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The Time Is Right to Work with FDA

“Time brings change” is an apt description of the relationship between FDA and the dietary supplements industry. Today, the agency and responsible members of industry seem more willing than ever before to work together on initiatives that promote the safety and integrity of dietary supplements on the market. But don’t take my word for it. Take FDA’s.

At the Council for Responsible Nutrition’s The Conference in California in October, guest speaker Steven Tave, FDA’s Director of the Office of Dietary Supplement Programs, spoke about “the common ground that we all”—agency and industry—“share towards the goal of a well-working dietary supplement market.” During his presentation, Tave highlighted several recent actions FDA and the dietary supplement industry each took to help protect consumer safety. One example he provided related to pure and highly concentrated caffeine products. In April of this year, FDA issued a final guidance warning the public about the dangers of products marketed as dietary supplements that contain highly concentrated, unsafe amounts of caffeine. Industry associations have also issued their own guidelines banning their memberships from selling concentrated caffeine products.

In his speech, Tave made sure to discriminate between responsible and irresponsible/illegal companies. When discussing the industry’s compliance with Good Manufacturing Practices, Tave said that while there is still a gap in overall compliance, “many firms are getting it right, and many firms are committed to ensuring that they deliver a quality product to their consumers—and that’s attributable in many ways to industry-led efforts to promote compliance.”

Comments like these give hope to industry that FDA is not out to act against all dietary supplements, but rather just those that are illegal and dangerous. Case in point, when Tave spoke about the agency’s enforcement actions against companies selling concentrated caffeine products, he made sure to point out that the agency “didn’t sweep too broadly and declare that all caffeine is hazardous.” He said the agency recognizes that caffeine, “when formulated and marketed appropriately, can be an ingredient in a safe dietary supplement product.” As such, he said, the agency was “conscious to leave a path for responsible firms…”

There’s been growing evidence in recent years that the agency and the industry are dialogueing more effectively. Take the agency’s draft guidance for new dietary ingredients (NDIs). While Tave did not have any updates on when FDA will release another revised or a final guidance, he did say that even as FDA grapples with how to handle some of the more complicated parts of the draft guidance, the agency also hopes to “make progress” on parts of the NDI draft guidance that are less contentious. He highlighted how the agency and the industry began discussions last October, at a public meeting held by FDA and attended by industry, on how best to handle the matter of determining which ingredients might not require an NDI notification (namely, those old dietary ingredients launched in the market prior to the passage of the Dietary Supplement Health and Education Act of 1994).

“The approach has been to try to make progress where we can on discreet topics, especially where there seems to be some consensus among stakeholders, and equally importantly, to do so in a transparent way while we continue to grapple with some of the difficult issues,” Tave said. He underlined: “We’ve committed to being transparent as we decide how to move forward on this issue.”

FDA’s willingness to communicate openly with the dietary supplements industry in a transparent fashion could be very important as industry looks toward upcoming industry initiatives. One developing industry topic under discussion, not only at the CRN conference but also among the industry behind doors, has been the topic of whether or not FDA should create a mandatory, federal product listing where companies must list their dietary supplement products, the idea being that FDA will have a better idea of which products are on the market so it can do a better job of regulating the industry.

Should industry take the optimistic road and accept FDA’s sentiments that the agency would like to work with, not against, the industry? And if so, will the industry be able to find new opportunities to work with FDA that could serve to better the regulatory framework for both industry and consumers? Only time will tell.

“I would say that I have never seen more possibility for cooperation, and in some cases, collaboration, with FDA since the passage of DSHEA as to what we have now,” Steve Mister, CRN’s president and CEO, told me. “I’ve never seen a time when the agency is so eager to work with the industry to solve problems. That’s not to suggest that we agree with them, or that they’re going to roll over on us, but there is a genuine effort to solve issues and make it a better marketplace for consumers. And, I mean, we can’t argue with that. That’s what we’re all looking to do.”

Of course, Mister points out, on something like the topic of a mandatory listing—which, for the record, CRN has not taken a position on, pro or con, and that FDA has not mentioned publicly itself—“I think we have to go in with eyes wide open.”

But, the fact is there may be no better time than now to work with FDA and those at the agency who seem to want to work with industry to solve problems. For, there’s no telling how long the spirit of cooperation at FDA will last. “You always have to think about the fact that the relationship you have now [with the agency] might be different in five years, particularly if the leadership changes,” Mister says. “So, you want to be sure that you’re protecting yourself against potential changes in that relationship, but this is a very good time to be working with the agency and to try to do some things that maybe we couldn’t have done in the past.”

Jennifer Grebow
Editor-in-Chief

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Jennifer Grebow
Editor-in-Chief
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Seventy-five percent of U.S. adults take some kind of dietary supplement, according to new numbers out from the Council for Responsible Nutrition’s 2018 Consumer Survey on Dietary Supplements. Not only did 75% of Americans surveyed say they take dietary supplements, but 87% said they have overall confidence in the safety, quality, and effectiveness of dietary supplement products—a notable feat in light of the negative press often published about dietary supplements these days.

Nikki Yas, vice president, professional brands, for Atrium Innovations, presented the 2018 topline survey results in October at the Council for Responsible Nutrition’s (CRN; Washington, DC) annual conference in Dana Point, CA. She pointed out that the percentage of Americans still confident in dietary supplement products (87%) remains the same as last year. “We’re holding our ground nicely, despite the constant drumbeat of negative press from the media,” she told conference attendees.

The percentage of U.S. adults who take some kind of dietary supplement (75%) is actually down one percentage point from last year—when it was 76%—but Yas said the survey’s conductor, Ipsos Public Affairs, said this drop is not worrying and that it is actually statistically insignificant, within the normal margin of error, and is likely due to some variances in this year’s survey population, which skewed slightly younger. Overall, Yas pointed out, there has been a 10% increase over the past 10 years in the number of Americans who take a dietary supplement.

Growth among Categories
Many supplement categories saw growing consumer usage, Yas said. The 2018 survey found that those surveyed who take dietary supplements use supplements in the following categories (based on the categories addressed by the survey):

- Vitamins/minerals (98%)
- Specialty supplements (51%)
- Herbs/botanicals (41%)
- Sports nutrition (32%)
- Weight management (20%)

Vitamins/minerals remain the most popular kind of supplement U.S. consumers take year over year. As far as the other categories, Yas said, “the rest are up one or two percentage points over the last year.” Diving deeper into specific ingredients, the survey revealed which types of supplements that those who use supplements take:

- Multivitamin (75%)
- Vitamin D (38%)
- Vitamin C (30%)
- Calcium (26%)
- Vitamin B/B complex (25%)
- Protein (22%)
- Magnesium (20%)
- Omega-3 fatty acids (20%)
- Probiotics (17%)
- Green tea (16%)
- Fiber (14%)
- Vitamin E (15%)
- Turmeric (14%)

Consumer Confidence and Trust
The report also breaks down which types of supplements U.S. supplement users have greatest confidence in:

- Vitamins/minerals (87%)
- Specialty supplements (65%)
- Herbs/botanicals (64%)
- Sports nutrition (54%)
- Weight management (46%)

When asked whether they trust the dietary supplements industry, 78% of U.S. adults said yes this year compared to 73% who said the same when the survey began asking the question in 2016. This is notable, said Brian Womack, CRN’s senior vice president, communications, in a press release: “We’re pleased to see a 5% increase in consumer trust in just two years.”

Yas also noted how those confident in the industry are divided among age groups. When asked whether they perceive the dietary supplement industry as being trustworthy, survey respondents aged 35-54 replied yes (80%), followed by adults 18- to 34-years-old (78%) and adults 55 and older (74%).

She said there are opportunities to increase loyalty among age groups. “What’s interesting here is you can look at the younger group—the 18- to 34-year-olds—and see this as an opportunity to garner some loyalty, some trust, and some long-term customers,” Yas said. “Our Gen Xers [age 35-54] are usually our biggest supporters as well” because these consumers grew up taking supplements, she said. And the growth in trust among the 55+ age group is good to see, she said. “This 74% is up 5 percentage points over last year. This is really interesting because this group of adults didn’t really grow up with supplement use in their houses. So the fact that it’s up 5% means our message is reaching that audience.”

When asked who they trust most for reliable information on dietary supplements, survey respondents said:

- Medical doctor/physician (57%)
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kind of information most influences their decisions. In addition, survey respondents also ranked what influenced them when making a purchasing decision. In general, [this data] shows a shift that [consumers] still trust their healthcare practitioners versus some of these celebrity spokespeople, so it's something to consider when we look at our budget planning for next year,” she said.

Seventy percent of respondents said that a product's label is the most important feature to them when making a purchasing decision. In addition, survey respondents also ranked what kind of information most influences their dietary supplement purchasing decisions:

- Quality seal (i.e., NSF, UL, USP) (36%)
- Label claims (e.g., “maintain heart health”) (30%)
- Labeled as natural (25%)
- Labeled as organic (17%)
- Marketing claims indicating a product or ingredients are backed by science (15%)
- Marketing claims indicating that a product is “#1 Recommended” or the “#1 Brand” (8%)

Yas said that the last two results for marketing claims may come as a surprise to marketers who might think that these are top purchase drivers when in fact they are not. “I think a lot of us have spent some time and energy garnering influencers—paying influencers, maybe even getting some of those really well-known celebrities to speak for our brands. In general, [this data] shows a shift that [consumers] still trust their healthcare practitioners versus some of these celebrity spokespeople, so it’s something to consider when we look at our budget planning for next year,” she said.

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Yas said that the last two results for marketing claims may come as a surprise to marketers who might think that these are top purchase drivers when in fact they are not. “I think a lot of us have spent some time and energy trying to substantiate that we’re number one—number-one recommended, number-one trusted—when in fact, people just want the facts. They want to know your product is of high quality. They want to see what it can do for them. They want to know what the ingredients are,” Yas said.

Price and Loyalty

Finally, the survey questioned respondents on price and loyalty. It found that 56% of supplement users said price is most important when purchasing supplements—a decrease from 63% in 2013—which could indicate shoppers are willing to pay more for high-quality products.

The Future

Looking ahead, 60% of supplement users surveyed said they anticipate increasing their use of supplements in the next five years. Age-wise, 71% of users who plan to increase usage are 18 to 34-years-old, followed by 67% of users 35 to 54-years-old and 45% of users 55 and older.

The full survey can be purchased from CRN. The survey was conducted online by Ipsos Public Affairs in late August 2018. Sample size was 2,004 adults ages 18 and older in the U.S.

SOPs to Advise Firms on Destroying Irreparably Damaged Herbal Materials

The American Botanical Council (ABC; Austin, TX), as part of the ABC-AHP-NCNPR Botanical Adulterants Prevention Program (BAPP), recently released a proposed “Best Practices SOP for the Disposal/Destruction of Irreparably Defective Articles.” The standard operating procedures (SOPs) are meant to guide companies on when and how to destroy what are deemed to be “irreparably damaged” raw materials received from suppliers, instead of returning those ingredients back to the supplier who may otherwise release the defective ingredients back into the supply chain. In October, BAPP invited the public to comment on the SOPs.

The organization says these SOPs allow industry to take better control of the supply chain and prevent the sale of unlawful ingredients.

“Basically, we’re saying that when something comes in and it’s defective, and it’s not repairable and the supplier can’t remediate it, don’t send it back. Because if you send it back for credit or for a refund, you know what’s going to happen,” explained Mike Blumenthal, speaking about the new SOPs at the Council for Responsible Nutrition's The Conference in Dana Point, CA, in October. “The supplier almost invariably is going to sell it to someone else who may have a lower level of quality-control regimen, and it [reenters] the supply chain and ends up in consumer products.”

