective properties.

Colletti points to a recent randomized, double-blind, placebo-controlled clinical trial on Kemin’s branded spearmint supplement Neumentix Phenolic Complex that involved 142 healthy, active men and women in their late 20s. The experimental group received a daily 900-mg dose of Neumentix, and participants were assessed using computerized cognitive test batteries after 0, 7, 30, and 90 days.

Says Colletti, “The participants taking Neumentix had significantly higher scores in sustained attention after 30 days of supplementation, and these improvements were still present after 90 days. These findings build on earlier work and further emphasize the uniqueness of this special ingredient.”

Ashwagandha Reduces Mental Stress and Enhances Neurotransmitter Effects in Studies

Ashwagandha (*Withania somnifera*) is an adaptogenic herb commonly used in Ayurvedic medicine. Bruce Abedon, PhD, vice president of scientific and regulatory affairs, NutraGenesis (Brattleboro, VT), says ashwagandha also supports normal memory function and cognition in addition to reducing cortisol levels in human clinical trials.

Abedon says that the glycowithanolide bioactives present in ashwagandha can also inhibit the enzymes that break down neurotransmitters, thereby extending the duration of neurotransmitter effects.

“For example, ashwagandha helps to inhibit acetylcholinesterase, an enzyme that breaks down acetylcholine. Acetylcholine is active in the hippocampus, which is associated with memory and learning. So, reduced degradation of acetylcholine can produce cognitive benefits (by enhancing memory and learning).”

One double-blind, placebo-controlled crossover human clinical trial followed 20 healthy subjects for 43 days. Subjects took 250 mg of NutraGenesis’ branded ashwagandha product Sensoril twice per day for 14 days, and were evaluated on cognitive function tests of reaction time, digital system substitution, digit vigilance tasks, and card sorting tests on day 15. After a 14-day washout period, the subjects crossed over to the opposite group for another 14 days.
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Brain Health

“In children, lutein makes up more than half of the brain's total carotenoids, which indicates that lutein plays a role in brain development,” says Kemin’s Snyder.

Subjects taking the ashwagandha supplement scored significantly higher on measures of psychomotor performance, working memory, reaction time, and information processing ability compared to the placebo group.

Abedon says that this study demonstrates the effectiveness of ashwagandha as a cognitive supplement: “This study shows that Sensoril is effective at multiple doses, in multiple populations, when assessed both subjectively and objectively using validated test measures.”

According to Abedon, NutraGenesis branded and patented ashwagandha product Sensoril differs from traditional ashwagandha in that it has standardized to contain over 1% glycowithanolides, whereas the concentration of this component in traditionally prepared ashwagandha can vary.

Curcumin Clears Amyloid Plaque and Neutralized Free Radicals
A linear diarylheptanoid extracted from the dried rhizomes of the Curcuma longa plant, curcumin is often used as a brain health supplement for its mood-stabilizing and stress-reducing properties. Now, research suggests that curcumin may play an important role in supporting a balanced immune response and clearing amyloid plaque in the brain.

In a recent double-blind randomized crossover clinical trial, 30 obese participants (BMI >30) with varying degrees of comorbid anxiety and depression received 1 gram of curcumin per day (or a corresponding placebo) for 30 days. After a two-week washout period, subjects crossed over to the alternate condition for an additional 30 days.

Participants were assessed on their anxiety and depression using the Beck Anxiety Inventory (BAI) and the Beck Depression Inventory at 0, 4, 6, and 10 weeks.

The study found that curcumin supplementation was associated with a statistically significant (p<0.05) reduction in mean BAI scores relative to a placebo.17

Shaheen Majeed, president, Sabinsa Worldwide (East Windsor, NJ), says this and other studies demonstrate the impressive brain health benefits of curcumin: “Several recent studies have demonstrated that curcumin can help restore equilibrium by improving mood, regulating stress and anxiety, and protecting the brain against aging and neurodegenerative diseases like Alzheimer’s.”

Lutein Benefits Memory and Academic Performance in Children
A naturally occurring terpenoid, lutein is commonly used as a supplement for the eye and skin health markets. As a brain health supplement, lutein is typically used to prevent age-related cognitive decline.

Kemin’s Global Manager of Vision Products Ceci Snyder says lutein is the predominant carotenoid in the brains of children and older adults.

