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*These statements have not been evaluated by the FDA*
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In a year of regulatory pain, it’s nice to celebrate good news for a change. The dietary supplement industry is enjoying a moment of triumph following Bayer Corp.’s recent victory over the FTC in a case about probiotic structure-function claims.

Read our take on the case online at ubm.social/Zuzy5x, but the bottom line is the judge affirmed that supplements are not to be regulated as drugs. More importantly, he said the FTC cannot, via regulatory creep, introduce new substantiation standards that run counter to the laws governing supplements, to FTC’s own guidance governing supplements, and to language already forged in existing consent orders.

“This was a great moment for industry in dealing with what has been, as an agency, one of our more rigorous opponents,” said attorney Marc Ullman of Rivkin Radler LLP during a SupplySide West panel in October.

For Jonathan Cohn of Sidley Austin LLP, one of the attorneys who argued the case on behalf of Bayer, one takeaway is: Industry should fight more cases when the FTC is trying to sidestep the appropriate route for changing legal statute.

“Try more cases,” he urged, speaking at October’s Council for Responsible Nutrition (CRN) annual conference. “Bottom line, industry can win. We did it before, and we can do it again.”

Others are happy, but cautious. “Don’t take this as the end of the issue,” Ullman warned. FTC will almost certainly try to flex its muscles in the future, and it can still appeal the Bayer case.

“What’s going to come next? Well, what I think is going to come next is more specific orders,” said attorney John Villafranco of Kelley Drye & Warren LLP, also speaking at the CRN event. He pointed to prior statements made by David Vladeck, former director of FTC’s Bureau of Consumer Protection, that FTC believes consent orders are more enforceable and stronger in court if they more specifically outline the kind of evidence required.

New FTC consent orders will provide hints of what’s to come, industry leaders say. And industry should monitor those orders closely.

Speaking to CRN conference attendees, FTC’s Mary Engle, associate director for advertising practices, Bureau of Consumer Protection, likewise advised companies to examine FTC’s complaints. While consent decrees only bind the companies under order, “they may provide some guidance as to where we’re drawing the line between when you need clinical trials and what broader claims that you may not necessarily need clinical trials [for].”

She added, “Sometimes competent and reliable scientific evidence is randomized controlled trials,” but also acknowledged that the agency has “pretty much stopped putting in our order provisions [a requirement for] at least two RCTs.” Instead, she said, “What you’ll see... is simply the requirement that the court put in the [amended consent order for] POM Wonderful [in its FTC case over disease claims] that they have clinical testing, without specifying that number.”

Companies should not take the Bayer case as a cue to relax; just the opposite. They should be more vigilant of their claims substantiation, said Michael McGuffin, president of the American Herbal Products Association, at the SupplySide West panel. “What the court’s decision did not do is tell us that we don’t have to have substantiation. We still need to have substantiation for our claims.”

“FTC is not going to go away,” added panelist Dan Fabricant, PhD, CEO of the Natural Products Association. “[The Bayer case is limited to] one jurisdiction [the state of New Jersey]. Even if the judge’s language is somewhat of an endorsement of Bayer’s procedure, that’s not going to get you real far. They’re going to find another jurisdiction to keep bringing these sorts of cases. They’ve already shown that from the start.”

In terms of RCTs, said Villafranco, FTC’s “thinking is really starting to evolve, and it’s becoming crystallized.” And even if the industry does not see orders delineating two RCTs in most cases, he said, pay attention to the fact that the FTC does not seem to flinch at requiring two RCTs for highly scrutinized categories like weight loss.

“Not a lot of companies have the conviction that Bayer had here or the resources or time to really dig in” and take the FTC on in court, he pointed out. For most companies, the more realistic path forward will be vigilance, careful stepping, and the sense not to become complacent when it comes to the FTC.

Jennifer Grebow
Editor-in-Chief

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Ultra-High Concentrates Are the New Omega-3s at SupplySide West

Omega-3 suppliers are now taking concentrates for dietary supplements into near-pharmaceutical territory. DSM Nutritional Products (Florham Park, NJ), BASF Human Nutrition (Florham Park, NJ), and FMC’s Epax division (Sandvika, Norway) unveiled new ultra-high-concentrate offerings at the SupplySide West trade show in October.

FMC debuted a fish-oil ultra-high concentrate in the triglyceride form. Its new Epax 4535 TGN triglyceride oil contains over 80% EPA/DHA fatty acids—a minimum of 450 mg/g EPA and a minimum of 350 mg/g DHA, for a total minimum omega-3 content of 860 mg/g. By contrast, a standard 1812 fish oil pill would offer only about 30% EPA/DHA content, or approximately 260 mg/g total, the firm says.

“To our knowledge, this is the highest concentration of EPA and DHA in a 90% triglyceride oil, which is the natural form of omega-3. This is the highest-concentration triglyceride product on the market today, so it’s a real category-leading innovation for us,” said Ravi Annavarapu, global platform manager, nutraceuticals and natural colors, FMC Health and Nutrition.

Epax touts the triglyceride form as more bioavailable. Omega-3 pharmaceuticals like Lovaza are in the ethyl ester form. But FMC is also active in the ethyl ester space, which for now outsizes the triglycerides market. At SupplySide, the company also promoted its Epax 4030 EE high-concentrate ethyl ester oil first introduced at this year’s Vitafoods show in May.

BASF’s new ultra-high-concentrate offering is Pronova Pure 46:38, which delivers up to 90% omega-3 content and an EPA:DHA ratio of 46:38. The company is targeting the cognitive and heart health markets with this ingredient. “If you look at the products on the market today, a lot of them have either just high EPA or just high DHA, and in this case, we have a high level of both, so you have the total health for both brain and heart health,” said marketing manager Eva Johnson.

Anne van Gastel, business director, BASF Human Nutrition, also pointed out in the company’s press release that the 46:38 ratio is “the most clinically studied, so it gives our customers a solid scientific foundation to market their products.”

As for DSM, a new ultra-high-concentrate addition to its Meg-3 omega-3 fish oil line offers up to 85% omega-3 content and is set to launch in Q1 2016. The company pointed out that the ingredient is “customizable,” meaning companies can tweak EPA and DHA levels to their liking.

First Algal High-Concentrate

Leveraging the algal-DHA expertise of its Martek Biosciences and life’sDHA algal omega-3 acquisition, DSM also has plans to roll out what it believes is the first high-concentrate algal oil on the market. The ingredient would offer up to 85% omega-3 DHA.

“We have the pioneers in this space,” said Andre Melo, business director, Meg-3, DSM Nutritional Products North America. “There is no other company that can get even close to us as far as our DHA technology. It comes from the Martek legacy, and with that technology that we have developed now that’s being implemented, we’ll be the only company able to achieve those high concentration levels for DHA. There’s nobody else that has the ability to do that.”

Georges Bergen, senior manager, regulatory affairs, DSM Nutritional Products North America, pointed out that the fermentation-derived algal oil “still fits within the original GRAS determination that we have. It’s just a change in manufacturing process…the same food-use applications still apply.”

Getting Close to Pharma?

When asked how close these ultra-high concentrates come to high-concentrate pharmaceutical omega-3 doses, FMC’s Annavarapu said of Epax 4535 TGN, “This is right around there, actually. There is now a set definition for what a pharmaceutical level is. A concentration range of 75%–97% is basically a pharmaceutical API, and this product falls in that range.”

“Of course,” he continued, “you cannot have a product which is exactly the same spec as a pharmaceutical because then it becomes an API. So our product is in a different form, but it’s in the same concentration range.”

Still, suppliers well accustomed to formulating higher concentrations for the pharmaceutical market are able to apply their expertise to the supplements space.

As the supplier of omega-3 pharmaceutical Lovaza, BASF has “over a decade of experience in pharmaceutical omega-3 products, so some of that technology is coming from that side,” Johnson said.

In addition to reducing pill size and the number of pills required to fulfill a proper dose, ultra-high concentrates offer other benefits to consumers who may be willing to pay a higher price for the privilege—namely, that they omit the fats and calories that consumers don’t need by delivering higher amounts of just the beneficial EPA and DHA fats that actually benefit health. “When you put this all in a capsule, you get the majority of ‘good stuff,’ because at the end of the day, you don’t want to get all this unnecessary fish fat,” FMC’s Annavarapu said.

Annavarapu called ultra-high concentrates the “next generation of innovation” in the nutraceutical omega-3 market. “I believe the wave of the future is higher concentrations of omega-3.”
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Probiotic Claims Crackdown Costs EU Yogurt Industry Billions

It’s no secret that the European Food Safety Authority (EFSA; Parma, Italy) has taken an unfavorable stance toward probiotic health claims in the last eight years, but soon-to-be published data from Euromonitor International is shedding new light on how much EFSA’s stance has actually cost the EU yogurt market.

Among just six of the EU member countries—Austria, Belgium, France, Germany, the Netherlands, and the United Kingdom—the probiotic health claims ban will cost as much as €1.5 billion (approximately $1.7 billion) in lost sales for drinking probiotic yogurts between 2012 and 2020, according to Ewa Hudson, head of health and wellness, Euromonitor International. Hudson shared Euromonitor’s latest findings at the recent Probiotics Workshop at SupplySide West, as part of her presentation, “Changing World of Probiotics—Global Market Snapshot.”

Hudson said that between 2002 and 2007, probiotic yogurt was the “driving force of overall yogurt in Europe” and grew much faster than non-probiotic yogurt. However, as EFSA began to crack down on probiotic health claims and eventually banned use of the term probiotic in the EU, the market soon began to decline.

“Regulations started to change around 2008, 2009, 2012, and that was the time when we saw the final scope of the legislation and the disappointment,” said Hudson. “You can see the market responded pretty much straight away. Both probiotic yogurt and non-probiotic yogurt started to decline—from one extreme to the other.”

The EU probiotic market saw more than 18% annual growth in 2002–2003, but by 2012–2013, the worst year on record, it was declining by nearly 8%, according to Euromonitor’s research across 20 EU member state markets. While the decline has slowed since 2013, the probiotic yogurt market is still far from growth.

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“Looking forward, we expect that the probiotic yogurt will continue to decline [in Europe],” said Hudson. “There is no growth on the horizon. The non-probiotic yogurt will see growth again toward the end of the forecast period, around 2020, because of the trend toward protein especially.”
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Hudson added, "We can already see that definitely, health claims do matter."

**Other Functional Ingredients Take the Wheel**

Hudson also spoke to the way many brands have had to reposition their European products now that EFSA has cracked down on use of the term *probiotic* on labels and descriptions of probiotic health benefits. Many brands continued to list *live cultures* on the label or include the name of the probiotic strain, but other functional ingredients with approved health claims soon became a more prominent marketing feature of these probiotic yogurts, Hudson said.

"For yogurts that were, for example, previously positioned for immunity, such as Actimel, the decision was probably quite fast actually to reformulate the product with the ingredient that contained claims or can be linked to specific health claims," said Hudson.

While these yogurts may still contain probiotic strains, the focus has instead shifted to other ingredients for which claims are allowed. Probiotics may now just be an "additional benefit" for informed consumers, said Hudson.

For instance, Danone's Activia yogurt brand has been able to reassert its digestive-health positioning by incorporating wheat bran fiber into its Activia Fibre yogurt, which launched earlier this year, said Hudson. Although the new yogurt still includes probiotic strain *Bifidobacterium lactis*, it's thanks to the inclusion of fiber that it can now feature the claim of "contributing to an acceleration of intestinal transit."

**A Different Picture around the World**

Although the European probiotic yogurt market is still in decline, the picture couldn't be more different in Asia. Hudson said growth in the global probiotic yogurt market is now driven by countries like China, which Euromonitor says added $1.4 billion in new sales between 2012 and 2014. Even more growth is expected in China this year, according to Hudson, as well as in Vietnam, Japan, and many other Asian countries.

In the United States, the probiotic yogurt market has declined while other yogurts, such as Greek yogurt or high-protein yogurt, have attracted more attention. But there is substantial growth in the U.S. market for probiotic supplements, which is the driving force behind global probiotic supplements.

Worldwide, probiotic supplements grew by 7.8% this year, making them "the fastest-growing supplements this year globally," said Hudson. Euromonitor also pegged Italy, Canada, Taiwan, and Japan as key growth markets for probiotic supplements.

The global probiotics market currently stands at approximately $35 billion, with Euromonitor anticipating it to reach $48 billion by 2020.
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Cargill’s Reb M Reb D Fermented Stevia Will Be Commercial Next Year

Cargill (Minneapolis) gave SupplySide West attendees a first taste of its new blend of fermentation-derived steviol glycosides Reb M and Reb D. The company said it would start supplying the new blend, EverSweet, next year.