Not all material needs to be destroyed. There are a variety of scenarios in which ingredients do not meet a manufacturer’s specifications but can be fixed either by the manufacturer or sent back to the supplier for remediation. For instance, Blumenthal said, a material’s mesh size may be too large, in which case the manufacturer might easily be able to fix the situation itself by simply grinding the material down to a smaller size. Or, an ingredient’s color might be different than what a manufacturer prefers, in which case the manufacturer can return that ingredient to the supplier who may be able to sell it to someone else because the safety and quality of the ingredient is not defective; just the color is off.

By contrast, the SOPs apply only to ingredients that are irreparably defective, both adulterated and misbranded, and cannot be remediated by either the buyer or supplier. At this point, this determination must be made by a third-party contract laboratory, not the in-house lab, the SOPs instruct. “[The third-party lab] must corroborate, using a validated method or a scientifically valid method,” said Blumenthal. “So, it’s not about just any rejected material; it’s about the material that needs to go out and be destroyed. And that material should be destroyed by a qualified third-party disposal company and/or incinerator, as per the SOPs.”

This is the only way to prevent reintroduction of unlawful ingredients into the supply chain, he explained. The bright side is that while these SOPs are an important measure for better controlling the supply chain, most responsible industry companies most likely have never had to resort to such measures. “The irony of the thing is that most of the people in this room [at the CRN conference] probably never had to utilize an SOP like this,” Blumenthal said. “They’re not buying into the market for a $5 or $15 per kilo better price, which puts you in a situation where you might be at risk.” Still, he said, “We believe that’s an ethical responsibility that management has—not to mention, obviously, the legal responsibility” not to return irreparably defective ingredients to the supply chain.
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Just when you thought the topic of protein had been sliced, diced, and hydrolyzed to a fare-thee-well, along comes another angle to contemplate: How much is enough? Or, perhaps more pointedly, how much is enough to optimize protein’s benefits—for muscle building, weight management, healthy aging, or any of the other facets of wellness it’s known to improve?

Of course, the question of protein “dosing” is nothing new, either for consumers or the product developers who court them. But by focusing on how much protein they pack into their formulations, product developers not only have a chance to help their audience meet their protein goals; they might also give their protein applications an edge in a crowded marketplace.

What’s in a Name?
It’s not hard to understand why consumers are clamoring for more protein. As Matthew Pikosky, PhD, RD, vice president, nutrition research, Dairy Management Inc. (DMI; Rosemont, IL), says, “Protein is an essential component of everyone’s diet. While typically associated with muscle health, it also supports bones, ligaments, and tendons; moves oxygen to muscles; helps us metabolize other nutrients; and takes part in keeping the immune system healthy.”

But where the equation starts getting tricky is in figuring out the protein “dose” to add to a particular product aimed at a particular consumer or purpose. And even here, notes Ermel Manuel, sports nutrition applications technical sales manager, FrieslandCampina Ingredients North America Inc. (Paramus, NJ), dose might not be the right word to have in mind.

“Dose is a term normally used in medicine and so doesn’t really fit with protein fortification,” he says. Neither does level, he believes, as he thinks it could be confused with the “levels” of protein structure that you may (or may not) remember learning about in college molecular biology class.

In any case, the bottom line for Manuel, at least, is that the amount of protein in a product—or an individual’s diet—should take its cues from the Dietary Reference Intakes (DRIs) and Recommended Daily Allowances (RDAs) that the Institute of Medicine, through its Food and Nutrition Board, sets for key nutrients—protein included.

“Setting a Floor
DMI’s Pikosky also sees value in leaning on those guidelines. “When discussing protein, it’s best to start with a grounding in current protein recommendations established by the Food and Nutrition Board of the Institute of Medicine,” he agrees. And as it stands, the RDA for protein for adults aged 18 and above is 0.8 g per kg body weight per day, which works out to 0.36 g of protein per lb, or 56 g per day for a 154-lb person.

Another way of specifying recommended protein intake is with the acceptable macronutrient distribution range (AMDR), which, as Pikosky explains, gives “a range of intake for a particular energy source that’s associated with reduced risk of chronic diseases while providing adequate intakes of essential nutrients.” Expressed as a percentage of total calories consumed, the AMDR for protein is 10%-15%, or 50 to 175 g of protein within a 2,000-calorie daily diet.

But while both the AMDR and the RDA set minimum protein consumption levels designed to avoid deficiency—and the consequences of it, including compromised growth in children, loss of muscle mass in adults, and frailty in seniors—neither lays out a plan for protein optimization.

Indeed, the goal of the AMDR is reduced risk of chronic disease; and as it’s defined, the RDA merely estimates the minimum daily average dietary intake to meet the protein requirements of 97%-98% of healthy individuals. In other words, says Pikosky, these guidelines “can be used to set the floor, so to speak, that people should be aiming for.” But they won’t help consumers maximize their protein potential, or reach more ambitious wellness goals.
How much is enough to optimize protein’s benefits—for muscle building, weight management, healthy aging, or any of the other facets of wellness it’s known to improve?
Beyond Basic

That’s where consuming more protein than in baseline recommendations can bring an advantage. As Kara McDonald, vice president, global marketing communications, U.S. Dairy Export Council (USDEC; Arlington, VA), says, “The evidence continues to build on the benefits of higher-protein diets—curbing hunger, maintaining a healthy weight, enhancing exercise recovery, getting lean, and maintaining muscle as we age.”

Pikosky agrees. “As research evolves,” he says, “health and wellness professionals are looking beyond minimum requirements to explore optimal protein levels that can provide benefits. A growing body of research supports the benefits of higher-protein diets—within the AMDR—for athletes and highly active adults, for weight management and to foster healthy aging.”

He believes the sports and exercise spaces have matured most in recognizing the importance of optimal protein intake, noting the “large body of science” underlying the benefits of whey protein and dairy foods in particular in promoting muscle recovery following exercise.

A 2016 joint position stand on nutrition and athletic performance from the American College of Sports Medicine, Academy of Nutrition and Dietetics, and Dietitians of Canada noted that dairy proteins appear superior to other proteins tested thanks to their content of the branched-chain amino acid leucine, as well as “the digestion and absorptive kinetics of branched-chain amino acids in fluid-based dairy foods,” Pikosky says. The position recommended 1.2 to 2.0 g of protein per kg body weight per day for adults to support muscle recovery from routine, vigorous exercise.

Similarly, the International Society of Sports Nutrition states in its 2017 position stand on protein and exercise, “Overall, research has shown that products containing animal and dairy-based proteins contain the highest percentage of EAAas”—essential amino acids—and result in greater hypertrophy and protein synthesis following resistance training when compared to a vegetarian protein-matched control, which typically lacks one or more EAAas.”

As for weight management, research shows that of all the macronutrients, protein—and higher-protein diets especially—produces the sense of satiety that can help reduce energy intake and, thereby, support weight management, Pikosky says.

“Additionally, one of the primary goals of anyone on a weight-loss plan is to preferentially lose body fat while preserving muscle mass, as muscle is important to supporting activities of daily living as well as contributing to resting energy expenditure,” Pikosky adds. To this end, higher protein intakes within the context of broader calorie reduction support...

THE KIDS ARE ALL RIGHT?

Adequate protein consumption is just as important to our little ones as it is to adults. So what does an appropriate dose for kids look like? Also, are children currently getting the amount of protein that they should, and what happens if they don’t?

Jeffrey Bernstein, food scientist at protein powder company Instapro (Burlington, NJ), a sister company to protein supplier AMCO Proteins, says data show that there are some groups in which intake is markedly low. “According to the National Health and Nutrition Examination Survey (NHANES), absolute protein intake is lowest in children ages one to three, regardless of socio-economic status. These developmental years are instrumental, and ensuring that children receive good-quality protein is paramount to their long-term health.”

School-aged children in the one- to seven-year-old age group also do not get enough daily protein, according to NHANES, he says. “The myriad effects associated with poor protein intake are poor concentration in school, decreased immunity, delayed growth, poor bone and joint development, chronic hunger, and more.”

What should children be consuming? Bernstein says the current dietary reference intake (DRI) for protein for children is 0.87 g per kg body weight and 0.76 g per kg body weight for children ages 1 to 3 and 4 to 8, respectively. These DRIs reflect the “minimum amount of dietary protein required to prevent a negative nitrogen balance, an indicator of protein deficiency.”

And, Bernstein says, the current protein DRI for children was shown in a 2011 study to “severely underestimate protein needs as determined by the amino acid oxidation method.” This is when supplementation can help. For instance, Bernstein says, adding one or two packets daily of his company’s protein powder delivers approximately 50% of the current recommended daily allowance (RDA) of protein for a child weighing 40 lb and in doing so “will help bring children’s net protein intake above current average levels” and will “help parents fortify their children’s foods with additional protein.”

By Jennifer Grebow, Editor-in-Chief

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GETTING THE MOST FROM PROTEIN

If you’re going to buy a protein product, chances are you’d like to make sure that you’re getting the most from that product. There are several ingredients on the market today that can be formulated concurrently with protein specifically to help improve the body’s absorption of amino acids from the supplemental protein.

Nutrition 21’s (Purchase, NY) Velositol ingredient is a patented amylopectin chromium dietary complex that, when added to protein, helps increase the body’s uptake of amino acids—in effect, “doubling the power of protein,” the company says. As Mallory Junggren, senior director of marketing, explains, Velositol stimulates insulin release and allows the body to safely increase insulin levels, which in turn triggers the body to enhance its amino acid uptake and thereby stimulate muscle protein synthesis. This mechanism was borne out most recently in a 2017 study published in the Journal of the International Society of Sports Nutrition.

At this year’s International Society of Sports Nutrition conference in Florida, Nutrition 21 presented new preclinical trial results further indicating how Velositol works to enhance muscle protein synthesis. The study, which examined Velositol’s effects when added to branched-chain amino acids (BCAA), pea protein, and increasing doses of whey protein, found that Velositol helped significantly increase the activity of the signaling proteins involved in the mTOR pathway—the primary pathway that regulates muscle protein synthesis and muscle hypertrophy (growth of muscle cells). “These results suggest that Velositol initiates and enhances muscle protein synthesis through activation of key downstream signaling factors in the mTOR pathway that are known to be involved in muscle growth and function. These new findings give insight into the mechanism by which Velositol enhances muscle protein synthesis,” Junggren says.

Protein-product marketers are taking advantage of Velositol’s ability to boost protein efficacy to set their products apart in the market. Companies like nutraceutical brand Medical Research Institute (MRI, Fairfield, OH) are not only adding Velositol to their protein products but calling out the benefits of Velositol right on the product label for the consumer to see. For instance, MRI’s Hydrolyzed Whey Protein Isolate product, launched last year (pictured above), boasts “Double the Power of Whey Protein” right on the label. At least 20 products on the market now feature Velositol, including post-workout protein powders, ready-to-drink post-workout beverages, and BCAA post-workout muscle-building powders, says Junggren. And the ingredient is not limited to sports nutrition products, either.

Velositol’s protein-boosting got us wondering: 1) is there ever danger that consumers will, as a result, get too high of a protein dose, and 2) if a company includes Velositol in its formulation, can it cut down on the amount of protein in the product and still get the same desired effect? We asked Nutrition 21’s senior manager, scientific affairs, Sara Perez-Ojalvo.

First, she says, while long-term protein intake above the recommended dietary allowance for adults is not advised and can lead to disorders in liver and kidney function, studies on Velositol have shown no adverse effects compared to placebo. Furthermore, she says, in a preclinical study looking at the effect of Velositol on liver and kidney function, researchers not only did not find any adverse effects on liver and kidney function but in fact saw a greater increase in levels of the enzyme aspartate aminotransaminase (AST) in Velositol subjects, suggesting that Velositol may actually promote healthy liver function. She says this study will be published soon.