“In children, lutein makes up more than half of the brain’s total carotenoids, which indicates that lutein plays a role in brain development. Higher brain levels of lutein are also related to better cognitive function in older adults.”

Snyder speaks of one recent clinical trial involving 40 children between ages seven and 10. In this randomized, parallel-design clinical trial, participants were assessed for aerobic fitness via a modified Balke treadmill protocol and completed a task to measure relational memory performance. Participants were also assessed for macular pigment optical density (MPOD) and adiposity.19

The study found that higher levels of aerobic fitness and MPOD were correlated with fewer memory errors, and that MPOD accounted for a significant amount of the variance in memory performance.

Snyder says this study is important because it demonstrates the importance of lutein throughout life. She states, “Lutein appears to help maintain brain health and function by protecting the brain from oxidative stress and inflammation.”

OmniActive (Morristown, NJ) Vice President of Global Marketing Lynda Doyle says lutein is also a potent antioxidant that boosts academic performance and prevents age-related cognitive decline. While the exact mechanism of action remains unclear, Doyle says the current rationale is that lutein has anti-inflammatory and antioxidant properties.

One double-blind, placebo-controlled clinical trial on 59 healthy subjects between 18 and 25 years of age measured the effects of lutein suplementation on a variety of markers such as antioxidant concentration, inflammation, and brain-derived neurotrophic factor (BDNF), a neurotrophin associated with learning, memory, and higher cognitive processes.19

This study found that relative to the placebo group, lutein supplementation significantly improved antioxidant and BDNF levels, and significantly decreased inflammation markers.

Doyle says that these results demonstrate lutein’s importance not only as an underlying anchor of healthy brain function, but also as a useful supplement for supporting day-to-day brain functioning.

Says Doyle, “BDNF is one of the most important compounds in the brain. It plays an essential role in central nervous system development, neural plasticity, and cognitive function. Our research shows that increasing BDNF levels with lutein supplementation is correlated with improvements in processing speed, composite memory, and sustained attention.”

Magnesium Sets the Clock Back on Aging Brains
There’s no shortage of vitamins and minerals that contribute to brain health, but one of the most essential is magnesium.

Jennifer Gu, PhD, chief science officer, AIDP (City of Industry, CA), says magnesium is an essential cofactor in more than 300 biochemical reactions, including nerve and brain function. She notes that magnesium is a critical brain health supplement for aging adults, particularly Baby Boomers.

“Our memory, reasoning, and cognitive functions peak at age 25,” Gu says. “After that, the area of the brain associated with complex thinking and decision-making starts to shrink, and our neural and synaptic function decreases.”

Gu says that the brain’s capacity for critical thinking shrinks by 50% between 25 and 80 years of age, and that over time,
brain cells have more and more difficulty relaying signals.

The results, she says, include a variety of conditions including decreased cognition, poor memory, reduced attention span, poor sleep quality, and anxiety. Gu believes, however, that magnesium supplements can restore old neurons to their previous state and boost synaptic function.

A recent randomized, double-blind, placebo-controlled, parallel-design human clinical trial examined the effects of a branded magnesium L-threonate supplement (labeled MMFS-01) on 44 subjects aged 50–70 with mild age-related cognitive impairment.

Subjects took 25 mg/kg/day of the magnesium supplement (or a corresponding placebo) for 12 weeks. Measurements included plasma, urine, and intracellular magnesium levels, as well as tests of visual search and attention, motor speed, working memory, recognition, and association.20

The experimental group had a significant increase in magnesium secretion, as well as an improvement in performance speed on the Trail Making Test, Part B, and an improvement in overall cognitive ability. The placebo group did exhibit a training effect on several of the tasks; however, after applying statistical controls, the study authors concluded that magnesium L-threonate improves cognitive ability.

Gu says these results represent a breakthrough: “One of the most striking outcomes of this study was that supplementation led to a 10% increase on TMT-B scores, and that the improvement in participants’ cognitive ability was equivalent to a brain that is nine years younger.”

NutraScience Labs (Farmingdale, NY) Vice President of Contract Manufacturing Vincent Tricarico feels the brain health category has seen a variety of recent innovations, with vitamin and mineral manufacturers eyeing specialty formulations based on well-vetted ingredients.