“Today is really the introduction to the market to gauge interest and give people a chance to taste it, and then we can start sampling customers, because most people’s formulation time is 12–18 months. So we want to give them a head start. And then we plan on being commercial in 2016,” said Andrew Ohmes, global commercial manager, Corn Milling, North America, Cargill.

Key Cargill customers are now sampling EverSweet. Beverages will be a target market out the gate. “Beverage is usually where we start. That’s obviously where the big volume is, and that’s where the biggest challenge is specifically in carbonated soft drinks. But it will easily move into yogurts, dairy beverages, baking, or even supplements,” Ohmes said.

As a fermented sweetener, EverSweet stands apart from Cargill’s other stevia offerings that focus strictly on traditional stevia leaf extraction. The company’s Truvia Reb A stevia is derived from the leaf, and its ViaTech system to determine best glycoside ratios, introduced last March, also revolves around leaf glycosides.

Compared to these other stevia sweeteners, EverSweet offers some important formulation advantages, Ohmes said. “Reb M and Reb D and the EverSweet product has a better temporal profile that’s more sugar-like than other stevia products—better up-front sweetness, less sweet linger, and virtually no bitterness at all. So you get a much more rounded sweetness.”

What this means is that in a carbonated soft drink, the company can achieve up to 100% zero-calorie sweetener substitution with EverSweet, whereas 100% replacement was not possible with the previous technologies. Before, Ohmes said, with “a high–Reb A product, you could probably do a 30% replacement, and it tastes pretty good. ViaTech will easily get you to 70%, and depending on the application might go all the way to 100%. But there might be a gap getting that last little bit, that last 15% or so.” EverSweet can get to 100% replacement easily, while maintaining a desirable taste profile, he said. Now,
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with EverSweet, he added, companies may not even need to use—or at least reduce their use of—taste maskers that are otherwise so often required to hide stevia’s bitter or licorice notes.

Fermentation-derived steviol glycosides offer numerous advantages. Most notably, they allow a business to mass-produce some of the sweetest glycosides in the stevia leaf that are otherwise generally present in very small amounts naturally. Some might call stevia fermentation synthetic because no part of the stevia leaf is involved in the process. In Ohmes’s words, with EverSweet, Cargill is “recreating the sweetness.” Ohmes said that the company is “transparent about how it’s made. We’re using an age-old process to solve a modern problem.”

On its website Q&A, Cargill addresses questions about fermentation and whether EverSweet would be considered a genetically modified organism (GMO). It says, “The sweet parts produced by the yeast—Reb M and Reb D—are identical to the Reb M and Reb D found in a stevia leaf. The baker’s yeast used to produce EverSweet is genetically modified. However, after the yeast produces Reb M and D, the yeast is completely filtered out, leaving only the great-tasting, zero-calorie sweetener. Laws and regulations vary significantly from country to country. In some geographies, the EverSweet product would not be required to be labeled as a GMO.”

Ohmes pointed out that on a food or beverage label, companies would still be able to label the ingredient as “steviol glycosides—because that’s what it is” or as Reb M or Reb D.

Ohmes said that EverSweet simply gives Cargill customers another option. “This gives our customers another choice. We’re still going to have our leaf-based business and our leaf-based ViaTech, which solves a lot of problems. This gives consumers and our customers another choice, rather than going to maybe a fully artificial sucralose or aspartame. They could have steviol glycoside that occurs in nature, just produced in a little different way.”

And does the company fear that EverSweet could shrink its own market for naturally obtained glycosides like Reb A?

“Actually, we feel it’s the opposite,” said Ohmes. “It will actually help grow the market, because this opens up a different market space where stevia hasn’t been able to go before, where steviol glycosides haven’t been able to go before. Zero-calorie carbonated soft drinks is a big one. Growing that market out—a rising tide will lift all boats.”

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Healthfulness may not be a key driver when consumers purchase snacks, but that hasn’t stopped marketers from trying to put better-for-you options in shoppers’ paths. Snack food makers continue to position products on health platforms of various kinds, from the “passive” (low fat, low calorie, natural, etc.) to the “active” (vitamin and mineral fortified or offering specific health benefits like support for bone health or heart health).

“Passive” Claims
The snack foods market, as defined by Innova Market Insights, includes not only traditional savory or salty snacks and snack nuts and seeds, but also products such as meat snacks, popcorn, and fruit-based snacks, as well as finger foods and hors d’oeuvres. Under this definition, 38% of global snacks launched in the 12 months ending April 2015 were positioned on a health platform of some kind, rising to over 70% in the United States alone, according to Innova Market Insights reports.

The majority of products advertise “passive” benefits, with “natural” and clean-label claims dominating the space. In fact, “natural,” “no additives/preservatives,” and/or organic claims were featured on nearly a quarter of global launches and nearly 44% of launches in just the United States.

Gluten-Free
“Gluten-free” also continues to feature strongly, used on 13% of global snack launches and 40% of launches in the United States. In terms of product and market development, the snacks category benefits particularly from the fact that many basic snack ingredients, such as potatoes, corn, soy, and nuts, are naturally gluten-free, so it is a claim that is relatively easy to achieve in many instances.

To offer gluten-free formulations, U.S. marketers are replacing wheat or other cereals with ingredients such as lentils, black beans, navy beans, cassava, brown rice, nuts, sweet potatoes, and a wide variety of other vegetables.

Protein Focus
Another key trend impacting snacks along with the rest of the food and drinks market is a heavier focus on protein and protein content. Just under 4% of total snack foods launches recorded by Innova Market Insights in the 12 months ending April 2015 used a “high in” or “source of” protein positioning, rising to nearly 13% in the United States.

Categories that are naturally high in protein or perceived to be good sources of protein are able to leverage this type of claim more widely—most notably, meat snacks, where protein claims featured on nearly 15% of global launches, rising to over 50% in the United States.

“Low” and “Light”
These claims persist today and began as far back as the mid-1980s, initially focusing on fat reduction and the use of healthier fats. More recently, reducing salt levels is an area of interest.

Although reducing salt is a key concern in government- and industry-driven health initiatives in recent years, there are signs that interest is limited, however. We see this in terms of product-launch activity.

Although the number of low-sodium snack launches recorded by Innova Market Insights has generally risen over the past five years, their share of total snack launches has fallen globally, from 2.5% to 1.9%. This is attributed to the significant technical challenges associated with making further reductions to salt content without adversely affecting product taste and shelf life.

Popped Snacks
In the “low” and “light” arena, popped snacks have grown especially popular in the bagged-snacks category. Made with potato or corn flakes or other cereal pieces, popped chips are turned into crisps using heat and pressure and are marketed as a healthier, guilt-free option to standard fried and baked products.

The original Popchips brand debuted in the United States in 2007 and continues to perform well today despite growing competition from other heavyweight brands, including Kellogg’s Special K Cracker Crisps, Mondelez’s Nabisco Wheat Thins Popped, and General Mills’ Chex Mix Popped. Most notably, U.S. snacks market leader FritoLay (PepsiCo) introduced its Lay’s Air Popped in 2013.
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To stay competitive, Popchips has launched numerous products, including a Veggie Chips brand in 2014 made with a blend of nine vegetables (kale, spinach, tomato, pumpkin, potato, beet, bell pepper, navy bean, and chickpea). The “popped” concept has also spread to other sectors, including tortilla chips like Balance Foods’ Poptillas.

Popped snacks are a strong up-and-coming trend, but the traditional popcorn market is still standing strong both in the United States and Europe. Gourmet lines already established in the United States are starting to make their way to Europe, bringing with them more complex flavors beyond popcorn’s traditional “movie theatre snack” image. Popcorn also checks the box in terms of healthfulness, being natural, low in calories, and high in fiber. Now, with new bold flavors and flavor combinations, including combos with kernels and more unusual ingredients, popcorn is set for continued growth.

What Is a “Snack”? 
As the definition of snacking broadens, high levels of new product and promotional activity will continue driving sales, including in more traditional snacks markets. In addition to focusing on a relatively healthy profile, other drivers include premium and super-premium products, often with unusual flavors and ingredients; developing existing brands; using new ingredients and formats; and targeting new usage occasions.

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As it becomes clear to consumers that physical fitness is an instrumental component of overall wellness and lasting vitality, everyone, from power walkers to CrossFit aficionados, is heading to the sports nutrition aisle in search of the right supplements.

According to Euromonitor International, the U.S. sports nutrition market reached $5.95 billion by the end of last year, with U.S. sales accounting for over half of the global $10 billion market.

With numbers like that, it’s obvious that the category’s shoppers are diverse—and, in response, so too are the offerings. In other words, the high-protein bars and powders valued by bodybuilder types are no longer the only offerings on the table.

“While we all know that protein is the leader in the sports nutrition market, not every consumer is looking for the same functional solution,” says Michael Bush, senior vice president at Ganeden (Cleveland, OH). “Consumers who eat a high-protein diet aren’t looking for more protein; they are looking for non-protein offerings that will support digestive and immune health, bone health, amino acid levels, energy, endurance, and recovery.”

Though still a smaller segment of the sports nutrition market, sales of non-protein offerings are growing. Euromonitor valued the non-protein segment at just $248.6 million in 2000; by 2014 it had grown to $667.9 million; this year, it jumped over 7% to $715.9 million.

According to Richard G. Mueller, president of Biothera Health Inc. (Eagan, MN), this upward trend is indicative of a shifting mentality among shoppers that started 20 years ago with eliminating “bad” ingredients like sugar, sodium, and artificial sweeteners. Today, while shoppers have clearly embraced adding in “good” ingredients like protein, the mentality has shifted yet again—and this time, it goes beyond adding and subtracting singular ingredients to focusing on broader benefits like heart health, joint health, energy, digestion, and immunity through a multipronged approach.

“With goals of the user expanding from just fat loss, muscle mass gain, or improved sports performance to improvements in overall energy, better mental focus, and decreased pain, the types of products people are looking for to optimize their performance is expanding beyond items like protein powders,” agrees Amanda Carlson-Phillips, MS, RD, CSSD, vice president of nutrition and research at sports supplement brand EXOS (Phoenix, AZ). “More and more, people are starting to understand that our body is a complex system and not a series of linear actions. Creating holistic game plans around nutrition and supplementation supports benefit attainment, versus trying to solve one problem at a time.”

Though protein remains the category leader—clocking in at $5.3 billion in sales in the United States alone in 2014, says Euromonitor—non-protein offerings represent an opportunity for growth if formulators can make the case that their ingredient or product makes sense alongside an existing protein regimen or as a part of a holistic health plan in support of general physical fitness.

Keeping Athletes Well
At Biothera, immune health is starting to creep into the sports nutrition category and remains an area of untapped potential. “What is often not correlated is that high-intensity exercise can temporarily weaken the immune system. This is commonly known as the ‘open window’ where the immune system is impaired, causing an increased risk of infection,” says Mueller. This
can pose a problem for athletes who can’t be derailed from their training programs.

To this end, the company’s Wellmune beta-gluca
non was found to reduce upper respiratory tract infection symptoms by 40% in mara-
thon runners, says Mueller, and can make sense combined with protein or probiotics in a sports nutrition product. More recently, University of North Texas researchers found that Wellmune may also benefit more-casual exercisers. At the National Strength and Con-
ditioning Association’s annual conference this July, the researchers presented the results of a study performed on 109 adults who were not regular exercisers. They found that after subjects supplemented with Wellmune and performed brisk treadmill walking or light jogging, they experienced a significant increase in salivary IgA—an antibody critical to mucosal immunity—an indicator that Well-
mune alleviated the mucosal immune sup-
pression that may come as a result of strenu-
ous exercise.

“These new results suggest that even a small amount of exercise stress can trigger a drop in immune responses and that Well-
mune can help enhance key immune func-
tions to keep individuals healthy,” said Brian McFarlin, PhD, the study’s lead researcher.

Within herbal supplements, immune-
health booster Rhodiola rosea may also sup-
port athlete health. A new study suggests for the first time that Rhodiola rosea may protect athletes from viral infections.

Researchers in North Carolina examined blood samples from 48 marathon runners to compare the effects of 600 mg/day of Rhodiola rosea versus a placebo on the body’s response to viral infections after heavy exer-
cise. Although initial studies found Rhodiola rosea had no impact on inflammation or oxi-
dative stress, additional testing of an in vitro assay found that polyphenolic compounds in Rhodiola rosea may have protected the runner’s cells against vesicular stomatitis virus (VSV) by delaying the infection for up to 12 hours after the marathon.