Continued on page 20
The company says Velositol is Generally Recognized as Safe at 2 g. The flavorless powder can be used in protein drinks and a variety of meal-replacement, energy, and protein bars. Perez-Ojvalo says the chromium picolinate fraction of the ingredient has also been shown to be safe at “extremely high doses.” Velositol can even help products with low protein doses better their effects on muscle protein synthesis—which ultimately expands its uses to a broad range of consumers.

Perez-Ojvalo explains, “There are many cases where products have lower doses of protein, including some protein bars or breakfast/meal-replacement bars, products marketed towards women who want lower-calorie products, and products marketed to the aging population where it can be difficult for them to ingest high doses of protein. Velositol is a great addition to these products because at just 2 g, it does not add a lot of bulk or calories, but it boosts the effect of protein on muscle protein synthesis and in a clinical study was shown to double the effect of 6 g of protein on muscle protein synthesis (MPS).”

Nutrition 21 also has preclinical animal data, presented at the International Society of Sports Nutrition conference, to show that Velositol increases muscle protein synthesis when used with both low- and high-dose protein products. “In a preclinical study, 6 g of whey protein with Velositol led to the same amount of MPS as 20 g of whey protein alone, and 20 g of whey protein with Velositol led to more MPS than 30 g or 40 g of whey protein alone, showing that Velositol can make your protein work harder for you at both low and high doses of protein,” Perez-Ojvalo says. “This means that it is a good idea to add Velositol to products with less protein like bars or those targeted to populations that want low-calorie protein products, because it makes low doses of protein more effective.”

“But no matter the amount of protein you take, Velositol is a smart addition as it boosts the effect of protein on MPS so you get greater benefits,” she concludes.

Another company, Kerry (Beloit, WA), offers a probiotic ingredient, Ganeden BC30 (Bacillus coagulans GBI-30, 6086), which, when paired with protein, was shown to help that protein more significantly increase recovery, reduce muscle damage, and help promote physical performance post-exercise. In a 2016 athlete study, researchers found Ganeden BC30 added to 20 g of protein—in this case, casein—was able to enhance levels of protection against muscle damage compared to casein alone.

By Jennifer Grebow, Editor-in-Chief

References
SYNTHUSIASM

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context of an individual’s overall dietary needs.

And they need to account for protein quality, which he says “is an important consideration that shouldn’t be overlooked when thinking about optimizing protein intake.”

As hinted at earlier, a protein’s quality reflects its amino acid composition—ideally supplying the full array of EAAs that the human body can’t produce on its own and in amounts sufficient to meet the body’s needs—as well as its digestibility and the amino acids’ bioavailability once digested and absorbed.

And it matters for protein intake optimization, Pikosky says, because “to obtain a similar amount of biologically available essential amino acids from a lower-quality protein would require that one consume more of the food or protein source.” From a practical standpoint, he says, “it makes sense to try to deliver those essential amino acids efficiently via foods that provide a highly concentrated, highly digestible, and biologically available source of them.”

Pikosky reiterates that the whey and casein proteins in dairy are among the highest-quality proteins available, with a protein digestibility corrected amino acid score (PDCAAS) of 1 and among the highest gram-for-gram concentrations of EAAs, including the branched-chain amino acid (BCAA) leucine. BCAAs are “primary drivers of muscle protein synthesis, ultimately leading to the building and maintenance of muscle,” Pikosky says.

By contrast, plant proteins tend to have lower quality scores because their amino acid complements lack certain EAAs, supply them in the wrong proportions, or are simply less digestible or bioavailable.

“Protein recommendations are now starting to incorporate considerations for protein quality,” Pikosky notes, with the aforementioned 2016 joint position stand on nutrition and athletic performance advising athletes and vigorously active adults to get 20 to 30 g of high-quality protein, providing about 10 g of EAAs, after workouts and at main meals. “Additionally,” he says, “the PROT-AGE Study Group recommends 25 to 30 g of protein and 2.5 to 2.8 g of leucine per meal. This is another example of how it’s not solely about trying to achieve a total protein target, but a targeted amount of essential amino acids and leucine to optimize the muscle protein synthesis response.”

It’s About Time

“In addition to total protein intake and the type, or quality, of protein consumed,” Pikosky continues, “protein timing, or the distribution of how one consumes that protein over the course of the day, is the last piece of the protein intake puzzle.”

Data from the CDC’s National Health and Nutrition Examination Surveys (NHANES) show that Americans typically “backload” their protein consumption, “eating small amounts at breakfast, moderate amounts at lunch, and large amounts at dinner,” Pikosky says. “Some experts have hypothesized that this isn’t the most effective way to distribute...
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protein intake, as our ability to use protein and amino acids to stimulate protein synthesis appears to have a threshold—a point of diminishing returns where additional protein beyond that threshold will not result in further increased protein synthesis.”

Current research puts that threshold at about 20 g of high-quality protein, with 10 g of essential amino acids, for adults, and 30 g of high-quality protein, with about 15 g of essential amino acids, for older adults. “Eating moderate amounts of high-quality protein at each main meal to maximize muscle protein synthesis throughout the day can serve as a practical strategy to support muscle health,” Pikosky says.

It’s even more important for athletes hoping to build muscle beyond the level of basic strength and health. “It’s been proven that having protein in your system pre- and post-workout is important with muscle building,” says FrieslandCampina’s Manuel. “Our bodies go through a cycle of muscle protein breakdown and synthesis, and when we don’t have enough protein in our systems, then the breakdown becomes more significant than the synthesis. What we want to avoid is not having enough protein to continue synthesis.”

That’s one reason Manuel suggests athletes consume casein in the evening, as its longer digestion horizon “helps continue the cycle over the extended time when you’re not taking in protein,” he explains.

By contrast, for athletes hoping to drive quick-digesting protein into hungry muscles right after exertion, Aaron Fanning, science manager, nutrition, NZMP, the global ingredients brand of dairy cooperative Fonterra (Auckland, New Zealand), recommends his company’s SureProtein Fast MPC brand of milk protein concentrate. Its quickly digested proteins supply more amino acids to muscles within the first two hours of consumption than do standard milk proteins, he says, “challenging conventional thinking on how fast proteins can deliver nutrition to the body.”

On the Shelf

As for how much of these, or any other, proteins should be formulated into a product serving, brands have some tough decisions to make.

One guide for deciding is to look at products already on shelves, where protein levels “vary vastly and cater to consumer needs,” Manuel says, and can range from as low as 2 to 3 g of protein per bar to fully 50 g per beverage. As always, he says, “This really depends on what consumer you want to cater to and what their needs are.”

It also depends on how much protein a formulation can sustain without taking a hit to its sensory profile. “Producing products with a high level of protein is challenging in terms of maintaining good taste and texture,” Fanning says. “To move into the higher doses that consumers are becoming accustomed to—up to 20 g and above—requires use of specialized ingredients that allow fortification without compromise.”

Years of protein R&D have given the industry an impressive catalogue of protein ingredients that do just that, including NZMP’s branded SureProtein WPC 550, a concentrated, shelf-stable whey protein.
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that allows formulations to palatably deliver a protein dose of up to 14% “to help build, repair, and maintain muscle,” Fanning says.

As for the search for that optimum protein dose, Manuel believes that the best advice for any formulator is “to truly understand your target consumer and formulate to their needs.” Those needs will determine protein levels, recommended timing and preferred source—even product platform. “After all, they’re the ones who are going to use the product.”

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

References

GIVING SENIORS A BOOST

A higher-protein version of Nestlé’s longstanding Boost drink made its debut on store shelves this summer. Nestlé says it reformulated the drink, which especially targets adults 50 years and older, with more protein to meet the latest expert recommendations for supporting healthy aging.

The new Boost High-Protein Complete Nutritional Drink features 33% more protein: 20 g of protein per 8-oz serving versus the former version’s 15 g per 8-oz serving. The reformulation also lowered carbohydrates from 33 g per serving to 28 g per serving. The drink contains 240 calories per serving and also includes 26 vitamins and minerals.

It’s a notable reformulation for one of the leading high-protein drinks in the adult nutrition market. After all, the former Boost drink was already considered a high-protein product with 15 g of protein per serving (30% of the Daily Value), says Nestlé Health Science. “In fact, products that contain 20% or more of the Daily Value (10 g of protein or more) are by FDA regulations considered to provide an excellent source of protein,” company representatives told Nutritional Outlook.

The decision to reformulate for an even higher protein content stems from growing evidence supporting the health benefits of higher protein intake in seniors, including higher bone mass density, slower rates of bone loss, and preservation of muscle mass, company representatives told Nutritional Outlook.

They said: “Recommendations from international expert groups1-2 have called for higher protein intakes, specifically 1.0 to 1.2 g of protein per kg body weight, to support optimal muscle and bone health for older adults. This translates to about 0.5 g of protein per pound of body weight. Thus, the protein needs of a healthy 65-year-old, 150-lb person would be about 75 g protein per day. Getting optimal amounts of protein with each meal (20 to 35 g) and snacks can help maximize protein synthesis and preserve muscle.3-4 Boost High Protein Drink with 20 g protein per serving can help consumers achieve optimal protein intake levels to support long-term health and achieve dietary goals.”

Nestlé Health Science also points out that Boost drinks are still considered conventional foods, not medical foods. The company noted, however, that “the benefits of higher protein intake for older adults are well documented in scientific literature.1,2,5,6,7,8 Consuming optimal amounts of protein has been shown to help preserve lean body mass, stimulate muscle protein synthesis, support bone health, and provide nutritional support for the body during recovery from wounds, falls, and fractures, as well as illness or surgery after hospitalization.”

Nestlé Health Science says it continues to raise awareness of the importance of ideal protein intake, including through its Boost website, www.boost.com. “New research shows that more than one in three adults ages 51 years and older are not meeting minimum daily protein requirements,” the company added. On its website, Boost offers a Protein Calculator Tool to help consumers determine their estimated daily protein requirement based on their age, weight, and activity level.

Nestlé says consumers are “eager” for protein education and learning more about protein sources. “As protein becomes increasingly relevant, the ‘high protein’ expectation is shifting from 10 to 15 g per serving to 20 to 30 g per serving,” the company added. In addition to the reformulated Boost High-Protein drink, Nestlé offers its Boost Optimum drink (with 22 g of protein per serving plus a range of additional nutrients) and Boost Max shake (with 30 g of protein per serving, geared to active older adults).

By Jennifer Grebow, Editor-in-Chief

References
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The number of protein-promoting foods and beverages launched in 2017 nearly topped 6,000, according to an inventory of Mintel’s Global New Products Database. But quick: Can you name even two introductions that truly stand out from the pack?

Okay, maybe you can. But you’re a professional; you get paid to keep track of this stuff. The average consumer, on the other hand, likely isn’t as well-informed. And it’s a good bet, too, that outside changes in his or her favorite brands and flavors, the average consumer can’t spare much processing capacity for noticing protein innovations, either—whether in beverages, bars, or beyond.

The upshot is that each of those roughly 6,000 protein-promoting debuts has precious little time or room in which to get its proverbial foot in the door. And that raises the question of how, in such a competitive and crowded protein category, any not-yet-established product can survive—let alone thrive.

Saturation Point
Clearly, some products aren’t. Consider that according to research firm IRI (Chicago), protein supplements alone—which the firm captures as “weight-control powders and liquids, either ready to drink or powder forms” (no bars included)—took in $3.4 billion in total sales at brick and mortar food, drug, and mass retail in 2017. That’s a boost of 3.4% over the previous year’s take, but it’s also a moderation of the annual growth the category had enjoyed since 2012, during which its CAGR was a healthy 8%.