Says Tricarico: “Across all of the brain formulations we’re currently working with, vitamin C, B-complex vitamins, magnesium, and calcium are the top ingredients sought by our clients. Most of the formulas we’ve seen have been crafted with a combination of specialized—and usually trademarked—ingredients, with a greater presence of specialty herbs than in the past.”

Brain Health Category Still Rich Ground for Innovators

With new research identifying positive brain health effects of a variety of nutritional ingredients, there’s no shortage of opportunities for companies to begin developing specialized and enriched formulations for brain health products. Memory and cognition supplements, in particular, are in high demand among working professionals, athletes, students, and seniors. As category growth continues, further research will undoubtedly examine new and growing
Brain Health

applications for these ingredients and formulations, making brain health a smart niche for manufacturers and distributors alike.

Mike Straus is a freelance journalist living in Kelowna, Canada. He has written for publications including Canadian Chiropractor Magazine, UX Booth, and Iconic Concierge Vancouver.

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Americans may be getting older, but there’s little indication that they’re eager to look or feel...well, old. That’s why collagen supplements aimed at improving everything from joint function to skin appearance are “sitting pretty,” so to speak, with consumers intent on slowing the aging process as best they can—and reaping the other benefits that collagen brings.

Says Lara Niemann, marketing director, Americas, Gelita (Sergeant Bluff, IA), “More people globally are adopting a ‘DIY’ mentality and proactive stance in achieving their health targets.” The result, she says, has been a “resurgence” of interest in collagen protein.

Elke De Clerck, global market development manager for Peptan, Rousselot (Peabody, MA), agrees—adding that collagen “has become a particularly hot topic” in the nutrition community over the past decade. “Traditionally a popular ingredient in the Asian region, collagen’s use has now significantly increased across the global industry, proving that it’s not just a passing trend,” she says. MarketsandMarkets research predicts the demand for collagen peptides to grow at a 7.1% CAGR between 2014 and 2019, likely surpassing $800 million in sales by the end of that five-year timeframe.

**It’s Everywhere**

Why the interest? Because collagen is well-nigh inescapable. The most abundant protein in the human body, it accounts for roughly 25–35% of the total protein content. And as collagen’s amino acids are wound together into triple helices that themselves twist into long fibrils, it’s no surprise that collagen is a key structural component of the fibrous tissues of tendons, ligaments, and skin, while also helping to build bones, cartilage, muscles, and the dentin in teeth.

As such, collagen supplementation “helps us stay flexible, mobile, beautiful, and strong,” Niemann says. “Worldwide, collagen is among the most trusted active ingredients for consumers who prioritize skin, nail, joint, bone, and muscle health.”

**Size Matters**

Both Niemann and De Clerck cite the utility of collagen peptides in effecting these results—and not by accident. Collagen peptides are the short-chain products that emerge when native collagen is enzymatically hydrolyzed “to obtain a specific bioactive peptide profile,” Niemann explains. “With their special amino acid composition and peptide profile, these specific collagen peptides influence the body’s collagen metabolism directly from the inside.”

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Nitrosigine® vs. other ingredients:

In Vitro Study

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*P<0.01 vs. other ingredients

MORE NITRIC OXIDE PRODUCTION THAN OTHER INGREDIENTS

5X}

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Peptides stimulating different cell types, they “can play a key role as part of a whole-diet approach to health promotion, increasing longevity and reducing the risks of a wide range of age-related conditions,” Niemann says.

Compared to unhydrolyzed proteins, collagen peptides are also more easily and effectively absorbed. The small protein segments travel right from the blood to target tissues “where they act as building blocks to boost production of new collagen fibers, and as biological messengers that stimulate cellular metabolism,” De Clerck says. Exhibit A: small collagen peptides in the skin may trick the body into thinking that native collagen is breaking down, “triggering the synthesis of new collagen fibers,” she says.

Easy Does It
Collagen peptides aren’t only more easily absorbed and incorporated than larger proteins; as soluble powders with a neutral color and taste profile, they’re also easier for formulators to work with. That being the case, collagen’s horizons have expanded beyond capsules and tablets to cover “pioneering clean-label formulations like yogurts, gummies, beverages, and chocolate, which fit today’s lifestyles and improve products’ overall wellness offering,” De Clerck says.