“Basically, after heavy exertion, bacteria and viruses can multiply at a higher rate than normal due to factors in the serum like stress hormones and inflammatory cytokines,” said David Nieman, PhD, lead author of the Rho-
diola rosea study. “This is why runners are six times more likely to get sick after a marathon.”

Also of interest, researchers from the Uni-
versity of Aberdeen (Aberdeen, Scotland) report that krill oil may increase markers of immune function after a bout of acute exer-

The study followed 19 men and 18 women who were randomly assigned to consume ei-
ther 2 g per day of krill oil or a placebo for six weeks. Aker Biomarine (Oslo, Norway) provided the Superba krill oil capsules used in the study.

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in a maximal exercise test and cycling time trial to evaluate exercise performance and illicit an immune response. The cycling time trial included participants cycling at 70 revolutions per minute with workload increasing every minute until volitional exhaustion.

Blood samples were collected before both exercise trials, as well as immediately after, one hour after, and three hours after exercise. Researchers examined the blood for markers of immune function, including erythrocyte fatty acid composition, plasma IL-6 concentration, thiobarbituric acid reactive substances (TBARS) concentration, natural killer (NK) cell cytotoxic activity, and peripheral blood mononuclear cell (PBMC) production.

Krill oil supplementation did not appear to modify exercise performance among study participants, but the experimental group did show increased PBMC IL-2 production and NK cell cytotoxic activity three hours post-exercise compared with the placebo group.

"The current study has demonstrated that NK cell cytotoxic activity and PBMC IL-2, but not other cytokines, are increased after krill oil supplementation," wrote the researchers. "What remains to be established are the mechanisms through which n-3 PUFA [polyunsaturated fatty acid] supplementation results in these alterations."

**Performance and Recovery**

Athletes and amateurs alike seek products boosting muscle enhancement and protection. While "protein will help you pack on muscle," says Janice Brown, technical sales/support, AstaReal Inc. (Burlington, NJ), "consumers are searching for supplements they can add to their protein regimen that will give them all-around performance benefits."

On the non-protein front, post-exercise benefits were reported by KD Pharma (Bexbach, Germany) in a study of its new KD Active omega-3 oil, launched at Vitafoods in May. In the study, the ingredient was found to alleviate delayed onset muscle soreness, the feeling of stiffness and soreness that hits 21 to 24 hours post-exercise.

Meanwhile, a recent 60-subject study found that a combination of Kyowa Hakko USA’s (New York City) Setria glutathione and L-citrulline may support athletes post-exercise. "In this study, we were able to determine that combining Setria glutathione with L-citrulline not only increased blood levels of nitrite and [nitric oxide], but sustained the increases for a longer period of time, compared to placebo," said lead researcher Darryn Willoughby, PhD. "The results of this first-of-its kind study indicate that Setria glutathione and L-citrulline may play a role in muscle protein synthesis and muscle performance when combined with resistance exercise."

Beta-alanine is an amino acid that supports the synthesis of muscle carnosine, helping to delay the onset of muscle fatigue and failure. It combines with histidine in the body to form carnosine, and it also helps buffer hydrogen ions that keep muscles contracting longer. The effect is not only recovery but endurance and peak performance.

The CarnoSyn brand of beta-alanine continues to ramp up research, says Mark LeDoux, chairman of the board and CEO of Natural Alternatives International (NAI; San Marco, CA), CarnoSyn’s distributor. The ingredient already has 55 clinical studies under its belt, and NAI has several in progress, including one in military populations to be published in the journal *Amino Acids*. The company recently launched a sustained-release version of the ingredient, SR CarnoSyn.

At October’s SupplySide West trade show, LeDoux said, “We discovered over the past couple of years that this isn’t just for bodybuilders anymore. There’s a huge market in aspirational athletics, people that go out and do a little workout on the weekend, decide
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they want to mow their lawn by pushing a lawnmower rather than riding on it, who are starting to get into shape by walking more.”

Also at SupplySide West, Ralf Jäger, co-founder of consulting firm Increnovo LLC (Milwaukee, WI), highlighted several promising ingredients during a sports market presentation.

One of the ingredients is beta-hydroxy beta-methylbutyrate (HMB), which has been shown to minimize muscle damage, decrease muscle protein breakdown, and increase protein synthesis. HMB is a naturally occurring metabolite of leucine. Jäger noted that “5% of leucine is converted to HMB” and that it would take 60 g of leucine or 600 g of whey protein to get 3 g of HMB.

He lauded an improved, better-absorbed format introduced recently by Metabolic Technologies Inc. (MTI; Ames, IA), branded BetaTOR. It is a pure, free-acid form of HMB (HMB-FA). A 2014 study showed that BetaTOR minimized or eliminated losses in strength and power during a two-week period of intense training. With this new form, Jäger said, “you have more HMB that gets into the bloodstream; as a consequence, more HMB is retained, so it’s a more efficacious form of HMB.”

Another ingredient Jäger highlighted is MediaTOR, a recently launched phosphatidic acid (PA) phospholipid ingredient from Chemi Nutra (Austin, TX). MediaTOR activates the body’s mTOR pathway, thereby stimulating muscle synthesis and resulting in muscle mass and strength gains. PA “directly binds and activates mTOR response to resistance exercise, causing muscle growth,” Jäger explained. He pointed to the ingredient’s most recent study, published in 2014 in Nutrition & Metabolism and showing significant improvements in total strength and lean body mass.

Jäger said it’s not often that “a really good new ingredient” comes along in sports nutrition—creatine is one example, he said—but he called the beginning research on these two ingredients, BetaTOR and MediaTOR, “very promising.”

The Joint-Health Connection

Joint health is integral to sports performance, and it is where several ingredient suppliers are extending their research.

New research from the American Physiological Society found that regular consumption of beet juice could yield heart-healthy effects during exercise and ultimately lead to increased endurance.

According to the researchers, the key lies in beet juice’s nitrate content, which is converted naturally in the body to produce nitric oxide and is credited with the ability to dilate blood vessels and increase blood flow, enhancing oxygen delivery and reducing the amount of work done by the heart during exercise. Ultimately, this translated to subjects being able to perform their workout for a longer period of time before fatigue set in.

“Beet juice increases athletic performance, improves stamina and strength, and also allows the body to recuperate better from physical activity by increasing the amount of oxygen and blood flow to the muscles, heart, and brain,” says Matt Herzog, president of beverage brand Beet Performer (Carmel, IN). “Beet juice also lowers blood pressure, purifies the blood, improves cardiovascular health, and reduces inflammation in the body.”

The good news is that the benefits of beets can be harnessed either in a juice or in a powdered supplement ingredient, depending on the demands of a particular formulation.

Beet Performer, a finished product, is 100% juice and appeals to consumers who want the convenience of pure juice but don’t have the time to juice themselves. Sabinsa Corp. (East Windsor, NJ) has harnessed the power of beetroot in its Sabeet beetroot extract. It is completely water soluble and, as such, makes sense in liquid products like energy and pre-workout shots. It is also available in a grade suitable for tablet formulation.

One supplier claims to have a nitric oxide–boosting ingredient that beats beets. PLT Health Solutions (Morristown, NJ) says that a nitrate-rich red-spinach extract (Amaranthus dubius), branded Oxystorm, provides “more than five times the amount of nitrate as beetroot powder and more than 50 times [that] of beet juice.”

The company is now supplying the ingredient, standardized to a minimum 9% nitrate content, in partnership with DolCas Biotech LLC (Chester, NJ). Offered in powder form, the ingredient is 100% water soluble and pH neutral, meaning it works in many types of formulas, including bars, powders, chewables, functional food, beverages, and supplements. Its production process is patent pending, and the company says that this process “delivers the highest nitrate content ingredient from the leaves of red spinach—9000 mg/100 g.”

“We have seen some interesting research demonstrating the use of nitrate in the form of beet juice or beetroot powder in positively impacting vascular and muscle function via nitric oxide production during workouts or athletic competition,” said Sid Hulse, director of new product development, PLT Health Solutions, in a press release. “What we see with beetroot powder and beet juice is that they have relatively low levels of nitrate in a typical serving and that these levels can vary widely based on where and how the plants were harvested and processed.” Also, Hulse added, Oxystorm is sugar free, whereas many beet-based products contain relatively high amounts of sugar.

In 2013, a study published in The FASEB Journal looked at the effects of methylsulfonylmethane (MSM) supplementation on 23 moderately exercised-trained men and found that supplementation may help reduce muscle soreness by way of increasing antioxidant capacity. More recently, in August, new study results presented by University of Memphis researchers indicate that MSM supplementation may help quicken joint recovery following knee-damaging exercises such as downhill running. The researchers studied the OptiMSM brand from Bergstrom Nutrition (Vancouver, WA).
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LEMON VERBENA EXTRACT MAY HELP ATHLETES SLEEP, RECOVER

New research7 suggests PLX, an extract from lemon verbena (Aloysia triphylla), may provide both mental and physical benefits to athletes recovering from exercise.

Researchers at the University of Miguel Hernandez of Elche (Alicante, Spain) conducted the study, which was commissioned by PLX-supplier Monteloeder (Alicante, Spain).

According to Monteloeder, researchers found that, compared to a placebo treatment, athletes who consumed 1.2 g of PLX per day for 21 days slept longer each night, reported less muscle pain, and had reduced levels of key blood markers for oxidative stress and inflammation that can inhibit recovery.

“In general, most sports supplements offering recovery benefits focus only on physical factors,” said Fernando Cartagena, global head of marketing, Monteloeder. “However, as any sports psychologist will tell you, there is more to it than just muscular pain. By improving sleep patterns and reducing anxiety and fatigue, PLX also enhances the mental recovery that is essential for sporting success.”

MSM’s benefits for joints are largely due to its high sulfur content, which helps maintain joints, tendons, ligaments, and other connective tissue. According to Rodney Benjamin, director of research, development, and technical support at Bergstrom Nutrition, the new University of Memphis study, which is now undergoing peer review, further illuminates MSM’s potential in the sports nutrition space.

“The new study looked at trained individuals and reinforced the potential benefit of MSM attenuating muscle soreness following exercise,” he says. Compared to the earlier The FASEB Journal study, he says, “there are some differences found in this study that suggest there may be additional mechanisms at play that fall outside of increased antioxidant capacity. This new study will also include some performance measurements, a component that was missing in the earlier studies,” not to mention the fact that the new study was conducted for much longer and in more subjects. Bergstrom Nutrition will continue exploring sports opportunities, he says, with studies in marathon runners and in downhill runners.

Last December, BioCell Technology (Newport Beach, CA) published a proof-of-concept study9 on the potential of its joint- and connective tissue. According to BioCell Technology, the study, which was commissioned by BioCell Collagen (Clearfield, UT) showcased a powdered-beverage version of its magnesium lysinate glycinate (MLG) ingredient targeting sports. The lysine in MLG helps increase muscle synthesis and provides energy for endurance, but it also plays a role in collagen synthesis, said Albion consultant Max Motyka. “Lysine is a component of collagen, and when you increase lysine intake, you increase collagen formation,” he said.

Chondroitin sulfate, major in joint health, also shows promise for sports, says Deanne Dolnick, science director for TR Nutritional (Alpharetta, GA). “Chondroitin sulfate has always played an important role for athletes. Just because somebody focuses on purchasing sports nutrition–type supplements does not mean that they don’t also purchase supplements being used by the general population,” she adds.

“Consumers are becoming increasingly health conscious, but are no longer interested in taking yet another pill,” says Ganeden’s Bush. “They want the health benefits of probiotics while consuming foods and beverages they already enjoy and without having to adjust their daily routine.”

Going forward, EXOS’s Carlson-Phillips predicts that the one-size-fits-few approach of yesterday’s sports nutrition market will only continue to shrink, making room for even more customizable, personalized options in the supplement aisle.

“Consumers are shifting focus to improved recovery, less pain, and optimized energy, all of which relate to improved performance,” she says. “The next trend will be around understanding your own physiology through easy accessible diagnostics and then the personalized programming and products that come from that knowledge.”

**Delivery Systems Matter, Too**

The non-protein supplement shopper also has a very different preference when it comes to delivery. Euromonitor noted in a recent report that even though energy concerns have always had their place in the sports nutrition market, many of the delivery systems traditionally associated with these supplements (think bulk powder formats) are unappealing to casual users. Drinks and foods, particularly, are making headway with this segment because they’re grab-and-go and already fit within consumers’ lifestyles.