“So it would appear that the protein supplement space may be slowing down or saturating after a good four- to five-year run of...
strong growth versus the rest of CPG,” observes Lisa C. Buono, client insights principal, IRI health care vertical.

Granted, protein sales may be strengthening online, contributing to a softening in brick and mortar, Buono notes. Nevertheless, another sign that protein supplements may possibly be finding their level, or reaching saturation with domestic households, is the apparent “dwindling of innovation,” as she calls it. “Over the last three years,” she says, “we’ve seen the percentage of dollar sales of protein supplements that were entirely new to the marketplace go from 6% down to 2% in 2017.”

Opportunities Abound
Yet, experts insist, opportunities to keep protein’s demand curve pointing up and to the right abound. After all, there doesn’t appear to be a shelf or section of the supermarket—or supplement shop—that protein can’t colonize. “Walking through the grocery aisles, you see high-protein claims on everything from cereals to ready meals and even ice cream,” says Stephanie Lynch, vice president of sales, marketing and technology, IDF (Springfield, MO). “There are very few segments that haven’t yet joined the protein trend, and consumers are eating it up.”

It doesn’t hurt that protein also possesses near-universal appeal. “The protein market attracts a broad range of consumers who seek it for sports recovery, weight management, satiety, and other reasons,” Lynch continues. “Athletes and fitness competitors aiming for muscle development seek products that deliver a high amount of quality protein rich in BCAAs and EAAs”—branched-chain and essential amino acids, respectively. “Meanwhile, health-conscious snackers look for protein-packed products that fit their nutritional and lifestyle goals, such as being gluten-free.”

Diet Tribes
Indeed, “lifestyle nutrition” is a key protein growth driver. When SPINS (Chicago) measured sales of productsflagging protein as the primary functional ingredient for the 52 weeks ending September 12, 2018, it found growth in nine out of 10 categories when products were also labeled “vegan,” notes Kimberly Kawa, retail reporting analyst at SPINS.

“And both of the categories where Paleo-positioned claims appear—shelf-stable wellness bars and gels, and protein supplements and meal replacements—have double- and triple-digit growth rates. So diet tribe marketing may be a consumer’s cue to look more closely at protein content, sourcing, and quality attributes,” she says.
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That’s certainly the case for diet tribes gravitating toward plant-based proteins—demand for which has been growing faster than for protein more generally, observes Jeff Hilton, chief marketing officer and co-founder, BrandHive (Salt Lake City). “And this category has not plateaued, in my opinion. The move to plant-based sources from animal-sourced whey is real, especially as the taste profile of pea and other proteins improves over time,” he says.

But pea protein is only the start. “Hemp and chickpea protein are on the radar and growing in awareness,” he adds. And though not plant-based, cricket protein “is continuing to bang away at the marketplace and pursue the consumer who just can bring him or herself to eat bugs,” says Hilton.

**Sage Advice**

And that would definitely set a protein product apart from the crowd—which is among the key qualities that Buono believes a new protein product needs to succeed. “Your product must have a point of difference to steal users who’ve already found their preferred protein supplement,” she says—especially at this time when the category seems to be slowing in growth and shaking out a bit in terms of brand availability.

As for further means of getting a leg up, Buono notes that protein products with natural ingredients—or just a “natural” feel or positioning”—resonate. “Consumers are craving authenticity and no GMOs these days,” she says. “Make that come through in your protein brand.”

Flavor experimentation is also important. “True, vanilla and chocolate are the primary flavors in this category, and for good reason, as they appeal to broad swaths of the population,” Buono goes on. “But more clever flavors may break through and earn shelf space.”

There’s more advice where that came from. Ahead, experts share a handful of suggestions for putting the spotlight on your protein product.

**Build a Big Tent**

A protein product has a better chance of standing out if it courts a broader base of potential suitors. And given protein’s popularity, that shouldn’t be hard to do.

“Protein’s continued growth is driven by the fact that it appeals to all demographic groups,” says Hilton. “Fitness for Millennials and Gen Xers, energy and weight management for boomers, and muscle loss prevention for seniors—protein is an entry point into supplementation for all ages, and people are comfortable with it because they trust the source, dairy or plant.”

**Terri Rexroat**, vice president, team lead, Latin America, U.S. Dairy Export Council (USDEC; Arlington, VA), agrees, adding that while protein pays dividends for athletes, brands shouldn’t pitch it solely to first-string players. “People often envision the well-established benefits of protein—increased muscle mass when combined with resistance training; aid in muscle recovery after endurance exercise—as being reserved for young, competitive athletes,” she says. “But new research shows that dairy proteins have great benefits for women—without adding bulk—as well as for older individuals in helping fight sarcopenia, or age-related muscle loss.”

With those wider benefits in mind, she suggests brands aim their products at consumers who “embrace all-day protein consumption via on-the-go applications, and who drive demand for the addition of protein to more ready-to-drink beverages and portable snacks.”

In other words, consumers for whom protein fuels daily life. As Hilton says, “Position your protein product for everyday performance—meaning being active, running the kids to soccer, walking in the park. Stay away from sports nutrition positioning: it’s a jungle in there.”

**Make Protein Snackable**

Rexroat was on to something in noting the potential of the protein-packed snack.

Indeed, says Hilton, “Protein snacks are hot, hot, hot!” With round-the-clock snacking replacing what he calls the “three-meals paradigm,” protein brands would be wise to give consumers “something to sustain energy between feedings.”

Of course, consumers have treated bars and beverages as snacks in the past. But they expect more now—and brands can give it to them. “Bar delivery and protein-enhanced functional drinks continue to drive the category,” Hilton says. “But protein-fortified snacks and even breakfast cereals are on the horizon. I think the greatest innovation is happening in better-for-you snacks and desserts.”

For her part, IDF’s Lynch believes “the next big thing” will be protein crisps and kid-friendly snack formats. “Fortified snacks could be a solution to helping kids get enough protein and nutrition needed for development,” she says. “Understandably, discerning parents no longer want to dole out snacks with little to no nutritional value, and they’d welcome a healthy option that allows children to enjoy their protein.”

**Stephanie Mattucci**, associate director, global, food science, Mintel (Chicago), adds a few more entrants to the roster of snack-ish protein vehicles, noting that “ overlooked categories, such as cottage cheese, and unexpected categories, such as biscuits, chocolate, and ice cream, are leveraging high-protein claims to appeal to protein-seeking consumers.”

**Promote the Protein**

According to Mintel, the average amount of protein per 100 g in high-/added-protein food and drink launches has slightly increased across most regions over the past five years. Yet surprisingly, some brands fail to capitalize on claims that may call attention to their products’ protein content.

“Consumers continue to seek protein in their diets, yet not all categories are using protein claims to their advantage,” Mattucci says. “So brands should consider using high-protein claims, especially in prepared meals and fish, meat, and egg products.”

That said, even though the percentage of global food and drink launches with a high-/ added-protein claim has doubled over the past five years, label claims alone “still may not be enough to help consumers know if they’re getting enough protein,” Mattucci continues. But they can certainly help, especially among the 62% of U.S. food purchasers who, Mintel found, agree that information on packaging is important when making food choices.

**Meat in the Middle**

Looking to cut through the noise in the protein bar space? Lynch has a tip: “None of the bars on Bodybuilding.com’s 2018 list of...”
The top-ten protein bars is meat-protein-based, showcasing an opportunity for innovation. And you thought cricket protein was novel. Yes, chicken meat may be a mealtime staple, but chicken protein powder is a newcomer in a sector long dominated by whey and soy. And Lynch makes a solid case for it. “Chicken meets most of today’s nutritionally based lifestyle trends and is a diet-friendly protein for nutrition products, supplements, and packaged foods,” she says. Her company, IDF, supplies a CHiKPRO powdered chicken protein that can go into everything from snacks to supplements and delivers 25 g of complete (PDCAAS score of 1) protein per 30-g scoop, along with zinc, iron, and a 2:1 potassium:sodium ratio.

Certified Paleo and keto-friendly, the powder is also free from common allergens like milk, soy, and tree nuts. USDA granted it an exemption whereby formulators can use it in supplements at up to 100% of the finished formulation without USDA inspection, and with the final product bearing a supplement facts panel rather than a nutrition facts panel—important information from a regulatory standpoint.

But more compelling is the fact that meat-based protein bars are winning consumers over, “in many cases through the combination of trusted protein sources and novel flavors,” Lynch says. “According to Datamonitor, the meat snack category will continue to see impressive growth.”

Ask Yourself, “Would I Eat This?”
Nobody’s going to keep buying a protein-packed product that’s unpalatable. But protein’s reputation as a “challenging” ingredient from a flavor standpoint is, alas, “well-earned,” says Hilton. “Brands struggle to balance taste, nutritional content, the need for sweeteners, and more.”

But balance is attainable. Hilton notes that he’s seen brands succeed by using a plant-based sweetener sourced from the Indonesian cassava plant, which, he says, “is very popular among those who make their own protein bars at home.”

And Rexroat reminds formulators that dairy proteins are an exception to that “challenging” flavor rule. In fact, research from North Carolina State University found that while plant proteins exhibit “beany, earthy, sulfurous, and sour notes” that often necessitate the use of flavor maskers and stabilizers—and complicate ingredient statements as a result—dairy proteins “are mild flavored and exhibit sweet aromatic and milky attributes,” Rexroat says. “These differences in sensory perception allow dairy proteins to offer a superior and more versatile sensory experience because they complement, rather than overpower, the flavors of the foods and beverages to which they’re added.”

Kimberly J. Decker writes for the food and nutrition industries from her base in the San Francisco area, where she enjoys eating food as much as she does writing about it.
What once was a dietary supplement landscape dominated by pills has since diversified, with delivery systems spanning everything from gummies and liquids to sublinguals, injectables, inhalables, chews, stick packs, and serving pods. Despite the competition, those longstanding, classic delivery systems are still going strong, and for good reason. While they may not have the novelty "flash" factor of a crystalline sprinkle system or edible wafer, these mainstays—capsules, softgels, tablets—continue to hold their own thanks to the undeniable benefits they offer: consumer familiarity, format reliability, and robust quality controls.

Recent technological advancements have made today’s softgels, capsules, and tablets even more convenient and more effective for consumers, and this next generation of classic delivery systems is well equipped to hold its own against newer formats. Here are just some of the scientific developments that are keeping traditional delivery systems at the top of the market.

Vegetarian Softgels Are Popular, but Still Challenging

The softgel industry is undergoing a shift with regard to ingredients and formulations in response to vegetarian demands. Steve Holtby, president and CEO of Soft Gel Technologies Inc. (Los Angeles, CA), says that rising demand for non-animal products is driving innovation in softgels—but further research and development is still needed to continue to improve the viability of non-animal softgels.

“There’s an increasing number of consumers who, for cultural, religious, or personal preference reasons, adhere to vegetarian, kosher, or halal diets,” Holtby says. “Additionally, the fear of animal-transmitted diseases is a growing concern. Softgel capsules can now be made from a variety of materials, including fish, chicken, and non-animal-derived gelatin, but vegetarian alternatives still present some drawbacks.”