She even thinks marketers should pair collagen with complementary nutrients “to create a wide range of nutritional blends with added health benefits.” A bone-health formulation might match collagen peptides with calcium and vitamin D to achieve “a synergistic effect and provide optimal protein content to build the bone matrix,” De Clerck suggests.

Niemann adds that while collagen has been a frequent flyer in topical beauty and personal-care products—face creams, body lotions, shampoo, and more—“recent scientific evidence confirms that the highest efficacy can be achieved when collagen is ingested orally. Consumer attitudes and preferences are now following suit.”

Collagen peptides aren’t one-size-fits-all ingredients. “Different collagen peptides offer optimized benefits for different body areas,” Niemann continues. “Manufacturers and retailers should seek specific collagen ingredients that meet their product objectives and, more importantly, meet their consumers’ demands while also providing rigorous scientific evidence.”

Ahead, we look at the latest research into collagen’s premier benefits.

More than Skin Deep
“As the population looks to slow the signs of aging,” observes Rousselot’s De Clerck, “oral intake of collagen peptides, as with nutricosmetics, has become an attractive solution for improved skin structure and appearance.” In fact, the results of a recent double-blind, placebo-controlled clinical trial showed that Rousselot’s brand of collagen peptides significantly decreased collagen fragmentation in the deep layer of the dermis by 18% after four weeks of intake, and by as much as 31% after 12 weeks. After four weeks of intake, the peptides also appeared to significantly increase collagen density in the dermis by 9%.

Such studies represent “breakthroughs” in antiaging skin science, De Clerck says, as they “clearly demonstrate that not only is the increase in collagen quantity in the dermis important to improving the properties of the skin, but the quality of the collagen network and fibers is key, too.”

Joint Venture
“Another key benefit of collagen peptides is their effect on promoting joint health,” De Clerck continues. An in vivo study published this year shows that supplementation with her company’s branded collagen peptide helps preserve the cartilage area during osteoarthrositis development while also protecting it from degeneration by stimulating chondrocyte and proteoglycan synthesis. The findings also demonstrate the ingredient’s effectiveness at reducing inflammation by normalizing synovial thickness and reducing the production of the inflammatory tumor necrosis factor (TNF).

“These results are particularly important,” De Clerck says, because “they not only show that our collagen peptides can help protect cartilage from degeneration, increase cell number, and stimulate proteoglycan synthesis, but can significantly and dose-dependently reduce inflammation of the synovial membrane. This level of mechanistic evidence is unique among collagen peptide products.”

Get to Work
If collagen peptide supplementation can ameliorate the painful symptoms of joint deterioration—and thus give hesitant weekend warriors the confidence to get out and start exercising again—wouldn’t it be handy if it could also improve the tone and strength of their newly working muscles? A 2015 study involving 53 elderly male subjects with the age-related muscle-loss condition known as sarcopenia found that those who supplemented with collagen peptides in conjunction with a 12-week course of guided resistance training exhibited significantly more pronounced increases in fat-free mass, bone mass, isokinetic quadriceps strength, and sensory motor control, plus a greater reduction in fat mass, compared to those not receiving supplementation.

Gelita’s Niemann says that the study—which looked at her company’s collagen-peptide product—“clearly demonstrates” that it “has a positive impact on body toning and muscle strength.”

An Inside Job
When we think of cellulite—and, boy, do we ever—we usually associate it with excess weight and poor muscle tone. But cellulite has a dermal component, too, and a double-blind, placebo-controlled clinical study published in 2015 shows that supplementation with targeted collagen peptides can affect it.

The study included 105 normal-weight and overweight female subjects aged 24 to 50 years with moderate cellulite. Subjects received either a daily oral dose of 2.5 g collagen peptides or a placebo for six months. At the end of this period, researchers found that among the normal-weight subjects, collagen-peptide supplementation yielded a statistically significant decrease in degree of cellulite and a reduction in skin waviness on the thighs, while also improving dermal density. Supplementation proved effective in the overweight subjects, too, albeit to a lesser extent.