View references online at NutritionalOutlook.com/sportsnutrition/1511

Melissa Kvidahl is a freelance journalist and copywriter specializing in the health and wellness industry.
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Current Trends in Sports Drinks

New flavors, “healthy” energy, and clean labels help sports drinks keep up with the times.

BY MAUREEN KINGSLEY

Sports performance products come in many forms: bars, powders, ready-to-drink formulas, and sports drinks. Among these, sports drinks such as Gatorade, which focus mainly on rehydration and recovery, and ready-to-drink (RTD) versions of powdered mix-in supplements are currently the most dynamic in the market, with sports drinks leading the entire Nutritional and Performance Drinks category, according to reports from market research firm Mintel. But across all segments of the sports nutrition market, a few other trends are also evident.

First, Sprinting Demand for Sports Drinks
Sales of all nutritional and performance drinks grew by 42% in the United States from 2009–2014 (29% when adjusted for inflation), according to Mintel’s January 2015 report on the market, with sports drinks in particular leading the way. (Mintel groups nutritional drinks—those offering nutrition and convenience and that fill a specific nutritional need—together with sports and performance drinks.)

The sports drink segment “benefits from a high perception of good flavor, affordability, and an interest in the products among general consumers, including non-athletes,” the report states.

A full 60% of U.S. adults consume sports drinks, Mintel reports, and not all of these consumers are athletes. This “broadening of usage occasion” will be important to the category in general, the firm adds, feeding trends such as blurring boundaries between hydration beverages (which are marketed to a broad swath of the population) and sports drinks, which have historically targeted athletes.

Clean Label and Label Transparency
Following today’s demand for clean label, sports nutrition companies are placing renewed focus on transparency regarding what ingredients the products contain. “A lot of brands are moving away from proprietary blends of ingredients toward what I call ‘open label,’” says Chris Schmidt at Euromonitor.

Lu Ann Williams of Innova Market Insights points to chia and beetroot as two ingredients perceived as very healthful that are now being used in sports nutrition powders, and she adds that organic protein ingredients are currently trending in this market, too.

Launched in June, Orgain’s Organic Hydration powders represent several growing trends in the sports nutrition product space, including a focus on organic and clean-label ingredients and a move towards fruit flavors that appeal to the masses.

Orgain’s new Organic Hydration powders, launched in June 2015, capitalizes on current demands for “clean” ingredients, transparent labeling, and organic protein sources. The company calls the powders the “first-ever USDA Organic hydration powder.” The products are made with organic coconut water; no synthetic vitamins or minerals; organic, food-based B vitamins; and plant-based, gluten-free, soy-free, non-GMO ingredients.
Sports Nutrition Powders Now on the Go in RTDs

“A number of sports nutrition companies have been encroaching on the sports- and energy-drink market with new RTD products” that are reformulations of existing mixable powder-supplement products, says Euromonitor’s Schmidt. This trend, Schmidt adds, began a few years ago with the launch of VPX’s Bang360 energy drink/pre-workout RTD product.

More recently, such companies as Optimum Nutrition and Nutrabolt/Cellucor have launched RTD versions of their intra- or pre-workout formulas, and MusclePharm is “rumored to be launching an RTD version of its Amino 1 intraworkout product later this year,” Schmidt says. “These launches are unique and innovative in that they go beyond the traditional hydration claims of energy drinks like Gatorade and Powerade with their energy-boosting and muscle breakdown-protection ingredients,” he adds.

Powder Products Still Strong

But do not take this to mean that powder products aren’t doing well; these are also still going strong, and according to some, the powder market is seeing resurging interest.

At the recent SupplySide West trade show in October, Dupont Nutrition & Health (St. Louis) cited Euromonitor estimates predicting that the global market for protein supplement powders will garner $2.7 billion in 2015 alone, up 11.3% compared to 2014. The larger sports nutrition powder category is expected to grow to $7.7 billion, up 10.4% compared to 2014.

“If you look back three or four years ago, or even about five years ago, the powder market wasn’t growing as rapidly as it is now,” said Greg Paul, PhD, marketing director, global consumer segments, Dupont Nutrition & Health. “It was more of a mature industry, and things like the bars and the ready-to-drink beverages and more convenient ones were growing faster. But in the last five years, there’s been a rejuvenation of that powder category, with people looking to get more protein in their diet and looking to supplement protein every day into their diet. That’s typically how powdered beverages are consumed.”

To meet this demand, Dupont launched its new quick-dissolve soy protein powder, Supro XT 221D, which disperses in liquid in just nine seconds—faster than any other isolated soy protein powder on the market today, the company says, noting that typically a good-dissolving powder will disperse in 25 seconds, and an average powder will do so in 35–40 seconds.

Minerals supplier Albion Human Nutrition (Clearfield, UT) is also looking to take its ingredients to powders. The firm debuted powder versions of its magnesium ingredients at SupplySide West: 1) for energy, a magnesium lysinate glycinate (MLG) powdered drink, and 2) for sports recovery, a magnesium glycinate glutamine (MGG) powdered drink.
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Magnesium’s profile in the sports nutrition market is growing because it is intrinsically involved in ATP formation and, thus, sports performance, the firm said. The lysine bound to magnesium in MLG has been shown to help increase muscle synthesis, while the glutamine in MGG helps promote the formation of glycogens and muscle tissue and fight muscle breakdown.

Healthy Energy
Formulators looking to provide an energy boost, but with healthier ingredients, are turning to proven alternatives. Take Driv, a new energy recovery and endurance drink mix powder from Fanda Labs.

Instead of caffeine, which the company says “can be dehydrating,” Driv features 2 g of Bioenergy Ribose, an ingredient marketed as “a game-changer for the athlete in all of us,” says Bioenergy Life Science’s (Ham Lake, MN) regional director Marianne McDonagh. “This product is all natural with no added sugar or artificial flavors or sweeteners,” she adds.

Fanda Labs describes Bioenergy Ribose as “a natural, clinically proven 5-carbon sugar that your body uses to make adenosine triphosphate (ATP). ATP is the source of all cellular energy.” Within Driv’s marketing message is evidence of the trend toward less-extreme or even non-athletes consuming sports nutrition beverages, as well as a focus on “clean” ingredients and transparent labeling.

Brands are “changing in the way they formulate and market their products,” adds McDonagh. They are “stepping away from the commonly used ingredients and incorporating all-natural, scientifically proven, FDA GRAS-affirmed ingredients that are proven effective. Consumers today are much more aware of what they are putting into their bodies and research the source of these ingredients and the science behind them.”

With healthy energy in mind, Novel Ingredients (East Hanover, NJ) highlighted its new Kinetiq ingredient at SupplySide West. As an improved version of the company’s previous Advantra Z Citrus aurantium thermogenic ingredient, Kinetiq contains several naturally occurring bioflavanoids which, when combined with Citrus aurantium, showed in a recent study a significant increase in resting metabolic rate of 183 kilocalories over a 24-hour period, according to Jeff Avila, vice president of marketing.

Avila said that today’s sports nutrition consumers are increasingly looking for “stimulant-free” energy, something that Kinetiq provides without increasing heart rate, blood pressure, or affecting the central nervous system or causing “jitters.”

“If I were to really talk about growth, I mean, thermogenics and weight management are always there, but I think in terms of sort of a changing trend, I’d say the focus is more around stimulant-free energy,” Avila added.

Closer to Food
Look for sports nutrition products to become more closely aligned with the overall food market in general. At a conference at SupplySide West, David Sprinkle, research director of Packaged Facts, spoke about how these two markets are converging. As an easy example, he said, more food marketers are looking to boost protein content, such as with Quaker’s Protein Baked Bars.

But sports nutrition marketers are also borrowing from the food industry, including finding flavors outside of classic sports nutrition flavors that will help this category appeal mainstream. Sports marketers are introducing fruity notes like the strawberries-and-cream version of CytoSport’s Muscle Milk. Sprinkle also pointed to products like Clif Organic Energy Food Pizza Margherita energy gel.

PepsiCo’s popular Gatorade G Series Lime Cucumber beverage exemplifies the market trend toward more “natural,” botanical flavors, Innova Market Insights’ Lu Ann Williams adds. “The incorporation of these types of ingredients conveys naturalness and wellness,” she says.

Look for boundaries to blur further between sports nutrition and general food, Sprinkle concluded. “We can see that sports nutrition increasingly fits in the mainstream market overall, because, after all, nutrition is nutrition.”

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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Protein

Aging like an Athlete
Whey protein’s role in the healthy-aging market
BY MICHAEL CRANE, ASSOCIATE EDITOR

There’s no disputing it: protein is one of the most successful categories on the functional food and beverage market today.

According to Innova Market Insights, product claims of being “high in protein” or a “source of protein” appeared on nearly 4% of global food and drink launches in the 12 months prior to July 2015. The power of protein appears to be even greater in the United States, and in the dairy market specifically, where more than 17% of U.S. dairy launches were “positioned on their protein content” in the same 12-month period, says Innova.

One of protein’s biggest players, whey protein, has made a name for itself on the sports nutrition market thanks to its potential benefits in muscle protein synthesis (MPS) and maintaining muscle during weight loss.

But new research and marketing campaigns may be taking whey beyond sports nutrition.

“Developing further from its traditional role as an excellent source of protein for muscle building and recovery for elite athletes, the muscle-related benefits of whey protein are now being transferred to the healthy-aging market,” says Noel Corcoran, sales and marketing director for whey supplier Carbery (Cork, Ireland). “Whey protein ingestion is an effective nutritional strategy to combat the age-related loss of muscle mass, strength, and function known as sarcopenia.”

Early research into whey’s potential to fight against sarcopenia has marketers and consumers looking at whey protein in a new light. Will this be the latest ingredient to expand into the healthy-aging market?

A Growing Problem
Among the older adult population, sarcopenia is a widespread, progressive, and potentially debilitating condition. An estimated 15% of people over the age of 65 and 50% of people over the age of 80 may experience some degree of sarcopenia. Beyond just causing a decline in muscle mass (reported at rates as high as a 2% loss each year after the age of 50), sarcopenia is often associated with physical inactivity, decreased mobility, poor physical endurance, and overall frailty.

Making the situation even more pressing is the fact that sarcopenia affects a slice of the population that is growing, and fast. By the year 2050, the world’s population of people aged 60 years and over is expected to triple.

Here’s where protein comes in. The current recommended dietary allowance (RDA) of protein is 0.8 g per kg of body weight, and studies as far back as 2008 have suggested that almost 40% of people over the age of 70 fail to meet this level of protein intake. High-protein diets have also been found to be associated with reduced instances of sarcopenia in older adults, although research into a causal link is still in the early stages.

But given the prevalence of sarcopenia, the growing elderly population, and the indications that protein intake may be linked to preserving muscle mass and strength, it’s easy to see how there could be a place for protein in the healthy-aging market. And what better candidate than whey, protein’s superstar, to stand up to sarcopenia?

“The problem of sarcopenia is only likely to worsen as a result of the world’s aging population,” says Anne Poulsen, business development manager of health and performance nutrition for dairy cooperative Arla Foods Ingredients (Viby J, Denmark). “This creates a significant opportunity to develop convenient, tasty, and healthy food and drink products that help seniors get more high-quality protein into their diet and prevent or even slow down the development of sarcopenia.”

Preliminary Research
Though the association between general protein intake and sarcopenia has been relatively well-researched, research into a causal link between sarcopenia and protein—and whey protein specifically—is still in the early stages. However, two studies published in 2015 do explore the relationship between a diet high in whey protein and sarcopenia in older adults.

Researchers in the Netherlands recently studied the effect of a supplement high in whey protein, leucine, and vitamin D on muscle mass preservation in obese older adults who were trying to lose weight. The double-blind, randomized, controlled trial followed 80 obese older adults who either took the whey protein/leucine/vitamin D...
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supplement or an isocaloric control supplement 10 times per week for 13 weeks. All participants also followed a hypocaloric diet of -600 kcal/day and performed resistance training three times per week. The experimental supplement contained 21 g of protein, and the mean age of study participants was 63.

Both the experimental and control groups showed similar reductions in body weight and fat mass over the course of the 13-week period. However, while the experimental group experienced an average increase in appendicular muscle mass of 0.4 g, the control group’s average appendicular muscle mass actually decreased by 0.5 g.