Holtby says vegetable-derived gelatin substitutes lack the strong shell that characterizes animal gelatin, instead having a porous outer wall. This can
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Tomato

Tomato (Lycopersicum esculentum) is an excellent source of magnesium, potassium, folate and choline, as well as the super-nutrient lycopene. Studies of tomato extracts and its constituents show that it can support healthy prostate, colon, and cardiovascular function, and normal seasonal histamine levels. It also contains other several carotenoids (phytoene, phytofluene, lutein, zeaxanthin, beta carotene, and alpha carotene) that are believed to have a synergistic effect. Flavonoids, including quercetin, and naringenin are found in the skin.*

Spinach

Spinach (Spinach oleracea) is like a veritable multivitamin and mineral supplement containing quite ample amounts of iron, magnesium, potassium, folate, riboflavin, choline, manganese, B-6, betaine, and vitamin A (Beta carotene). As a super source of lutein and zeaxanthin, spinach can help support healthy vision and eye health. It may also support normal inflammation response, cognitive aging, cardiovascular health, and skin health. Spinach contains luteolin, and 20- hydroxyecdysterone.*

Artichoke

Artichoke (Cynara scolymus) is from the Thistle family, and is a good source of choline, folate, niacin, magnesium, potassium, iron, manganese, and copper. It contains taraxasterol which is also found in dandelion, and is rich in the flavonoids luteolin and apigenin. It also contains inulin, liver protective cynarin, and chlorogenic acid. Artichoke supports healthy liver function, normal cholesterol and triglyceride levels, digestive function, and stomach comfort. It has one of the highest polyphenol and ORAC values among vegetables.*

Asparagus

Asparagus (Asparagus officinalis) is a source of folate, magnesium, potassium, iron, and copper. Its extract supports healthy cholesterol levels, liver health, weight management, and cognitive health. Asparagus is high in antioxidants, and its minerals account for up to 2% of the dry weight. The stem is a good source of furostanol saponins, and protodioscin.*

Broccoli

Broccoli (Brassica oleracea, Capitata cultivar group) is an excellent source of vitamin C and folate, and is a very good source of pantothenic acid, iron, calcium, magnesium, potassium, manganese, selenium, B-6, niacin, and B-2. It has one of the highest "cellular antioxidant activities" and stimulates the antioxidant response element (ARE). Broccoli supports normal inflammation, colon health, normal cell function, and cardiovascular health. In addition, it promotes breast health, and prostate health.*

Bell Pepper

Bell Pepper (Capsicum annuum) is an excellent source of carotenoids, vitamin C, folate, niacin, B-6, potassium, and vitamin A. It is also a good source of vitamin E, and contains the important bioactive capsaicin at different levels depending on the pungency and heat of the cultivar. Capsaicin is thermogenic, helps support normal inflammation response, and helps with weight management. The pepper’s flavonoids include quercetin and luteolin.*

Pumpkin

Pumpkin (Curcubita pepo) is a great source of zinc, copper, manganese, choline, riboflavin, and potassium. It contains beta carotene (vitamin A) for healthy skin, immunity, and eye health; and is an unusually rich source of beta cryptoxanthin, a carotenoid for positively influencing bone, joint, and liver health.*
**Carrot** (Daucus carota) root is a good source of calcium, magnesium, potassium, niacin, pantothenic acid, B-6, and folate; and has very high levels of vitamin A as beta carotene and alpha carotene. It supports healthy eyes, skin, and immunity from its high vitamin A content. It also supports healthy bone density, normal histamine responses, colon health, and normal blood sugar levels. Carrots contain the chlorogenic acid, and falcarinol. *

**Beet** root is a good source of potassium, magnesium, manganese, and folate. It contains kaempferol, quercetin, betaine, and purple-red anthocyanins such as betacyanin. Betaine especially supports liver health by helping it detoxify harmful substances. Beets also improve tolerance of high intensity exercise, and boost SOD (superoxide dismutase) activity. Excellent source of nitrates, which help build blood-pressure-lowering nitric oxide.

**Celery** stalks and seeds, found in many food and supplement products have wide ranging nutritional benefits. The stalk is an excellent source of nitrates, and also contains calcium, potassium and folate. L-3-n-butylphthalide, from the seeds, may support cognitive health and joint health, and may also help counter inflammation. Celery extract also promotes digestive and cardiovascular health, and helps maintain normal cholesterol and triglyceride levels. Other bioactive constituents are the flavonoids apigenin and luteolin.

**Bitter melon** (Momordica charantia) is used in Asian cuisine and is an excellent source of vitamin C, folate, and potassium. An extract of the vegetable helps support normal blood sugar levels, normal body weight, and glucose and amino acid uptake in muscles. It increases adiponectin and leptin activity, hormones which are known to decrease appetite. It also supports healthy breast cells, helps maintain normal blood pressure, and helps maintain skin keratincyle and fibroblast synthesis. Bitter melon also contains gallic acid, chlorogenic acid, epicatechin, and conjugated linolenic acid. *

**Brussel Sprouts** *Brassica oleracea, Gemmifera group* are a source of vitamin C, iron, potassium, choline, manganese, folate, and thiamin. The extract helps maintain healthy DNA molecular structure, supports healthy cell function, and helps stimulate liver detoxification enzymes. The vegetable is also a good source of lutein and zeaxanthin, and contains isothiocyanates. *

*This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.*
Fruits and vegetables are ready-made powerhouses of vitality that are important building blocks for a healthy body. Studies show that high consumption of fruits and vegetables can significantly promote heart health, strengthen immune system function, as well as play a prominent role in supporting healthy blood glucose levels. Fruits and vegetables are also our best source of antioxidants like polyphenols, flavonoids, carotenoids, lignans, and other important anti-aging agents. **Potent, nutritious, and functional,** Draco Fruit, Vegetable & Mushroom Bioactive Botanical Extracts are effective ingredients for functional food, beverage, dietary supplement, and topical skin care applications.

**Legendary Draco Manufacturing**

Our fruits and vegetables are Full Spectrum extracted in pure, natural water, resulting in a clean, balanced, efficacious extract powder, which is also water soluble/dispersible. Our extracts are never subjected to the high heat of drum drying, which can damage important compounds. Due to our unique spray-drying process, our fruit and vegetable Phytoconcentrates are also carrier-free, with no added excipients. **Draco’s Fruit & Vegetable Phytoconcentrates™** are nutrient dense, whole food extract ingredients. To make a “phytoconcentrate”, we use an innovative, proprietary two-stage process by first juicing the entire plant part, including skin, seeds and fruit. We then perform an exhaustive pure water extraction with the remaining plant biomass, thoroughly unlocking a full spectrum of plant nutrition. We use between 10 and 20 kilograms of fresh fruit or vegetable to create one kilo of powdered extract.

We process our extracts in our own state-of-the-art 120,000 square foot processing facility, which is Certified Organic to both USDA: NOP and European EEC/834 2007 guidelines. We were the first certified organic botanical extraction facility in China. Our facilities are also Food GMP Certified, GFSI, ISO 9001:2015 Certified, HACCP Certified, Kosher and Halal Certified. As part of our “Seed to Drum” monitoring process, our extracts undergo rigorous analytical testing for constituent assays, moisture, bulk density, heavy metals, pesticides, and microbial counts. We lead the botanical extracts industry in purity with plate counts that are frequently several times lower than our competitors and we never irradiate or fumigate either our plants or finished extracts. Draco’s Fruit & Vegetable Phytoconcentrates™ are pure, clean, safe, and natural.
mean vegetarian softgels have weaker shells than animal-derived gelatins, and are less capable of protecting ingredients from oxidation and degradation.

“Many find the oil inside vegetarian softgels to be rancid after only a few months,” Holtby explains. “Further research and development is needed on this front.”

Robin Koon, executive vice president of contract manufacturer Best Formulations (City of Industry, CA), says vegetarian starch–based technologies are gaining popularity in capsules and tablets as well. However, Koon says that manufacturer adoption is a slow process.

“We’re seeing interest in tapioca, pullulan, and enteric hardshell capsules,” Koon says. “Vegetarian technologies are continuing to expand, and there’s key interest in using various technologies to improve absorption and bioavailability. However, we’re not seeing any change in orders or production compared to traditional dosage forms, mainly due to price differential. Newer technologies generally cost more, so not everyone is switching to newer delivery systems.” Several companies like Captek Softgel International (Cerritos, CA) and SwissCaps USA (Miami, FL) are already using vegetarian options like HPMC, carrageenan, and tapioca starch.

The higher cost of materials and specialized equipment involved in making vegetarian delivery systems still presents challenges, but expect more advancements in the years to come.

LMP Technology Opens the Door to Fine-Tuned Delivery Systems

Recent developments in delivery technologies are improving the effectiveness of ingredients by allowing manufacturers to better design supplements with specific dissolution rates and release times. Tyler White, head of global consumer solutions innovation for Lonza (Basel, Switzerland), says that a delivery system known as Lipid Multi-Particulate (LMP) technology is starting to take hold in the industry for a variety of reasons.

A new form of microencapsulation, LMP enables manufacturers to vary the timing and rate of dissolution and ingredient release by enclosing active ingredients inside microspheres, White explains. These microspheres can be formulated to contain a specific microdose of active ingredients like botanicals, amino acids, or vitamins, and can deliver a metered dose at a timed release.

“LMPs also mask the taste of bitter ingredients like theacrine and botanical extracts,” White says. “Because LMP microspheres have excellent flow properties, they work in a broad range of finished dose formats, including powders and sticks for reconstitution in liquids, powder-filled capsules, liquid-filled capsules, ‘sprinkle’ capsules, and even tablets.”

White says that delivery system innovation trends are emphasizing a better consumer experience through easier use, and that the functional-food trend is evidence of this. If manufacturers can better align supplements with the experience provided by functional foods, he says, consumers may better incorporate supplements into their daily routine.

Easier to Swallow

Another recent development improving the user experience of softgels and capsules is addressing a common consumer frustration: difficulty swallowing supplements. Humera Ahmad, director of product development for Softgel–Asia Pacific for Catalent (Somerset, NJ), says that chewable softgels are now on the market, making swallowing problems a thing of the past.

“Catalent’s EasyBurst is a chewable softgel that delivers a strong burst of flavor along with the nutritional supplement,” Ahmad says. “It helps avoid problems swallowing, and it doesn’t require water.”

Ahmad points to consumer studies showing that softgels remain consumers’ preferred dosage format due to their ability to deliver a uniform dose and oxidant-resistant shell. Overcoming oxidation, Ahmad says, is a key manufacturer priority, especially as delivery systems become more innovative.

Says Ahmad: “With omega-3 delivery systems in particular, oxidation is a concern.
Oxidation of omega-3 oils is irreversible, can introduce unpleasant physical characteristics, and may also reduce their nutritional value. One technique manufacturers are implementing to overcome this challenge is to introduce an antioxidant molecule to scavenge the free radicals that oxidation produces. Ahmad says manufacturers commonly use tocopherol, citric and ascorbic acid, and various spice extracts as antioxidant agents in omega-3 supplements. She notes that Catalent also uses a closed manufacturing system that blankets omega-3 oils in an inert gas from storage to processing to packaging, thereby preventing oxidation.

**Delivery Systems to Become More Diverse, More Personalized**

White says that traditional delivery systems are facing heightened competition from newer options, a challenge he says is typical of all longstanding technologies. A smaller barrier to entry means more diversity in delivery systems, with formats like gummies quickly gaining attention thanks to their novelty.

However, Barri Sigvertsen, Lonza’s marketing manager for consumer health and nutrition, cautions that gummies are not the nail in the coffin for capsules and tablets. Rather, Sigvertsen says traditional formats have a staying power built on consumer trust.