“While this study on its own is compelling,” notes Niemann, “it’s even more meaningful in conjunction with other recently published studies showing that, taken orally, specific collagen peptides influence the skin’s collagen...”
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**Strong Foundation**

That collagen is a structural constituent of fibrous tissues like tendons and ligaments makes sense; that it’s structurally important in, say, bone, is less intuitive. But, says De Clerck, “Collagen peptides have also been shown to provide bone and skeletal support.” In *in vitro* and *in vivo* studies\(^6\) and in a recently published review,\(^7\) her company’s branded collagen peptide demonstrated an ability to improve bone metabolism—with supplementation helping to restore bone mineral density and improve bone microarchitecture and solidity.

“On a mechanistic level,” De Clerck says, the collagen ingredient “was shown to stimulate bone formation by promoting proliferation, differentiation, and mineralization of osteoblasts, and to slow bone breakdown by inhibiting osteoclasts.”

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<td><a href="http://www.batorynutra.com">www.batorynutra.com</a></td>
<td>800/451-9067</td>
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<td>52</td>
<td>Best Formulations</td>
<td><a href="http://www.bestformulations.com">www.bestformulations.com</a></td>
<td>626/912-9998</td>
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<td>Capsugel</td>
<td><a href="http://www.capsugel.com">www.capsugel.com</a></td>
<td>888/783-6361</td>
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<td>37</td>
<td>Cargill</td>
<td><a href="http://www.cargill.com">www.cargill.com</a></td>
<td>866/456-8872</td>
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<td>20,62</td>
<td>Evolva</td>
<td><a href="http://www.veriteresveratrol.com">www.veriteresveratrol.com</a></td>
<td>800/250-1032</td>
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<td>28</td>
<td>FrieslandCampina Ingredients</td>
<td><a href="http://www.dmv.nl">www.dmv.nl</a></td>
<td>+31 (0)33 713 33 33</td>
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<td><a href="http://www.grainprocessing.com">www.grainprocessing.com</a></td>
<td>563/264-4265</td>
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<td>209/667-6076</td>
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<td>49</td>
<td>IgY Nutrition</td>
<td><a href="http://www.igymax.com">www.igymax.com</a></td>
<td>405/242-5381</td>
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<td>Ingredia Dairy Experts</td>
<td><a href="http://www.ingredia.com">www.ingredia.com</a></td>
<td>419/738-4060</td>
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<td><a href="http://www.jdlabs.com">www.jdlabs.com</a></td>
<td>760/734-6800</td>
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<td>314/428-4300</td>
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<td>Kemin Health, L.C.</td>
<td><a href="http://www.kemin.com">www.kemin.com</a></td>
<td>866/536-4666</td>
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<td>Kyowa Hakko</td>
<td><a href="http://www.kyowa-usa.com">www.kyowa-usa.com</a></td>
<td>212/319-5353</td>
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<td>Natreon Inc.</td>
<td><a href="http://www.natreoninc.com">www.natreoninc.com</a></td>
<td>732/296-1080</td>
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<td>56</td>
<td>Nutraceuticals International Group</td>
<td><a href="http://www.nutraitngroup.com">www.nutraitngroup.com</a></td>
<td>800/651-2587</td>
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<td>13,59</td>
<td>Nutrition 21</td>
<td><a href="http://www.nutrition21.com">www.nutrition21.com</a></td>
<td>914/701-4500</td>
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<td>21</td>
<td>OmniActive Health Technologies</td>
<td><a href="http://www.omniactives.com">www.omniactives.com</a></td>
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<td>PallayPack</td>
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<td>514/630-1818</td>
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<td>Pharmachem Laboratories Inc.</td>
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<td>800/526-0609</td>
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<td>Prinova</td>
<td><a href="http://www.prinovausa.com">www.prinovausa.com</a></td>
<td>630/868-0300</td>
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<td>33</td>
<td>Ross, Charles &amp; Son Co.</td>
<td><a href="http://www.mixers.com">www.mixers.com</a></td>
<td>800/243-7677</td>
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<td>11,39,TAB2</td>
<td>Sabinsa Corp.</td>
<td><a href="http://www.sabinsa.com">www.sabinsa.com</a></td>
<td>732/777-1111</td>
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<td>TAB1</td>
<td>Soft Gel Technologies Inc.</td>
<td><a href="http://www.soft-gel.com">www.soft-gel.com</a></td>
<td>800/360-7484</td>
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<td>908/281-5577</td>
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<td>IBC</td>
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<td><a href="http://www.synergytaste.com">www.synergytaste.com</a></td>
<td>847/487-1011</td>
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<td><a href="http://www.vestainingredients.com">www.vestainingredients.com</a></td>
<td>888/558-3782</td>
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<td>Vidya Herbs Pvt. Ltd.</td>
<td><a href="http://www.vidyaherbs.com">www.vidyaherbs.com</a></td>
<td>714/992-1288</td>
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<td>Wellmune, A Kerry Brand</td>
<td><a href="http://www.wellmune.com">www.wellmune.com</a></td>
<td>612/443-7958</td>
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When it comes to natural colors, consumers have spoken loud and clear: gone are the days of indifference about artificial colors and preservatives. Tammi Higgins, business unit head, colors, Lycored (Orange, NJ), points to recent Nielsen data indicating that more than three in five consumers globally say they do their best to avoid artificial colors. She notes that when Lycored conducted a 506-person survey to determine whether consumers would be willing to pay more for products featuring natural colors and flavors, nearly nine in 10 said that they would. And while it’s clear that natural colors are in, it can still be difficult for formulators to find stable, natural color solutions, namely because of the challenges natural colors face.