The researchers concluded that “a high whey protein-, leucine-, and vitamin D–enriched supplement, compared with isocaloric control, preserves appendicular muscle mass in obese older adults during a hypocaloric diet and resistance-exercise program, and might therefore reduce the risk of sarcopenia.”

It is difficult to draw conclusions about whey protein alone from this study since its effect on sarcopenia symptoms was only studied in combination with vitamin D and leucine, but it’s certainly a promising sign for whey protein as a healthy-aging ingredient.

Also published this year, a new research review examines the breadth of research that has previously linked protein consumption with diminished muscle mass resulting from aging. Again, there is still not enough evidence to establish a strict causal link between whey protein intake and protection against sarcopenia symptoms. The review does, however, provide some compelling circumstantial evidence in favor of whey protein for healthy aging.

“Whey protein has been shown to stimulate MPS to a greater extent than casein and soy protein at rest and following exercise in young and older individuals,” according to the review. Later, the study also notes that higher protein intakes have been found to be protective against weight and lean-mass loss in older adults, and “are positively associated with muscle mass” in older adults.

So if general protein intake is associated with a reduction of sarcopenia symptoms, and whey is the best protein for stimulating muscle protein synthesis, then it certainly seems possible that whey protein may have beneficial effects on sarcopenia.

Future research may establish a more concrete, causal connection between consuming whey protein and staving off the effects of sarcopenia, but in the meantime several companies, as well as the National Dairy Council (NDC; Rosemont, IL), are already getting excited about the potential healthy-aging benefits of whey protein.

“If the growing elderly population doesn’t put more emphasis on muscle mass, strength, and functionality, they run the risk of increased falling, loss of autonomy, and greater dependency,” says Moises Torres-Gonzalez, PhD, director of nutrition research, NDC.
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"Powering up diets with more high-quality proteins, such as whey protein, spreading that protein intake throughout the day, and exercising more regularly are three simple steps for maintaining, and even increasing, muscle mass in older adults."

**Marketing to Seniors**

Many whey protein suppliers have already begun using language about healthy aging in marketing materials, and others, such as Arla Foods Ingredients, have launched new ingredients that are specifically marketed for older consumers.

Earlier this year, Arla launched Nutrilac Ageless, "a new whey protein and calcium ingredient that will enable dairy companies to create yogurts and desserts for active seniors who reject the idea that they are old," says Arla’s Poulsen. She adds that Arla is “predicting a long-term increase in demand for whey protein ingredients suitable for use in products that address sarcopenia in seniors.”

Dairy cooperative FrieslandCampina (Amersfoort, The Netherlands) also sees the potential in whey protein as a healthy-aging ingredient, but suggests seniors may still need to be educated on the potential benefits of whey protein.

“The main challenge in the elderly target group is to communicate the benefits of protein to maintain muscle mass during aging,” says Mieke Acda, nutritionist, FrieslandCampina. “This might also be the reason why elderly nutrition is not widely implemented in the market at the moment.”

**MUSCLE RECOVERY**

Healthy aging aside, an area of growing research for whey protein is its potential to promote muscle recovery after exercise. A recent study, published in the *International Journal of Sport Nutrition and Exercise Metabolism*, suggests that orienteering runners who supplemented their diets with whey protein hydrolysate showed reduced markers of muscle damage and improved in exercise performance over a control group.

For one week, 18 “elite orienteers” participated in 13 exercise sessions as part of the randomized controlled intervention trial. Half of the runners ingested a protein drink before each exercise session and a protein-carbohydrate drink after each exercise session, while the other half ingested only energy and time-matched carbohydrate drinks. Blood and saliva were obtained throughout the week, and participants completed questionnaires about their performance capacity and motivation.

Over the course of the week, researchers observed that the control group experienced a greater increase in serum creatine kinase, a marker of muscle damage, than the protein group. The control group also reported a greater sense of reduced performance capacity than the whey protein group. Both groups participated in a 4-km run on the final day of the trial, and while the control group’s performance did not improve, the protein group did demonstrate improved performance in the final run.

“In conclusion, ingestion of whey protein hydrolysate before and after each exercise session improves performance and reduces markers of muscle damage during a strenuous one-week training camp,” the researchers concluded.

Based on FrieslandCampina’s own research, Acda suggests elderly consumers are “looking for products with an increased protein level that can be easily included in their existing eating habits.” Another challenge in bringing whey protein to the healthy-aging market could be ensuring that new products taste good and can easily be incorporated into the diet of older adults, says Acda.

The early state of the research may also be an obstacle to marketing whey protein for possible benefits against sarcopenia. Brent Petersen, associate director of research, Glanbia Nutritional (Fitchburg, WI), points out that although several research projects are investigating the effects of whey protein on joint health and sarcopenia, “no significant breakthrough results have been published.”

Yet, even if the research is still preliminary, it would appear the momentum has already begun to build behind whey protein for healthy aging.

**Challenges Ahead for Whey**

Aside from branching out into new health areas like healthy aging, what else is in store for the future whey protein market? According to Aude Ragot, marketing manager, Ingredia Functional (Wapakoneta, OH), the biggest challenge ahead for whey is adapting to market trends and finding ways to stand out in the increasingly crowded market of other proteins.

“Indeed, plant proteins are gaining market share and have appeal to certain consumer segments, so it’s important to highlight the benefits of milk proteins compared to plant proteins,” says Ragot. The healthy-aging market may offer the opportunity to do just that. Ragot says, “milk protein, and specifically whey proteins, is one of the most important ingredients used to target active seniors.”

View references online at NutritionalOutlook.com/1511/protein
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A rthritis can take credit for a significant portion of healthcare costs in the United States. By 2030, as many as 67 million U.S. adults over the age of 18 will be diagnosed with some form of arthritis, according to Centers for Disease Control (CDC) estimates; back in 2013, nearly a quarter of U.S. adults had already been diagnosed with the disease.

Osteoarthritis (OA) is by far the most prevalent form of arthritis. Nearly 27 million adults were diagnosed with osteoarthritis in 2005. OA symptoms develop over time, the most common among them joint pain and tenderness, stiffness, and loss of flexibility. Studies suggest that frequent knee pain (resulting from arthritis and other causes) affects approximately 25% of adults, leading to significantly limited function and mobility and adversely impacting quality of life. Risk factors for OA include increasing age, obesity, and the presence of other chronic conditions, such as diabetes, gout, or rheumatoid arthritis.

The cost of dealing with these symptoms is great. Even as far back as 2003, the CDC estimated that medical care and lost earnings resulting from arthritic conditions totaled $128 billion. And, of course, no dollar figure can quantify the impact of lost quality of life those with arthritis face.

**Views on Arthritis Are Changing**

While inflammation plays a big role in autoimmune joint conditions such as rheumatoid arthritis, OA has historically not been considered an inflammatory condition. However, the paradigm through which OA is viewed has shifted dramatically over the years. Researchers now suggest that inflammatory processes localized within joint tissue play a significant part in the progression of OA. Similarly, research is also showing that inflammatory processes play a role in knee pain that occurs as a result of strenuous activity, even when the criteria for OA are not met. Thus, inflammation is an important factor in rheumatoid arthritis, OA, and frequent knee pain and discomfort.

Conventional medicine currently offers no known cure for OA; instead, treatment is aimed at relieving symptoms with acetaminophen and non-steroidal anti-inflammatory drugs. These drugs, however, are not without their risks; worse, they may even accelerate the degradation of cartilage within joint tissue with longer-term use. Thus, natural alternatives that are effective and that don’t come with these downsides are attractive to consumers looking for joint support.

The popularity of glucosamine and chondroitin as natural therapeutics for joint health is well documented; however, these compounds aren’t effective for everyone with OA or non-OA related joint pain. Recent research has illuminated the benefits of several unique and potentially effective brand-name nutraceutical compounds derived from natural sources that may be used in conjunction with glucosamine and chondroitin supplements or as alternatives to these popular choices. These include NEM eggshell membrane, UC-II undenatured type II collagen, and AppleActiv dried apple peel powder.

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Joint Health

A recent multicenter, open-label clinical study led by Ulrich Danesch and colleagues from Germany was conducted to assess the effectiveness of NEM eggshell membrane from ESM Technologies (Carthage, MO) in individuals with knee and hip OA.8 Forty-four individuals aged 18 and over with moderate, persistent knee or hip pain due to OA were included in the trial and were asked to consume 500 mg of NEM daily. The primary outcome measures included changes in pain and stiffness based on a questionnaire derived from the Western Ontario and McMasters University Osteoarthritis Index questionnaire (WOMAC). Individuals were assessed at baseline and then again at 10, 30, and 60 days after initiation of supplementation with eggshell membrane.

Significant reductions in pain were noted with eggshell membrane supplementation at 10 days, and a greater magnitude of pain relief was found at 30 and 60 days. Measures of joint stiffness were also improved at 30 and 60 days, with high physician and patient ratings of treatment effectiveness. More than 75% of individuals showed moderate or significant improvement from baseline by the end of the study period. In addition, the use of acetaminophen as rescue medication (assessed for the 30 days prior to study initiation) dropped substantially after 30 and 60 days in individuals supplementing with NEM. The results of the study indicate that NEM is effective for rapid as well as sustained pain relief in individuals with hip and knee OA.

The study by Danesch and colleagues highlighted above followed earlier human studies conducted in the United States showing efficacy of NEM eggshell membrane for individuals with OA. These studies showed that NEM was also effective in a European population.

One of the earlier clinical trials was a randomized, double-blind, placebo-controlled study in which 60 participants with moderate OA of the knee (the intent-to-treat population) received either NEM (500 mg daily) or placebo for eight weeks.9 The primary endpoint of this trial was the change in overall WOMAC scores as well as changes in the pain, stiffness, and function subscales of the same questionnaire. Individuals were assessed at baseline and again at 10, 30, and 60 days after supplementation commenced. There was a trend towards improvement. The overall dropout rate of the participant group in this study was relatively high and may have contributed to the lack of statistically significant improvements in overall WOMAC and functional improvement scores; however, the pain and stiffness subscales of the WOMAC questionnaire showed significant improvement, resulting in reduced joint pain and stiffness compared to placebo at 10, 30, and 60 days.

This placebo-controlled study came on the heels of two pilot open-label trials in which individuals over the age of 18 with joint and connective tissue disorders consuming 500 mg of eggshell membrane daily for four weeks had significantly improved joint flexibility and reduced overall pain as well as reductions in range-of-motion associated pain10, suggesting substantial benefits of NEM eggshell membrane for joint health and pain reduction.

Recent investigations have focused on determining the potential mechanisms behind eggshell membrane’s joint-health benefits. The clinical effects seen in human studies as well as preliminary in vitro studies indicate that a potential mechanism of NEM is an anti-inflammatory one.

Kevin Ruff and Dale Devore of ESM Technologies and Membrell LLC (Carthage, MO) undertook an exploratory study in rats in which the animals consumed NEM for seven days, and effects on inflammatory cytokines were evaluated.11 The results of the study showed that two major cytokines identified as primary mediators of arthritic inflammation in the early phase, IL-1β and TNF-α, demonstrated trends towards reduction in...
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rats after seven days, while nearly all of the cytokines known to play crucial roles in the pathogenesis of late-phase inflammation in arthritis—including those known to impact cartilage degradation and disrupt chondrocyte activity (cells involved in cartilage synthesis and repair)—were significantly reduced by NEM.

A further rat study conducted at Daejon University in Daejon, South Korea, by Boo Yong Sim and colleagues seems to provide the first evidence of a direct cartilage-protective or-preserving effect of eggshell membrane.12 Rats in which arthritis was chemically induced received NEM at three different concentrations. The results of this study showed that several inflammatory cytokines and cartilage-degrading enzymes were reduced in serum, while the production of nitric oxide and high-sensitivity CRP—markers of inflammation—was also decreased in comparison with controls. In addition, patellar cartilage volume increased significantly in rats given NEM, indicating its benefits for cartilage preservation.

In other research, investigators from Missouri State University in Springfield, MO, found that eggshell membrane actually activates the signaling protein NF-kB in vitro.13 While this may initially seem to be a counterproductive benefit—that NEM activated this protein involved in promoting pro-inflammatory effects—the authors suggest that this preliminary finding may indicate that NEM functions by inducing oral tolerance via activation of NF-kB in the gastrointestinal tract. (Oral tolerance may be induced by repeated exposure of the immune system to an antigen that is taken in from the diet, leading to the body becoming “tolerant” to the substance, preventing the immune system from mounting an unnecessary or inappropriate immune response.) If this mechanism is born out in future research on NEM, it gives greater importance to the comprehensive joint-supportive benefits this natural substance confers.