**BARRIERS TO INNOVATION: THE FIRST-TO-MARKET PANDORA’S BOX**

Best Formulations’ Robin Koon says that delivery system innovation in general is facing a very specific barrier: No manufacturer wants to be first to market with a new delivery system unless there is a clear market-based need or demand. The high cost of and unknown demand for new technologies make delivery system innovation an uncertain realm, and some of the newer technologies available to manufacturers have a steep and costly learning curve. However, Koon also notes that emerging approaches in the prescription drug industry may soon move into the nutritional supplement industry.

Says Koon: “Enteric systems, floating drug delivery systems, swelling and expanding systems, polymeric bioadhesives, and delayed gastric emptying are just some of the approaches in the drug channel. Oral dosage has progressed from immediate release to targeted delivery, and a variety of modified-release systems have emerged. These approaches, currently used in the prescription drug channel, will move into the nutritional channel,” he predicts.
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“The 2018 SORD study”—produced from NMI’s Supplements/OTC/Rx Database and co-sponsored by Lonza—“shows that capsules are still preferred by 41% of supplement users,” Sigvertsen says, “with tablets and softgels in second and third place at 36% and 33%, respectively. Traditional delivery systems have proven performance and experience, while novel solutions might not be effective or fit into routine use.”

Holtby notes that classic formats are faring well against newer competitors like gummies, mostly because manufacturers have had quite some time to maximize active ingredient bioavailability with these older delivery systems. Factors like disintegration time, dissolution percentage, type of excipient, and nutrient form can all impact the bioavailability of any given supplement’s active ingredient, and manufacturers of classic deliveries have had time to work out the kinks—and excel. Softgels in particular, Holtby says, are widely recognized for their ability to increase bioavailability.

Sigvertsen says that consumers may experiment with newer delivery formats out of a drive to have more diverse experiences. However, consumers who are following a regular supplement regimen, Sigvertsen claims, will ultimately lean on the tried-and-true formats.

“While they might like to try the latest delivery innovation, consumers still prefer the simplicity, convenience, and ease of swallowability of established formats,” Sigvertsen says. “And with an encapsulated supplement, you’re only consuming what you need instead of the fillers that are present in bars and liquids.”

White expects that as personalized nutrition continues to evolve, mass manufacturing of small-batch delivery formats will drive success. While tablets, capsules, and softgels demand large batch sizes to maximize cost-efficiency, White says that the personalized nutrition market will result in innovations that make customized small batches of 30 to 50 units easier to manufacture.

Holtby says that an industry push to create a more substantial effect with a smaller supplement or dose size is going to open up opportunities in delivery systems. Synergistic ingredient blends, he adds, are enabling manufacturers to fit more functional ingredients into smaller supplements. “Convenience still has to remain top of mind for supplement manufacturers. Compliance increases with fewer doses and pills, capsules, and softgels that are easy to swallow,” he says.

As delivery systems continue to advance, softgels, capsules, and tablets will combine the benefits of a tried-and-true format that has widespread consumer familiarity with innovations that improve effectiveness and ease of use. Ultimately, these delivery systems combine the best of old and new technology, hence their staying power.

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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Gummy supplements continue to drive new consumers to the dietary supplements aisle, breathing life into a market that’s been traditionally dominated by pills. Alternatives to pill-form supplements made up 47% of dietary supplements in 2017, according to numbers presented by Nutrition Business Journal (NBJ) at Natural Products Expo West 2018. This was up from 34% in 2015, based on IRI data analysis from the previous year, when gummy supplements made up 30% of the non-pill segment. New research from Transparency Market Research (Albany, NY) estimates that the gummy vitamins market will grow at a compound annual growth rate of 5.2% between 2017 and 2025 to reach $4.17 billion. The growth and popularity of gummies can be attributed to their taste and convenience, motivating children and adults alike to take their vitamins.

In fact, adults have made up the larger portion of consumers of gummy supplements compared to kids. In 2017, reported NBJ, adult gummy products accounted for 65% of all gummy supplements. According to Gary Ricco, president and CEO of gummy specialist Mount Franklin Foods (El Paso, TX), the adult-gummy portion of the gummy market is now bigger than it was in 2017. “The children’s market is only 20% of the gummy supplement market today,” he tells Nutritional Outlook. “The majority of our products target adult consumers. Multivitamins are the most popular supplements among adults and children.”

Adults have more incentive to incorporate gummy supplements into their regimen considering that they are more likely to be taking a prescription drug daily and are susceptible to pill fatigue. A 2005 AARP study found that adults 45 and older on average take four prescription medications daily.

Continued demand for gummies creates challenges for manufacturers who have to find solutions for on-trend ingredients and other consumer demands. “The trends in ingredients are focused on healthier products: reduced sugars, clean label, organic, and non-GMO,” says Ricco. “A continued challenge in
the industry is flavor masking to make the best tasting piece possible. Additionally, our process continues to evolve on overcoming gritty textures on some ingredients and balancing supplement load with piece size."

Sugar content has definitely been a concern for consumers and part of the give and take of gummy supplements. They taste great because they are sweetened, and active-nutrient doses are smaller per gummy compared to pills, which means one must eat more gummies to get the desired nutrients, increasing sugar consumption in the process. (The number of gummies that must be consumed can also depend on the type of ingredient in the gummy. For example, recent vitamin C gummies on the market contain 2 g of sugar per serving of two gummies. However, some multivitamin formulas have a bigger serving size such as six gummies per day, amounting to 7 g of sugar per serving.)

Manufacturers are offering consumers different gummy options with sugar-free products as well as using alternative sweeteners. One innovation that is gaining traction, Ricco says, is the use of honey as a natural sweetener in gummies. This is in line with consumer preferences for honey as a sweetener, as published in a recent white paper by ingredient supplier Kerry (Beloit, WI).

There are a few considerations when formulating gummy supplements, especially when trying to reduce sugar content, starting with the gummy itself. "Mount Franklin Nutritional development work to date on the non-supplement side has focused on sugar reduction using inulin (fiber) and fruit juice as sweetness replacers and maltodextrin to support texture," explains Ricco. When reducing sugar in a gummy with a gelatin base, "You need to verify the right amount of inulin for texture and taste," he adds. "The use of fruit juices and specialty starches can improve the flavor impression when properly balanced in the formula."

When it comes to adding the nutrients, that's when it gets more difficult. It's all about striking a balance and understanding which nutrients work best in a gummy and require minimal masking. "Not all actives are suitable for gummies," explains Ricco. "Iron is difficult to mask and can be harmful if a child were to eat too many. Gummies are most effective when they taste great and carry a reasonable supplement load when compared to a pill or capsule."

B-vitamins, zinc, and herbs are also difficult to mask, says Ricco. "At Mount Franklin Nutritional, we are using taste modifiers developed specifically for certain classes of compounds," he explains. "In addition, we use flavors which also mask off-flavor components."

Gummy supplements have their limitations and pose some challenges to manufacturers but definitely offer value to brands who can give their consumers a more convenient way to get their vitamins and minerals. Anticipate more competition in this space and continued innovation to meet consumer demand for specific ingredients as well as organic, non-GMO, and low-sugar options. In 2017, Nutrition Business Journal reported that adult gummy products accounted for 65% of all gummy supplements.
Few formulation challenges are more sensitive than designing a safe and wholesome infant formula. After all, this is one audience that depends on us completely to get things right.

And as competition among brands heats up—with the stiffest competition coming from the breast itself—savvy parents increasingly, and justifiably, scrutinize everything they feed their littlest family members, holding infant formulas to the strictest standards of all.

So now that “safe and wholesome” alone no longer cut it, infant formula brands have to ramp up the innovation to build a product that delivers what’s best for baby—which nowadays means what comes closest to the breastmilk ideal.

None of which surprises Sigalit Zchut, PhD, chief scientist, Advanced Lipids, a joint venture of lipids companies AAK (Malmo, Sweden) and Enzymotec (Migdal HaEmeq, Israel). “Consumers naturally want the best for their kids,” she says. “Yes, quality has always been the number-one consideration when it comes to infant formula, but more often it’s not just about quality, but about quality plus specific nutritional benefits.” Benefits that bridge the breastmilk gap.

Going Global
It’s no secret that sales of infant and baby nutrition products have trended flat in wealthy countries as women have embraced breastfeeding. But it’s a big world out there, and the global market for infant formula has almost tripled since 2006, Zchut says, currently boasting a retail value of over $45 billion.

China alone accounts for almost half this value, making it the world’s largest infant formula market by far. “But we’re also seeing interesting developments in other regions,” Zchut observes. “In Latin America, for example, the market is currently worth around $2.2 billion, or 150,000 metric tons in volume, and significant growth is forecast, so it’s promising territory for formula companies.”

Baseline Formula
Regardless of the region a brand targets, the baseline goal in developing any infant formula is to create a product that’s safe beyond a doubt, and that provides the nutrients essential for an infant’s optimal development.
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Meeting that goal starts with the composition of the base powder, which supplies the formula’s protein and carbohydrate fractions, at 10%-15% and 52%-57% of the total formulation, respectively. “These fractions usually come from whole milk or a combination of skim milk and whey protein,” Zchut explains.

As for the fat fraction—which typically clocks in at 22%-28% of the finished formula base—“it’s mostly sourced from vegetable oils, but sometimes partially from milkfat,” Zchut continues.

Last but not least are the vitamins, minerals, and other micronutrients that bring a formula closer to nutritional completion. Though their relative proportion in the finished product is low—roughly 4%-6%, in total—“they’re just as crucial for the baby’s healthy development” as the formula’s other components, Zchut insists.

Setting Standards
Currently, the nutrient content of infant formulas sold domestically falls under FDA purview and is based on recommendations from the American Academy of Pediatrics Committee on Nutrition.

Present guidelines deem that all formulas made in the United States must contain protein, carbohydrates, fat, and linoleic acid. All formulas must also include vitamins A, C, D, E, K, thiamin (B1), riboflavin (B2), niacin (B3), pantothenic acid (B5), pyridoxine (B6), folic acid (B9), and cyanocobalamin (B12). Calcium, magnesium, iron, zinc, manganese, copper, phosphorus, and iodine are also required, as are the electrolytes sodium chloride and potassium chloride and some of the nucleotides found naturally in human breastmilk, like uridine, inosine, and cytidine.

Regulatory tightening has improved formula compositions over the years, with one key change tracing back to the nutrient requirements specified in the Infant Formula Act of 1980, passed in response to a 1979 recall of chloride-deficient formulas that sickened thousands of infants and yielded enough lawsuits to get the regulations changed.

Breast Is Best
But even with enhanced regulatory oversight and the laundry list of required nutrients, infant formulas don’t match the composition or nutritional potency of human breastmilk, which, Zchut concedes, “is the gold standard toward which every formula brand should strive. It provides the optimal nutrition for infants, delivering a perfect balance of nutrients that naturally meets every need in the first months of life.”
What are telomeres?
Telomeres are the protective ends of our chromosomes that support healthy cell replication. Telomeres play a key role in protecting our chromosomes from damage and the critical shortening.

Why is telomere length important?
Telomere shortening is correlated with human disease and aging. Short telomeres impair the ability of healthy cells to divide and function properly. Longer telomeres are associated with healthy cell replication and longevity. Telomeres hold remarkable information about the path of our health and may provide the single most important biomarker of aging.

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TeloYear Age™ is the DNA health test of our Cellular Age. It lets you track it based on your telomere length. Your telomere length tells you your age in TeloYear which may be older or younger than your real age.

Telos95® is validated by human clinical trials to significantly decrease your TeloYear cellular age.

2018 Human Clinical Trial
Telos95® Decreases TeloYear Cellular Age by 8.52 Years

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**Average TeloYear Age™ Decrease**

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CONCLUSION: A total of fifty (50) subjects completed all aspects of the study. Group A decreased their TeloYear Age™ on average by 7.43 years. Group B decreased their TeloYear Age™ by 8.52 years.