For one thing, natural colors are often more expensive to formulate with than their artificial counterparts. The main challenge, however, is creating a natural color that holds up when exposed to particular rigors of the manufacturing process. Light exposure, heat sensitivity, and interactions with other ingredients are key challenges natural color companies face—obstacles that are largely avoided when working with synthetic ingredients. "The synthetic food colorants that the food industry came to rely on over the past 50–60 years are relatively very well-behaved and consistent in their performance," Winston Boyd, director of technical services, Gold Coast Ingredients (Commerce, CA), tells Nutritional Outlook. "Natural colorants, on the other hand, may have issues with pH, heat, and light stability."

In addition, it’s critical that manufacturers understand a natural color’s behavior can be "highly dependent on the application," Boyd states.

The behavior of certain color ingredients, for instance, may be affected by other ingredients within the same food or beverage formulation. "For example," says Campbell Barnum, vice president, branding and marketing, D.D. Williamson (DDW; Louisville, KY), "vitamin C will enhance the stability of finished beverage products colored with carotenoids like beta-carotene and paprika oleoresin, but the same vitamin will cause the degradation of anthocyanins."

Even once a natural color is successfully formulated, however, keeping the color of a finished product vibrant once it hits the market can be just as tricky.

To ensure the stability of its natural colors, DDW, Gold Coast, and Lycored are focusing on testing and research. "DDW has standard methods to test parameters that influence the stability of colors," Barnum says. "We use instrumentation to measure color before and after product application stress testing in heat, light, or different pH environments. For example, we will store food products with colors for eight weeks at elevated temperature. The heat test allows DDW to approximate the shelf life of colors in finished products," Barnum says DDW’s NaturBrown ingredients, for instance, are formulated from 100% natural sources and “have the optimal balance between stability, flavor, and color.”

Lycored has focused its innovation in the natural colors category on bright, bold reds, yellows, and oranges, including its lycopene-based Tomat-O-Red colorant, which is formulated from the carotenoid extracted from tomatoes and is highly heat, light, and pH stable. But even these colors can face challenges at times, the company says, which is why it continues to embark on extreme stability testing to improve performance.

Gold Coast, meanwhile, says it is "working daily to develop specific color formulations to meet the demanding challenges of our customer base." Boyd says that Gold Coast currently has some "entirely new concepts" in the pipeline aimed at solving some of the challenges associated with working with natural colorants.

Ultimately, one of the best ways for color manufacturers to ensure natural color stability is identifying the right colorant. Both Higgins and Boyd stress the importance of selecting a colorant that you know is going to give you stability. "It’s much better doing that than adding chemicals to prevent bleeding, or changing your manufacturing processes," Higgins says.

Boyd agrees: "A knowledgeable color technologist can steer the product developer to the right class [or] formulation of natural food colorant for the application. If we understand the challenges earlier in the process, it gives us much more flexibility in achieving the desired result."

If companies want to get in on the natural trend, there’s certainly work to be done—but they won’t be starting from scratch, thanks to supplier advancements. Given the manufacturing challenges and costs associated with achieving convincing, highly stable natural colors, is it worth it? Naturally.
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*These statements have not been evaluated by the Food and Drug Administration. This ingredient is not intended to diagnose, treat, cure, or prevent any disease.