**UC-II Undenatured Collagen**

UC-II from InterHealth Nutraceuticals Inc. (Benicia, CA) is an extract from chicken sternal cartilage containing approximately 25% undenatured type II collagen. Undenatured collagen is native collagen that is extracted to maintain its unprocessed or natural form.

Data from two recent randomized, double-blind, placebo-controlled studies on UC-II collagen were presented at the 2015 Scripps Natural Supplement Conference in San Diego, California.14 A total of 186 individuals with OA were divided into three groups and asked to consume either 40 mg of UC-II, 1500 mg of glucosamine hydrochloride with 1200 mg of chondroitin sulfate, or a placebo daily for 180 days. The primary outcome measure was a change in WOMAC scores compared to placebo.

The results of the studies showed that UC-II supplementation led to a statistically significant reduction in WOMAC scores versus placebo treatment, with individuals in the UC-II group reporting significant reductions in pain and stiffness, and improved joint function.

An earlier study published in 2009 also supports the beneficial effect of UC-II in OA of the knee joint.15 In this comparative clinical trial, a total of 52 subjects (male and female, aged 40 to 75) with moderate OA of the knee were randomly assigned daily for 90 days to either supplementation with UC-II (40 mg per day, with 10 mg of bioactive undenatured type II collagen) or a combination of 1500 mg of glucosamine hydrochloride plus 1200 mg of chondroitin sulfate. Clinical assessments were conducted on each individual at the initial visit as well as at 30, 60, and 90 days. The assessments included WOMAC questionnaires, pain scores as measured on a visual analog scale, and a functional assessment using Lequesne’s index.

Supplementation with UC-II reduced WOMAC scores by 33% compared to a reduction of only 14% by glucosamine plus chondroitin at 90 days, while pain scores on the visual analog scale assessed at 90 days declined by 40% in the UC-II group versus by 15% in the group taking glucosamine and chondroitin. Furthermore, participants consuming UC-II saw significant improvements then again at baseline and at 7, 30, 60, 90, and 120 days. Forty-six individuals completed the study and were included in the final analysis.

The authors found that supplementation with UC-II led to statistically significant increases in knee extension compared to placebo and to baseline function after 120 days. In addition, supplementation led to a statistically significant increase in time to onset of initial joint pain as measured during the stepmill exertion test versus baseline at both 90 and 120 days. The findings of the study indicate that UC-II is able to improve joint function in healthy individuals experiencing joint pain with strenuous activity.

In discussing the potential mechanism of action of UC-II for joint-health issues, the authors point to evidence indicating that the substance works via an oral tolerance mechanism by desensitizing the immune system from mounting an inappropriate immune response, resulting in a localized decrease in inflammation in the affected joint. In fact, earlier investigations into UC-II and its effects in individuals with rheumatoid arthritis, an autoimmune condition, demonstrate...
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its ability to function via an oral tolerance mechanism.\(^\text{16}\) Given the relatively small dose required for benefits, it seems that modulating the immune response to reduce localized joint inflammation is indeed also the way in which UC-II benefits joint health in OA and in healthy individuals with joint discomfort.

**AppleActiv Dried Apple Peel Powder**

Apples contain a variety of phytonutrients that confer health benefits. The peel of the apple contains the highest concentration of such antioxidant-rich polyphenols and flavonoids.\(^\text{17}\) AppleActiv, an ingredient from Leahy Orchards Inc. (Franklin, QC, Canada), is an organic dried apple peel powder.

A recent pilot study evaluated dried apple peel powder (AppleActiv) for its benefits to joint health and range of motion.\(^\text{18}\) Twelve participants (male and female) aged 45–75 with more than six months of chronic joint pain and decreased joint range of motion in well-defined areas were included in the open-label clinical trial. Individuals consumed 4.25 g of dried apple peel powder daily (divided into three doses per day) for a period of 12 weeks and were monitored at baseline and after 2, 4, 8, and 12 weeks. Comprehensive range-of-motion assessments were conducted at each visit using digital inclinometry.

Range-of-motion improvements occurred rapidly in some joints, while improvements in other joints also were shown to be statistically significant compared to baseline at the 8- or 12-week visit. Moreover, eight of the study participants had an area of primary pain in a joint where range of motion was being assessed using the digital inclinometry. Of these eight individuals, seven showed an improvement of range of motion in the primary joint during the study period, while in six of these individuals, the authors classified the improvement as robust. Pain reduction measured by a visual-analog scale also reached statistically significant levels at four weeks for both the primary and secondary areas of complaint in each individual and continued to improve throughout the 12-week study.

Additional explorations by the authors in the same study aimed to assess the mechanism of action of the apple peel powder in improving joint function and reducing pain. Using an assay known as CAP-e, which is a measure of the ability of compounds with antioxidant effects to show these benefits inside of cells, the authors of the study found the apple peel powder to provide a clear dose response, indicating measurable cellular protection. In addition, serum measures of antioxidant protection were also found to be significant and increased throughout the first eight weeks of the study in individuals consuming the apple peel powder capsules.

Furthermore, the effects of apple peel powder on inflammation were assessed in multiple ways, with results indicating that the supplement inhibits the production of free radicals from polymorphonuclear leukocytes (PMN), a type of white blood cell. The dried apple peel powder also inhibited cyclooxygenase-2 (COX-2) and lipoxygenase enzymes in laboratory assays. (Both inflammatory enzymes contribute to joint inflammation and dysfunction.) Thus, it is likely that both anti-inflammatory and antioxidant benefits are at play here with regard to dried apple peel powder’s benefits on joint function and pain relief.

**Moving Forward**

Joint-health issues, and specifically joint pain and discomfort, are naturally front and center in the minds of those suffering through them. When an individual is in pain, the natural instinct is to do whatever it takes to remove the pain. Thus, symptomatic relief is an important goal for those with OA and other joint concerns.

While comprehensively addressing joint conditions includes addressing the risk factors associated with poor joint health, the armamentarium for natural therapies that address the fundamental experience of pain and discomfort continues to grow. Utilizing these nutraceutical options with existing therapies for joint conditions may have an additive effect. The fact that these natural substances also address long-term goals of a joint-health protocol, including reducing inflammation and oxidative stress, as well as providing structural support to joint tissue, is also a big plus. Furthermore, unlike conventional symptomatic therapies that are often counterproductive to the long-term healing process of the joint, natural solutions have a high degree of safety and deserve consideration for their potential to benefit a chronically suffering population. N

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As we go through life, we run up against some numbers we just can’t forget: a key anniversary, a child’s birth weight, the final score of our home team’s Super Bowl win, our trusty SSN. Increasingly, though, we’re adding a few more figures to these memorable-digits lists, and our cholesterol levels and blood-pressure readings are chief among them.

For good reason: With heart disease accounting for one in every four deaths in the United States each year, per Centers for Disease Control and Prevention (CDC) data, such numbers serve as revealing barometers of cardiovascular health. Yet the high-profile test results only tell part of the heart-health story, for absent amidst the triglyceride counts and HDL/LDL ratios is any quantitative reflection of vascular function.

And that’s a pity. Because the more we learn about what makes a heart healthy, the clearer it becomes that healthy vessels with a healthy endothelium are fundamental to it. True, you may have heard this claim before, as endothelial health seems perpetually poised to go mainstream. But stick with us here, for experts say it’s only a matter of time until endothelial health achieves the breakout velocity it needs to make a difference both to consumers and to the supplement marketers who pursue them.

**Back of the Bus**

As far as Sébastien Bornet, vice president, global sales and marketing, Horphag Research (Hoboken, NJ), is concerned, “Endothelial health is an emerging area of research and innovation, and one to which manufacturers and marketers should devote the same attention as they do to other areas of cardiovascular health.” Yet it remains relegated to a back seat in an increasingly crowded cardiovascular bus. After all, Bornet admits, “not everyone is familiar with endothelial terminology or even knows what endothelial function is.”

If that includes you, here’s the gist: The endothelium is the thin layer of cells lining the inner surface of blood vessels. In addition to acting as a semipermeable barrier between vascular tissues and the contents of its lumen, endothelial cells are also “in charge of managing an intricate and complex mechanism of cell signaling that aids in maintaining homeostasis, helping to repair and assure proper functioning of the blood vessel,” says Jimmy Salas Rushford, MD, a San Juan, PR-based internal-medicine specialist and an advisor to Maypro Industries (Purchase, NY).

If that’s what a properly functioning endothelium does, what happens when endothelial health goes south—as can happen under conditions of oxidation, or when vascular walls become calcified? “Studies have shown,” Salas Rushford continues, “that endothelial dysfunction correlates with the development of cardiovascular events and disorders,” ranging from coronary artery disease, cerebrovascular disease, and rheumatological heart disease to congenital heart disease and venous and arterial disease.

**Keeping a Low Profile**

In light of such dire outcomes, it’s astounding that the promotion and preservation of a healthy endothelium doesn’t get more attention from media, consumers, or marketers than it does. “My personal opinion is that..."
no one has figured out how to effectively communicate the appeal of maintaining or improving endothelial health and function,” posits Harry B. Rice, PhD, vice president of regulatory and scientific affairs, the Global Organization for EPA and DHA (GOED; Salt Lake City).

Another impediment to wider endothelial awareness is the lack of a “rapid, relatively inexpensive test” to measure endothelial function, he adds. “You can go to your family doctor and ask about your blood cholesterol or triglycerides level or blood pressure,” he notes, “but you’d likely get a weird look if you asked about your endothelial health.” This “shows how much we have to learn about endothelial health and function in general.”

Eric Anderson, global vice president, sales and marketing, NattoPharma USA Inc. (Metuchen, NJ), agrees. In addition to blaming “ever-changing diet fads and their effect on cholesterol” for keeping lipid levels in the spotlight, he, like Rice, cites the echo chamber that common medical tests create, noting that although “a simple test to measure one’s cholesterol currently exists and is part of nearly every regular physical, the only current way to measure how calcified one’s arteries are is with a coronary calcium scan.”

### Shifting Emphases

But endothelial health’s prospects for breakout are hardly doomed. Even though “cholesterol has been a centerpiece of heart-health discussions for as long as anyone can remember,” Anderson says, “that’s beginning to shift.”

Some momentum appears to come from a paper1 published this year in *Expert Review of Clinical Pharmacology* that paints oft-prescribed cholesterol-lowering statin drugs as “mitochondrial toxins” liable to harm the heart and vessels by depleting them of coenzyme Q10 (CoQ10) and inhibiting the synthesis of vitamin K2, a cofactor essential to removing calcium from arteries.

“So the conversation,” Anderson says, “is, in fact, changing. But more education is needed to teach Americans about what vascular health means and that addressing optimum vascular function is critical. It’s still not an aspect of cardiovascular wellness that’s top of mind among consumers.”

For his part, Bornet is bullish on endothelial health’s future. “As consumers become more educated about their health, proactively checking whether or not the products they buy contain evidence-based, safe, and efficacious ingredients, they better understand why endothelial health is so important,” he says. “This is why the segment is definitely gaining more attention in the natural-ingredients and supplement market.”

---

Discussions of heart disease can make anyone feel paranoid, what with the risks lurking around every apparent corner. Case in point: If you consider just three common cardiovascular risk factors alone—dyslipidemia, hypertension, and tobacco use—research shows that as many as 47% of Americans exhibit at least one of them.

And there are more risk factors where those came from, including overweight, obesity, hyperglycemia—even the inevitable passage of time. Given that each predisposes a person as much to endothelial disease specifically as to cardiovascular disease more generally, it should come as no surprise that “a large percentage of the population is thus at risk of developing endothelial dysfunction and the subsequent development of atherosclerosis,” says Jimmy Salas Rushford, MD, a San Juan, PR–based internal-medicine specialists and an advisor to Maypro Industries (Purchase, NY).

For those in the supplement industry, the question, then, becomes, “How can we prevent endothelial dysfunction, and if such dysfunction occurs, what can we do to help the body heal?” Salas Rushford concludes. The most obvious answer, he says, is to attack the risk factors most within our control—excess weight, inactivity, smoking—while warding off others like high levels of blood pressure, blood sugar, and blood cholesterol.

Most relevant to industry: “All this should be accompanied by proper nutrition and supplementation with ingredients that help with the pro-inflammatory state that characterizes endothelial damage,” he says.