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But, notes Steen Lyck, global business director for HMO, DuPont Nutrition & Health (Madison, WI), "Human breastmilk is very complex, and it’s impossible to mimic its composition."

Zchut agrees. "Human milk contains a lot of biological components that are impossible to copy, such as immunoglobulins—antibodies produced by the mother to protect the infant from infections in early life," she points out. Breastmilk is also always changing. "Its composition in the day after birth is different from its composition when the baby’s one, three, or six months old," Zchut continues. "All that is very difficult to copy, and there are many more differences to count."

**Closing the Gap**

Yet despite the head start that millennia of evolution gave us in fine-tuning the nutritional perfection that is breastmilk, the infant nutrition industry has to work within the span of a product cycle. Even so, it’s making genuine strides in closing the gap between mom’s product and its own.

"Infant formula has improved significantly over the past two decades thanks to scientific research that studies human milk composition on one hand, and clinical studies that test the effect of key ingredients on the wellbeing of the baby on the other," Zchut says.

**Structured Fats**

The result is the addition of "specialty" ingredients to formulas that wouldn’t have appeared there even a few years ago. Consider the industry’s efforts better to replicate the unique lipid structure of breastmilk. Most of the palmitic acid in human milk fat is attached to the central carbon in the fat’s glycerol backbone. SN2 palmitate or OPO (oleic and palmitic fatty acid structure) is a structured triglyceride that mimics this conformation, and, says Zchut, "We can now develop OPO from vegetable sources and offer it as an ingredient in formulas. By mimicking the fatty acid positioning of human milk, it delivers many of the same benefits."

A recent clinical trial involving INFAT, her company’s branded OPO ingredient, found that it enhanced fatty acid absorption to more closely resemble breastfeeding, she says. "Research also shows that it offers benefits for comfort, healthy growth, and immunity."

**Beneficial Oligosaccharides**

Human milk oligosaccharides, or HMO, comprise another class of ingredients finding their way into infant formulas. These are a collection of indigestible short-chain carbohydrates—glucose, galactose, fucose, sialic acid, and N-acetyl-glucosamine among them—with pre-clinically and clinically validated benefits for infants.

"Some of their healthful effects include promoting a *Bifidobacteria*-rich microbiome, creation of the building blocks for brain development, prevention of pathogens and viruses, and stimulation of the immune system," says DuPont Nutrition & Health’s Lyck. "By introducing commercially produced HMO that are structurally identical to those found in breastfeeding, we can narrow the gap between human milk and formula."

Granted, while human breastmilk contains hundreds of HMO, "We’re only introducing a few" in commercial formulas, Lyck
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concedes. “So there’s still a long way to go.” And the optimal levels at which to add them are still up for discussion.

For example, the most abundant HMO in human breastmilk, appearing on average at 2.4 g/L, is 2′fucosyllactose (2′-FL). “But this varies a lot from woman to woman, region to region, and where the mother is in the lactation period,” Lyck explains. And while 2.4 g/L is the HMO addition level that FDA regulations approve in infant formulas, the EU approves only half that amount, basing its decision on the few infant clinical studies carried out so far.

In 2016, two companies, DuPont and Inbiose (Ghent, Belgium), entered into a joint development and licensing agreement for the exclusive rights to produce and commercialize a 2′-FL ingredient that is “fully identical to the 2′-FL HMO found in human milk.” The companies announced the ingredient had been granted EU Novel Food regulatory approval for infant formulas in December 2017 and U.S. Generally Recognized as Safe (GRAS) status in April 2018.

In May, another company, FrieslandCampina Domo (Amersfoort, The Netherlands), announced its new 2′-FL ingredient received EU Novel Food approval and GRAS status in the U.S. In 2016, FrieslandCampina Domo partnered with U.S.-based carbohydrates firm Glycosyn to develop a range of infant nutrition ingredients. FrieslandCampina Domo says that this new 2′-FL ingredient will be the first in a range of HMOs that the companies are developing. The company also says that it is currently building a new manufacturing plant in Italy dedicated to large-scale production of 2′-FL HMOs, which is slated for completion by the end of the year. The new 2′-FL ingredient will be marketed under the brand name Aequival.

Critical Membranes

Because the fat source used in most infant formulas are plant-derived oils, they lack an important tri-layered protein and lipid structure that encases every milk fat globule found in human, as well as bovine, milk. This membranous structure, known as milk fat globule membrane (MFGM), is also rich in bioactive gangliosides, phospholipids, glycolipids, glycoproteins, and carbohydrates with demonstrated benefits for an infant’s brain development, gut health, nutrient absorption, and immune function. A 2017 review of studies examining the effects of adding MFGM to infant formulas concluded, “Available evidence from model studies and clinical trials indicates the potential of beneficial effects of the combination of bioactive compounds or any specific component of MFGM to improve infant formulas. Importantly this relates to actual health during infancy and may contribute to optimizing the long-term programming of the immune system and cognitive functions.”

While the researchers called for more study before implementing widespread addition of MFGM to infant formulas, they do note, “The availability of some corresponding components from bovine milk or biotechnological production offers the possibility to include these components into formulas and to further close the gap between formula-feeding and breast-feeding.” Something to keep your eye on for the future.

Building Baby’s Microbiome

As Lyck notes, “Infant-specific probiotics have been added to formula to mimic the microbiome that’s transferred from mother to baby during birth and breastfeeding.” And given the excitement surrounding their potential benefits for the broader public, curiosity about how they might help improve infants’ prospects seems like a logical extension.
Indeed, says John Quilter, vice president and general manager, GanedenBC30 and Wellmune, Kerry (Beloit, WI), “Currently, three out of four U.S. consumers are aware of probiotics. As this awareness continues to grow both in the U.S. and globally, probiotics as an ingredient in infant formulas may become more commonplace.”

And for good reason: “There are a variety of factors that can negatively affect the natural bacteria and digestive development of infants and toddlers,” Quilter explains. “Furthermore, babies are born with sterile digestive tracts and must work to build their beneficial gut bacteria and create a healthy microbiome.” Evidence suggests that probiotics can help.

His company’s GanedenBC30 (Bacillus coagulans GBI-30, 6086) probiotic has scientific support for its digestive and immune benefits and, as a spore-former, “has a natural, protective shell that allows it to remain dormant through most manufacturing processes and gastric transit, and has a three-year shelf life, making it an excellent choice for powdered infant and toddler formulas,” Quilter says. Just as impressive, in 2017 it was the first B. coagulans probiotic to receive FDA GRAS status for use in infant formula.

Jumping through Hoops
That matter of FDA go-ahead is no small consideration for formula manufacturers, and understandably so. “The regulation of infant formula is very rigorous because it’s the sole source of food for the newborn infant and is therefore an extremely sensitive type of food,” Zchut says. “It undergoes much more rigorous review by regulatory authorities than does food for adults.”

Because regulations differ globally, how long it takes to get new ingredients approved varies, but you’re almost always looking at an expensive process that unfolds over a years-long horizon—“in some countries one to two years, and in others closer to five,” Lyck says. “This includes developing and documenting safety data, maybe clinical studies, documentation of a constant and safe process—all of this collected in a dossier and followed by approval of the dossier and publication.”

But the trouble is worth it to start Junior out on the right footing. As Lyck says, “We know that the first 100 to 1,000 days in a baby’s life determine so many health aspects later in life, as well.”

References

Kimberly J. Decker writes for the food and nutrition industries from her base in the San Francisco area, where she enjoys eating food as much as she does writing about it.
More than half a million people in the United States die of heart disease every year, according to the Centers for Disease Control and Prevention. Heart disease causes one in four deaths; it is the leading cause of death for both men and women. It’s no surprise, then, that supplements for cardiovascular health remain popular. CoQ10, reported on by Nutritional Outlook earlier this year, continues to be in high demand and in good standing among physicians, consumers, and media outlets alike. Fish oil and other omega-3 fatty acid sources are ubiquitous on retail shelves and in online marketplaces, and ranked second among the most popular supplements in the United States in 2017 by Consumerlab.com. Fiber, garlic, and flaxseed are also universally known and commonly associated with cardiovascular wellness.

What follows is an overview of a variety of on-trend heart health ingredients—from the big household names to the smaller and more obscure—and the scientific studies that are advancing our knowledge of them.

Omega-3 Fatty Acids

EPA and DHA. As ingredients for promoting cardiovascular health, omega-3 fatty acids have been the subject of many years of research and considerable debate. Recent meta-analyses and a systematic review reach various conclusions, furthering the ambiguity.

In one meta-analysis, published by *JAMA Cardiology* in January 2018, the authors found a “non-statistically significant 7% reduction in CHD risk” with EPA and DHA supplementation. In another meta-analysis, published in the *Journal of Clinical Lipidology* and funded by omega-3 trade group the Global Organization for EPA and DHA Omega-3s (GOED; Salt Lake City, UT) in 2017, the authors found an 8% statistically significant reduction in cardiac death risk as a primary outcome overall, and “an even greater risk reduction, 17%, in those with high LDL or triglycerides,” Chris Gearheart, GOED’s director of member communications and engagement, explains. The greatest reduction in cardiac death rates—an almost 30% risk reduction—was observed in trials that utilized dosages of more than 1 g of EPA and DHA per day.
For over 20 years, *Nutritional Outlook* has remained the leading publication in the North American nutraceuticals market. Now with the UBM family of brands inclusive of magazines, websites, digital products, and trade shows, the leading information provider has become the biggest international powerhouse in the industry. *Nutritional Outlook* is the most comprehensive and effective platform providing you with innovative content, reliable products and services and unlimited ways to reach your potential customers across the world!
Heart Health

In the U.S., heart disease causes one in four deaths; it is the leading cause of death for both men and women. Supplements for cardiovascular health remain popular.

To help clear up confusion and better summarize the state of the science, Gearheart points to a GOED-commissioned editorial written by Kevin C. Maki (author of the GOED-funded *Journal of Clinical Lipidology* meta-analysis) and Mary R. Dicklin that explores the reasons behind the conflicting conclusions on the ingredients in question—and implications for future studies. Published this past July in *Nutrients*, the piece by Maki and Dicklin states, “Although randomized clinical trial data accumulated to date have failed to provide unequivocal evidence of CVD risk reduction with long-chain omega-3 polyunsaturated fatty acid (n-3 PUFA) supplementation, many studies were limited by design issues, including low dosage, no assessment of n-3 status, and absence of a clear biological target or pathophysiologic hypothesis for the intervention.” The authors add that, in their analysis, the “most promising” evidence supports long-chain omega-3 polyunsaturated fatty acid supplementation for prevention of cardiac death.

Gearheart adds that since the beginning of 2017, GOED has been focused on commissioning research on omega-3s and heart health “to fill in the research gaps” and “continue to strengthen the body of science around” omega-3s. To this end, Gearheart says, results from two large randomized clinical trials on EPA and DHA and heart health will be enlightening. One is the Reduction of Cardiovascular Event Outcomes (REDUCE-IT) trial, which includes more than 8,000 subjects and was expected to determine whether Amarin Corp’s EPA omega-3-based drug, Vascepa, makes an efficient add-on-treatment for patients already on statin therapy. In September, Amarin released topline results from the REDUCE-IT trial, stating that researchers found a statistically significant risk reduction of 25% in the first occurrence of major adverse cardiovascular events in subjects taking 4 g/day of Vascepa, compared to placebo. Amarin said it would release more details from the results at the 2018 Scientific Sessions of the American Heart Association in November.

The second trial whose results could support the promise of omega-3s in the heart health realm is the Vitamin D and Omega-3 Trial (VITAL), which follows 25,000 subjects, is sponsored by Brigham and Women’s Hospital, and is intended to measure whether taking vitamin D supplements or omega-3s reduces the risk of developing cancer, heart disease, or stroke in healthy people. Gearheart says GOED expects that the results of the VITAL trial will be positive; however, he expresses concern that the possibility of neutral or “not statistically significant” results could “result in headlines that inaccurately portray omega-3s as not effective,” which have plagued the industry in the past.

ALA and SDA. While much of the recent research and meta-analyses on omega-3 fatty acids have centered on DHA and EPA from marine sources, a review published this past July in *Cochrane Database of Systemic Reviews* examined trials that included plant-sourced omega-3 fatty acids as well.¹

Nena Dockery, technical services manager for Stratum Nutrition (Carthage, MO), supplier of plant-based Ahiflower oil, calls the Cochrane review “significant in that it revealed a more promising effect from [omega-3] alpha-linolenic acid (ALA) consumption in reducing cardiovascular events, coronary mortality, and heart arrhythmia compared to EPA and DHA supplementation or fatty-fish consumption.”


**IMAGE COURTESY IKA - STOCK.ADOBE.COM.**
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Heart Health

More than half a million people in the United States die of heart disease every year, according to the Centers for Disease Control and Prevention.

Stratum’s Ahiflower oil, from the ahiflower plant (Buglossoides arvensis), contains omega-3 ALA, plus stearidonic acid (SDA), the “beneficial omega-6 fatty acid gamma linolenic acid,” and the omega-9 fatty acid oleic acid, Dockery says. She adds that the Ahiflower product is “unique in its content of SDA that converts much more readily in the body to EPA than does ALA, increasing the benefits associated with EPA above that from other plant sources.”

(Editor’s note: Some in the omega-3 industry have questioned the conclusions of the aforementioned Cochrane review. In Nutritional Outlook’s October 2018 issue, Bill Harris, PhD, omega-3 researcher and founder of OmegaQuant, bylined an article titled “Deep Dive” criticizing the Cochrane researchers.)

Plant Sterols

Plant sterols represent another plant-sourced ingredient marketed for cardiovascular wellness. Cargill’s (Minneapolis) plant sterols, branded within its CoroWise line of ingredients, are concentrated forms of plant compounds that can be formulated into foods and beverages as a “convenient way for consumers to try to help improve their LDL cholesterol levels and reduce their risk of heart disease,” says Pam Stauffer, global marketing programs manager for Cargill.

Stauffer says plant sterols are clinically shown to lower cholesterol and are recommended by the National Cholesterol Education Program of the National Heart, Lung, and Blood Institute of the National Institutes for Health. Stauffer points to two Frost & Sullivan reports to support her assertions: Small Prevention: Health Care Cost Savings and Supplements², published in 2014, and the more recent Healthcare Cost Savings of Phytosterol Food Supplements in the European Union³, commissioned by Food Supplements Europe and published in 2017. The former maintains that between the years 2013 and 2020, nearly 2.3 million medical events could be avoided in American adults older than 55 with coronary heart disease through supplementation of plant sterols at preventative intake levels. The report was funded by the dietary supplement association the Council for Responsible Nutrition (Washington, DC).

The latter report found that daily consumption of 1.7 g of plant sterols by adults older than 55 in the EU with severe high cholesterol could provide healthcare savings of €5.3 billion per year and prevent more than 170,000 hospitalizations, according to Car- gill’s Alex Eapen, principal scientist.

Tocotrienol: The Other “E”

“The emerging trend in the vitamin E market” is how American River Nutrition’s (Hadley, MA) Anne Trias, MS, characterizes the ingredient tocotrienol. This form of vitamin E has been shown to safely lower cholesterol and triglyceride levels by 15%-20%, Trias says, while also reducing C-reactive protein—a measure of inflammation—by up to 40%. Additionally, a recent study² published in The Turkish Journal of Gastroenterology elucidates the ingredient’s benefits in reducing cardiometabolic symptoms, improving fatty-liver index, and lowering body weight and inflammatory markers.

“Tocotrienol is clearly the emerging trend in the vitamin E market, and we will be seeing a significant amount of research published in the next few years, adding to the growing body of science supporting this important ingredient.”

Resveratrol

The substance resveratrol has experienced upswings and downswings during the past 15 years or so. Resveratrol supplier Evolva (Reinach, Switzerland), however, says that the ingredient still supports normal blood pressure, reduces “the plasma total cholesterol level and the risk of arteriosclerosis,” activates endogenous antioxidant defense mechanisms, reduces inflammation, and more, according to Johannes Haerle, Evolva’s senior technical manager, commercial, and Gene Adamski, national sales manager.

“A very recent review and meta-analysis study summarizing resveratrol and its beneficial effect on cardiovascular disease was published in January of this year in Food Science and Nutrition,” Evolva’s Adamski says. The meta-analysis² referred to resveratrol as a “nutraceutical” and concluded that “the favorable effect of resveratrol emerging from the current meta-analysis suggests [its possible use] as an active compound in order to promote cardiovascular health, mostly when used in a high daily dose (≥300 mg/day) and in diabetic patients.”

Ingredient supplier TR Nutritional (Alpharetta, GA) also supplies resveratrol, and Deanne Dolnick, science director at the company, describes resveratrol as a “very popular” heart health ingredient at the company. TR Nutritional offers “100% natural” resveratrol 50% and resveratrol 98%, she says.

High-Curcuminoids Turmeric Extract

TR Nutritional calls high-curcuminoids tur- meric extract “one of the newer ingredients to support heart health,” and cites a recent meta-analysis of randomized controlled trials published in 2017 in Nutrition Journal." Those researchers concluded in their analy- sis of seven eligible studies that turmeric
and curcumin “may protect patients at risk of cardiovascular disease through improving serum lipid levels.” However, links between heart health and curcumin need more investigating, with the researchers concluding that additional research is required to resolve uncertainties related to dosage form, dose, and more.

Tomato Carotenoids

Tomato carotenoids, such as lycopene, have been extensively researched and proven to beneficially modulate many of the key factors involved in cardiometabolic well-being and overall health over time,” says Karin Hermoni, PhD, head of science and nutrition at Lycored (Secaucus, NJ). The company has recently launched its second-generation tomato-carotenoid product, a “cardio-optimized” and “strictly standardized” tomato-nutrient complex called Cardiomato. The complex combines lycopene, vitamin E, and phytosterols in a proprietary formula whose clinical studies the company says provide evidence for the support of heart and cardiovascular health via healthy circulation, healthy blood pressure, and “boosting the body’s own protection mechanisms” against oxidative stress.

In October 2016, researchers published a study10 backed by Lycored of 150 subjects taking a carotenoid-rich tomato extract (CRTE) supplement daily after a meal. Overall, the results of this study indicate that CRTE taken once daily for two weeks has a favorable effect on postprandial LDL oxidation, glucose, insulin, and triglyceride levels for up to eight hours. CRTE was well tolerated throughout the study period, the authors write, “and additional trials are needed to prove the repeatability of these results in other sub-populations, such as those at risk of cardiovascular diseases.”

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Maureen Kingsley is a freelance writer, editor, and proofreader based in Los Angeles. She covers a variety of industries, including medical technology, food-ingredient manufacturing, and cinematography.

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Plants for All

Vegan and vegetarian for the masses

BY SEBASTIAN KRAWIEC, ASSOCIATE EDITOR

Vegans and vegetarians are not the biggest consumers of vegan and vegetarian products. According to Nielsen¹, 6% of Americans follow a strictly vegetarian diet and 3% follow a strictly vegan lifestyle; yet in 2017, 19.5% of food and beverage retail dollars came from plant-based products. This is because more consumers in general are looking to reduce their meat consumption—39% in 2017, to be exact, based on a recent Nielsen Homescan survey¹. Growing health and environmental consciousness among consumers has driven interest in plant-based products and encouraged innovation within the category. Innovation has, in turn, made plant-based foods and lifestyles more accessible, allowing for a smoother transition that brings even more consumers into the category.

“Innovative technologies, both internal and external, have enabled us to maintain the quality of vegetarian/vegan flavor and evolve the texture of our food to align with consumer taste preferences,” explains Melissa Cash, senior director, brand marketing, Kellogg Company, which owns MorningStar Farms, a leading vegetarian and vegan food brand. “We have really ramped up our offerings over the years to include more flavorful options like the Vegan BBQ Chik’n Nuggets or the Meat Lovers and Veggie Lovers vegan burgers that deliver delicious plant protein in every bite.”

For example, while traditional vegan and vegetarian fare such as tofu, brown rice, and granola have gone down in sales—minus 1.3% in the year ending April 7, 2018, according to Nielsen—sales in other options have seen double-digit growth¹. Namely, sales of plant-based meat alternatives, cheese alternatives, and yogurt have grown 30%, 45%, and 31%, respectively².

It’s notable that plant-based foods mimicking animal-based products are experiencing such growth. Such products allow vegans and vegetarians to enjoy some of their favorite foods ethically while also making plant-based foods accessible and palatable to non-vegans or vegetarians dipping their toes into plant-based waters. Products names like “Meat Lovers Vegan Burger” really demonstrate just how diverse the plant-based food consumer can be.

“A recent study by NPD group found that 86% of the 43 million U.S. consumers who regularly use plant-based alternatives don’t identify as vegan or vegetarian,” Cash tells Nutritional Outlook. “MorningStar Farms continues to deliver on what people want by rolling out more flavorful choices.”

In fact, the large percentage of consumers who don’t identify exclusively as vegan or vegetarian but who are purchasing plant-based alternatives is an important reason why plant-based food innovation continues. According to Innova Market Insights, the forecasted value of global meat substitutes alone is expected to reach $4.2 billion in 2022².

Plant-based milk alternatives have played an important part in normalizing alternatives to dairy and other animal products to a broader audience seeking alternatives due to intolerance to lactose or other health reasons not related to the typical ethical concerns of vegans and vegetarians. Almond milk alone has experienced a combined three-year annual growth rate of 8.2%, says Nielsen¹. While plant-based milk products are growing, there are still many customers who buy both dairy and non-dairy. In a white paper titled “The Shifting Global Dairy Market: Ushering in a New Era of Dairy Products,” Cargill (Wayzata, MN) reported results from a survey on the dairy-buying habits of consumers and emphasized that while overall dairy milk consumption fell by 22% between 2000 and 2016, dairy milk sales still remain significant, with 90% of American households reporting dairy consumption.

“Dairy consumption overall remains strong in the United States, with two-thirds of respondents calling real dairy a regular part of their diet, while absolute dairy avoidance is comparatively low at just more than one in ten shoppers,” states the white paper. What is more significant, says Cargill, is that nearly half of respondents, 42%, reported consuming both dairy and dairy alternatives. Whether it’s with dairy or meat alternatives, manufacturers are no longer just targeting vegans or vegetarians.

The realization by manufacturers that they are making plant-based products for a wider audience may very well make them more gung-ho about pursuing this category, and expanding options will ultimately benefit vegans and vegetarians in the long term. According to Ingredient Communications (London), which commissioned an online survey of 1,000 consumers (half from the U.S. and half from the U.K.), nearly half of vegans (46%) and a quarter of vegetarians (23%) are dissatisfied with the choice of food products available to them. This same survey found that 42% of meat eaters intended to reduce their meat consumption or stop eating it altogether. Of all the respondents, vegans and vegetarians combined made up only 8% of the 1,000 respondents. There is a greater incentive for manufacturers to capture that 42% than that 8%. This will eventually result in more plant-based food choices, which will be important as more of those consumers ultimately remove animals from their diet entirely


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