Antioxidants and Nitric Oxide

To be sure, one attribute that characterizes cardiovascular risk factors is their tendency to promote inflammation, Salas Rushford says. That inflammation, in turn, causes endothelial dysfunction that “may lead to a loss of vasodilator and prothrombotic products,” and it also involves an increased presence of reactive oxygen species, or pro-oxidative free radicals. So it’s promising to note that antioxidants “have been shown to help modulate the capacity of the endothelium to deal with oxidative stress,” Salas Rushford says.

One such antioxidant is a patented, flavanol-rich blend of lychee fruit extract and green tea that’s been processed to convert its native high-molecular-weight proanthocyanidins to more bioavailable, lower-molecular-weight forms. It’s in part thanks to this depolymerization, Salas Rushford says, that the ingredient—trade-named Oligonol and marketed by Maypro—“can provide superior antioxidant activity with higher bioavailability.”

“Studies have shown increases in circulation following Oligonol ingestion, and this is thought to be through the enhancement of nitric oxide production,” he explains. This matters because nitric oxide (NO) is an intracellular signaling molecule that modulates vasorelaxation, endothelial regeneration, and platelet adhesion along the endothelium, among its other functions. Damage to endothelial cells impairs their ability to produce, liberate, and use NO to such an extent that diminished NO bioavailability is a recognized sign of endothelial dysfunction. The upshot, Salas Rushford says, is that compromised NO bioavailability or effectiveness “translates into a more rigid blood vessel and a decreased ability of the endothelium to handle oxidative stress, such as that induced by diabetes or tobacco use.”

Pine Bark Promise

Another antioxidant that improves the endothelium’s NO profile is Pycnogenol, a natural plant extract harvested from the bark of the French maritime pine tree. The ingredient appears to activate an enzyme known as endothelial nitric oxide synthase (eNOS), allowing for a more efficient generation of NO from the precursor amino acid L-arginine.

As evidence of the compound’s efficacy, a study published this year in International Angiology evaluated the level of oxidative stress in 32 hypertensives, 31 hyperlipidemics, and 30 hyperglycemics, half of each group of whom supplemented with 150 mg/day of Pycnogenol and the other half of...
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whom didn’t. (A group of 31 normal subjects participated as a control.) At eight and 12 weeks into the treatment, measures of oxidative stress were significantly decreased in the Pycnogenol subjects, while only minor differences emerged in the controls, indicating that daily supplementation with the ingredient may help improve endothelial function among those with borderline hypertension, hyperglycemia, and hyperlipidemia.

According to Carolina Burki-Sozzi, director of product development, Horphag Research (Hoboken, NJ), the worldwide exclusive supplier of Pycnogenol, the ingredient’s cardiovascular benefits represent its “strongest area of research, as it helps normalize blood pressure and platelet function and improve blood lipids, as well as blood sugar values,” she says. “It does so by increasing the blood vessels’ ability to enlarge when needed, which improves blood flow overall, and helps to reduce blood clots.” Further studies show that it enhances the body’s innate ability to counteract vascular constriction, which “naturally helps maintain blood pressure that is already in the normal range,” Burki-Sozzi says.

“The large percentage of the population is at risk of developing endothelial dysfunction” and atherosclerosis, says Jimmy Salas Rushford, MD.

The Vitamin K Way

NO isn’t the only game in town for improving endothelial function, says Eric Anderson, global vice president, sales and marketing, NattoPharma USA Inc. (Metuchen, NJ). He notes that calcium regulation in the vessels is crucial, too.

“Calcium accumulation in the arteries is an actively regulated process, strongly influenced by matrix Gla-protein, or MGP—the most potent inhibitor of calcification presently known,” he explains. But for MGP to inhibit calcification effectively, vitamin K2 must activate it via a carboxylation reaction. If insufficient vitamin K2 is available to do so, MGP remains insufficiently carboxylated and unable to function. This hampers removal of calcium from the arteries and increases the risk of blood-vessel calcification. Even worse, Anderson says, “Since this process occurs in the vessel wall, it leads to thickening of the wall via calcified plaques—that is, typical atherosclerosis progression—which is associated with a higher risk of cardiovascular events.”

All of which argues for looking at vitamin K supplementation as a healthy hedge. A study, published in Thrombosis and Haemostasis in May 2015, involved 244 healthy,
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postmenopausal women who supplemented with 180 mcg of vitamin K2 in the long-acting MK-7 form (NattoPharma’s MenaQ7) or placebo. Carotid artery distensibility—a sign of a vessel’s elasticity, or ability to stretch or dilate—improved significantly over a three-year period in the treatment group compared to the placebo. "Also," Anderson says, "pulse-wave velocity significantly decreased in the vitamin K2 group, but not the placebo group, demonstrating an increase in elasticity." At the study’s conclusion, the beta stiffness index, a measure of arterial stiffness, in the MK-7 group with high initial arterial stiffness had fallen significantly, whereas the same measure in the placebo group had risen slightly. "Results confirmed that a nutritional dose of 180 mcg MenaQ7 taken daily for three years not only inhibited age-related stiffening of the artery walls but also made a statistically significant improvement in vascular elasticity," Anderson says.

Incidentally, a more recent study, a rat study published in the journal *Nutrients*, hints that MenaQ7 Pure, a synthetic form of vitamin K2 MK-7 that NattoPharma recently added to its MenaQ7 line, may inhibit cardiovascular muscle damage caused by chronic kidney disease. Kidney disease patients often suffer from cardiovascular complications such as calcification of the aorta and coronary arteries, so the researchers created an in vivo rat model system for kidney disease to study MenaQ7 Pure’s effect on cardiovascular health. The researchers found that MenaQ7 Pure supplementation "inhibited cardiovascular calcification and decreased aortic alkaline phosphatase tissue concentrations." They hypothesized that "the protective effect of MK-7 may be related to the inhibition of secondary mineralization of damaged vascular structures." The researchers concluded that, based on the study findings, the ingredient could be a "promising therapeutic agent" in protecting against cardiovascular calcification. "Being able to provide the researchers with our new nature-identical MenaQ7 Pure to add to our growing body of clinical validation marks a true milestone for us," said Hogne Vik, CEO, NattoPharma, in a press release.

At this October’s SupplySide West trade show, Kate Quackenbush, director of communications, NattoPharma, added that, "Most of our studies utilize our natural
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Heart Health Ingredients

As an antioxidant, Pycnogenol, an ingredient derived from the bark of the French maritime pine tree, helps activate an enzyme known as endothelial nitric oxide synthase.

material, MenaQ7, but this was the first legitimate, peer-reviewed publication using the PURE version. So it was good to see. We’ve done bioequivalency studies that have shown our PURE material is equivalent to our original source material, which has been utilized in most of the studies, so this was just another piece of that puzzle showing that we’re going to start doing clinical validation on the PURE now that it’s out to market.” She said the company plans to pursue further studies exploring how the benefits of the synthetic PURE form compare to the benefits of natural-form MenaQ7.

Long Odds for Long Chains?
What about the role of the long-chain polyunsaturated fatty acids (PUFAs) docosahexaenoic acid (DHA) plus eicosapentaenoic acid (EPA)? These omega-3 fatty acids have received praise for delivering all sorts of health benefits, including cardiovascular ones. What aid, if any, can they bring to endothelial function?

More research needs to investigate the role of omega-3 fatty acids in improving endothelial function “before we can come to a more definitive conclusion about their role,” says GOED’s Harry Rice, PhD.

According to Harry B. Rice, PhD, vice president of regulatory and scientific affairs, the Global Organization for EPA and DHA (GOED: Salt Lake City), the jury’s still kinda out. “Although current evidence suggests a possible role for EPA+DHA in improving
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A ROLE FOR HIGH PROTEIN?

BY MICHAEL CRANE, ASSOCIATE EDITOR

Researchers at the University of East Anglia (Norwich, United Kingdom) have found that women who consume high levels of certain amino acids present in meat and plant-based protein may also have lower blood pressure and lower arterial stiffness.

What’s more, the association was similar in magnitude to the impact of other lifestyle risk factors previously studied on blood pressure, such as salt intake, physical activity, alcohol consumption, and smoking, researchers reported.

“Results from previous studies have provided evidence that increased dietary protein may be associated with lower blood pressure,” said Amy Jennings, PhD, lead author of the study. “We wanted to know whether protein from animal sources or plant-based sources was more beneficial—so we drilled down and looked at the different amino acids found in both meat and vegetables.”

The study investigated the link between intake of seven amino acids and the cardiovascular health of 1898 female twins aged 18-75 years with a healthy body mass index. Researchers studied the diet of participants based on food-frequency questionnaires, calculated amino acid intake from the questionnaires, and compared the results with clinical measures of blood pressure, blood vessel thickness, and blood vessel stiffness.

The researchers found that a higher intake of amino acids found in animal sources was more closely linked with lower levels of arterial stiffness, while a higher intake of amino acids found in plant-based sources was especially associated with lower blood pressure.

“We studied seven amino acids—arginine, cysteine, glutamic acid, glycine, histidine, leucine, and tyrosine. Glutamic acid, leucine, and tyrosine are found in animal sources, and a higher intake was associated with lower levels of arterial stiffness,” said Jennings.

“All seven amino acids, and particularly those from plant-based sources, were associated with lower blood pressure.”

Jennings said the most surprising finding of the study was the strength of the association between high protein intake and these markers of cardiovascular health—even rivaling the association of salt intake, alcohol consumption, or physical activity. For arterial stiffness in particular, “the association [observed in the study] was similar to the magnitude of change previously associated with not smoking.”

According to Jennings, the beneficial daily amounts of protein equates to a 75-g portion of steak, a 100-g salmon fillet, or a 500-ml glass of skimmed milk.

The cross-sectional study included twins from the TwinsUK registry. Arterial stiffness and atherosclerosis were measured based on central systolic blood pressure, mean arterial pressure, augmentation index, pulse wave velocity, and intima-media thickness.

In a recent study, women consuming high levels of amino acids from protein had lower levels of arterial stiffness.

And in another study published the same year in Biomedicine & Pharmacotherapy, 10 subjects received either 4 g/day of EPA+DHA or a placebo in a four-week, crossover-design trial. Among other measurements, researchers assessed the participants’ endothelial function using flow-mediated dilation and found that the omega-3 combination reduced endothelial dysfunction compared to the placebo. “While the short-term results look good,” Rice says, “the long-term implications have yet to be determined.”

So at least as far as EPA+DHA is concerned, caution is in order. But still: hope springs eternal. And on the topic of endothelial improvement, Salas Rushford is hopeful.

“Our cardiovascular health is maintained by a very complex and tightly regulated system in which endothelial cells play a crucial role,” he says. “The study of how these cells behave and react to injury will bring to light options for prevention and treatment of many diseases. It’s becoming apparent that nutritional therapies will play a synergistic role with medication and lifestyle modifications in the treatment of chronic diseases.”

View references online at NutritionalOutlook.com/hearthealth/1511

Kimberly J. Decker writes for the food and nutrition industries from her base in the San Francisco area, where she enjoys eating food as much as she does writing about it.
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A trend is persistently growing among consumer advocates to know more about food and dietary supplements, the ingredients added to them, and even the packaging in which the finished product is sold. This call for manufacturer transparency includes a demand for simple to read, “clean” labels, with fewer multisyllabic chemical names and, most specifically, a decrease in the use of preservatives and processing aids.

The U.S. Food and Drug Administration (FDA) feels the heat from consumers as well and has declared its interest in more transparency in all phases of U.S. food production, as described in the recent release (September 17, 2015) of the Food Safety Modernization Act (FSMA) final rule. In the agency’s words, FSMA’s goal is “to better protect human and animal health by helping to ensure the safety and security of the food and feed supply.”

Especially now under FMSA, it is crucial that firms know the basics of ingredient identification. Ahead, we outline some key points.

Specifications: Know Your Ingredient

In order to make a uniform, consistent, and safe product, a manufacturer must have specifications that define each ingredient. Specifications should state characterizing information critical to the identity of the ingredient, such as data on chemical and physical properties. These can be used as a metaphorical “fingerprint” for identification and also provide the appropriate analyses that help ensure the safety of an ingredient by defining the tests to be conducted to analyze for contaminants. A specification sheet should include information on the detection method, along with the acceptance criteria for each test.

In the regulations for the manufacture of dietary supplements, FDA states that individual components of a product should have specifications established to: (1) confirm the identity of each component; (2) ensure that the purity, strength, and composition of any produced final product are met; and (3) place limits on the types of contamination that may adulterate or may lead to adulteration of the finished product.

The guidance for the specifications of ingredients added to dietary supplements is consistent with regulations for establishing the safety of food additives under the food additive petition (FAP) process and, by extension, generally recognized as safe (GRAS) substances, which state that “specifications for identity and purity of the petitioned food additive should be proposed.” The FDA guidance for food additives indicates that the following criteria are necessary to identify, characterize, and define purity of a new ingredient. In FDA’s words:

1. A description of the food additive (e.g., physical form, odor, color, and solubility). For food additives derived from natural sources, the sources themselves should be clearly identified.
2. Identification tests for the food additive, including the method(s) used or reference(s) for a suitable method(s).
3. An assay of purity for the additive, including the method used or reference for a suitable method.
4. Physico-chemical characteristics of the food additive (e.g., ash content, moisture content, melting point, density, refractive index, pH).
5. Parameters related to the particle size, shape, and surface properties of the food additive, as appropriate, if particle size is important for the identity and functionality of the additive.
6. Limits for impurities and contaminants:
   a. A limit for lead should be proposed. In addition, limits for arsenic and heavy metals, such as cadmium and mercury, should be considered when their presence needs to be controlled.
   b. Limits for any known natural toxicants or for microbial contaminants in or on a food additive derived from a natural source should be proposed.
   c. Limits for residual reactants, reaction by-products, and residual solvents should be proposed.

The acceptance criteria for specifications are typically numerical ranges for the described tests, and each batch of the ingredient must fall within these ranges to be considered acceptable for use in production of the final product. Occasionally, specifications comprise qualitative criteria, such as for color or physical form or appearance such as granule or powder and in the case of the latter two, particle size and distribution, etc.

The determination of food additive or
GRAS status is based on the safety of the product, which is determined by toxicity testing conducted on an ingredient with certain specifications. If an ingredient is used in the product that does not meet specifications, there is a chance that it could have toxic contaminants from an alteration in the production process that led to the out-of-spec product. Further, if a substance does not meet specifications of the original GRAS or FAP, it is not considered to be the ingredient that was approved and, thus, FDA considers the ingredient an adulterant.

Examples of specifications for ingredients may be found in the Food Chemicals Codex (FCC), a compendium of nationally recognized standards for the purity and identity of food ingredients. Specifications may be submitted to FCC, but this is only on a voluntary basis. Specifications must be focused enough such that they define and describe the ingredient, but not so unreasonably strict that a significant number of individual batches would need to be discarded for reasons that are not of a safety concern. An example of a hypothetical specification sheet for a novel food oil is provided in Table 1 on page 70. For food additives, FDA requests that five batches be evaluated (three of which are nonconsecutive) and meet the specifications. These “batches” do not need to be commercial-size production batches, but can be a smaller, “pilot plant” size; however, “bench-top”-type batches may not be truly scalable and may not represent commercial production run. The request for the batch analysis is to determine if the company can consistently produce an ingredient that meets the specifications the company has set for itself.

The evaluation of the specifications for acceptance of an ingredient is only as good as the analytical method that is followed; that is, if the method provides inconsistent results, less of the ingredient will meet the overall specifications, ultimately increasing both production timelines and financial loss. The methods used to verify that ingredient specifications have been met must also be shown to be valid for the specific ingredient matrix: analyses for phytosterols in a fruit extract may not be appropriate for determining the level of phytosterols in a microalgal concentrate, for instance. Therefore, FDA also requests that methods used in determining specifications must be validated for the specific use. Validation in this context means that the analytical methodology is accurate, specific, and reproducible for the specific matrix being tested. A number of different methods have been published by various organizations, including the United States Pharmacopeia (USP) and AOAC International; methods used in the analysis of food specifications do not need to be published, but do need documentation that they have been validated for the particular parameter and the matrix (e.g., oil-based or water-based ingredients).

The importance of a manufacturer’s degree of rigor for specification conformance was
highlighted in a recent FDA warning letter to a dietary supplement manufacturer. While the letter lists numerous violations for a variety of subjects, one that is applicable in the present context is the lack of label specifications for the supplements the firm packaged, labeled, and held. FDA made clear in the letter that the firm had an obligation to ensure that products conformed to established specifications. Further, the firm failed to examine supplier information on shipments, which led to a separate violation, as one of the packaged products was voluntarily recalled due to an undeclared drug ingredient—another example of the importance of verification of the identity and purity of the ingredient.

**Verification and Validation**

Verifying that the ingredients being used in the production of your food or supplement product is only one small, but integral, aspect of the increased level of transparency being required by consumers and FDA. The core concept of the FSMA final rule is to utilize science-based preventative controls throughout the food supply, a main component of which is extensive use of ingredient and final product tracking and analysis, along with documentation of the company-established control mechanisms to limit food contamination (i.e., preventative control rules). Under FSMA, product testing must be scientifically valid and must identify the test(s) conducted, including the analytical method(s) used. In addition, both food and dietary ingredient suppliers will be required to have a written plan that: (1) evaluates hazards that are reasonably likely to occur in their ingredients, such as pathogens, allergens, and contaminants; (2) outlines the steps that will be put in place to minimize or prevent hazards from occurring; (3) specifies how these controls for hazard mitigation will be maintained; (4) maintains routine monitoring records and; (5) details what corrective actions will be taken when necessary.

FDA uses the terms **verification** and **validation** within the FSMA final rule employing specific definitions that are not commonly used in daily vernacular. Under the FSMA definition, verification is intended to ensure that controls taken during risk-reduction activities are effective. Verification is described, in part, as “validating with scientific evidence that a preventive control is capable of effectively controlling an identified hazard.” Product testing can be considered a verification activity. Validation is a subset of verification and focuses on giving scientific basis to a preventive controls plan to ensure that the plan is effective in controlling food hazards. FDA requires that all preventive controls listed in a food safety plan are validated.

It is important to recognize the subtle differences when addressing different food regulations (e.g., FSMA risk-control activities versus product specifications for food ingredients under FSMA). Analyzing batches of an ingredient to determine if they meet the correct specifications, which define both the identity and safety aspects of a food or dietary ingredient, is an integral part of the FSMA process to continuously verify that there is no potential safety hazard with the ingredients being incorporated in a final product.

**Table 1. An Example of a Specification Sheet for a Hypothetical Oil-Based Ingredient**

<table>
<thead>
<tr>
<th>Analysis</th>
<th>Method</th>
<th>Limits</th>
<th>Average</th>
<th>Range</th>
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<tbody>
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<td>Appearance</td>
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<td>Light yellow</td>
<td>Pass</td>
<td>NA</td>
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<tr>
<td>Moisture (g/100 g)</td>
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<td>&lt; 5.0</td>
<td>2.5</td>
<td>1.0 – 3.2</td>
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<td>Lipid Composition (g/100 g)</td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total polar lipids</td>
<td>31P-NMR + 1H-NMR</td>
<td>10 – 30</td>
<td>13.33</td>
<td>12.3 – 24.1</td>
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<td>Total phospholipid</td>
<td>31P-NMR</td>
<td>2 – 10</td>
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<td>1H-NMR</td>
<td>5 – 18</td>
<td>10.23</td>
<td>7.2 – 15.2</td>
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<td>Fatty acid profile (g/100 g)</td>
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<td></td>
</tr>
<tr>
<td>C20:5ω3 (EPA)</td>
<td>AOAC 963.22</td>
<td>20 – 35</td>
<td>23.35</td>
<td>22.2 – 34.8</td>
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<td>22 – 33.15</td>
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<td>Total fatty acid</td>
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<td>&lt; 5.0</td>
<td>&lt;2.0</td>
<td>0 – 5.0</td>
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<td>Microbiology</td>
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<td>Aerobic plate count (CFU/g)</td>
<td>USP 61, USP 62</td>
<td>&lt;100</td>
<td>&lt;10</td>
<td>&lt;10</td>
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<td>Escherichia coli (CFU/10 g)</td>
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<td>&lt;10</td>
<td>&lt;10</td>
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<tr>
<td>Coliform (CFU/g)</td>
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<td>&lt;10</td>
<td>&lt;10</td>
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<tr>
<td>Salmonella (CFU/25 g)</td>
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<td>ND</td>
<td>ND</td>
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<tr>
<td>Mold and yeast (CFU/g)</td>
<td>USP 61, USP 62</td>
<td>&lt;100</td>
<td>&lt;10</td>
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<tr>
<td>Miscellaneous</td>
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<td>Inorganic arsenic (ppm)</td>
<td>ICP</td>
<td>&lt; 0.1</td>
<td>0.03</td>
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<td>Lead (ppm)</td>
<td>ICP</td>
<td>≤ 0.1</td>
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<tr>
<td>Mercury (ppm)</td>
<td>ICP</td>
<td>&lt; 0.1</td>
<td>&lt;0.01</td>
<td>&lt;0.01</td>
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<tr>
<td>Cadmium (ppm)</td>
<td>ICP</td>
<td>&lt; 0.1</td>
<td>0.01</td>
<td>&lt;0.01</td>
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**Toxicologist Alex LeBeau, PhD, and director of toxicology Ray A. Matulka, PhD, represent the Burdock Group, the leading food safety and regulatory consulting firm headquartered in Orlando, FL.**
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Clean Cocoa

There’s more than one way to meet demand for clean-label cocoa.

BY MICHAEL CRANE, ASSOCIATE EDITOR

Clean-label ingredients are all the rage, but determining what clean label actually means is often challenging. With no comprehensive federal definition to rely on, ingredient suppliers frequently turn to their customers and end-users for a better idea of clean-label priorities.

“Following guidelines of FDA and USDA is important, but listening and responding to customer needs is equally, if not more, important to the success of a natural or clean-label product,” says Stacy Reed, product development manager, cocoa and chocolate, Cargill (Amsterdam, the Netherlands).

But for an ingredient like cocoa, there may be more than one path to a clean-label solution. Which is the best? It depends.

Alkali-Free Cocoa

One strategy to boost cocoa’s clean-label appeal is removing the alkalizing agent, or alkali, that cocoa processors have historically used to mitigate cocoa’s bitterness and improve its solubility. Potassium carbonate, or potash, is one common alkalizing agent.

In August, cocoa supplier Archer Daniels Midland (ADM; Rolle, Switzerland) extended its DeZaan cocoa range with the launch of TrueDark, a dark cocoa powder made completely without an alkalizing agent. ADM says TrueDark is the first dark, non-alkalized cocoa powder, which is especially noteworthy since darker cocoa powders typically require a more intense alkalization process than lighter powders.

Potential alkalizing agents aside, cocoa is otherwise free of additives. “Thus, removing the alkali gives the cocoa a full clean-label status,” suggests Rinus Heemskerk, global innovations director, DeZaan.

ADM believes formulators will be able to offer finished products with enhanced clean-label appeal thanks to its TrueDark powder. But are there any limitations to formulating with non-alkalized cocoa?

Cargill’s Reed chimes in. One challenge could be “being limited to the type of beans used to make the powder or [having to] potentially manipulate the product during the remainder of the process to enable changes in color, flavor, and pH, as alkalizing is a strong contributor to certain aspects of the cocoa product.” Reed says Cargill cannot comment on whether it has plans to create its own non-alkalized cocoa.

The low pH of a non-alkalized cocoa powder may also be an obstacle for food applications like dairy and pudding, suggests Leanne de Muijnck, R&D cocoa director for cocoa manufacturer Barry Callebaut (Zurich, Switzerland). Barry Callebaut has been offering non-alkalized cocoa powder since June.

However, DeZaan’s Heemskerk says ADM’s non-alkalized TrueDark actually requires less formulation adjustment than alkalized cocoa because of its low pH of 5.5.

“Getting the same color and flavor intensity, but without the alkali, can actually prove to be a cure, rather than a cause, of problems,” says Heemskerk.

More Clean-Label Strategies

Looking beyond the topic of alkalization, other ingredients may also play a role in consumers’ perception of cocoa’s clean-label appeal.

Cargill’s Reed suggests cocoa manufacturers consider looking at other ingredients that, while allowed in cocoa processing under the Code of Federal Regulations, consumers might frown upon. For example, lowering sodium levels might be a possibility to clean up the Nutrition Facts panel of cocoa products.

Barry Callebaut’s de Muijnck says the key is for manufacturers to provide a range of natural cocoa powders to meet whatever definition of clean label is necessary for a given formulation. Barry Callebaut offers both alkalized and non-alkalized organic cocoa powders, as well as high-fat and low-fat options.

The search for a cleaner cocoa is on. And with an ingredient as popular as cocoa, this is likely just the beginning.
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