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FEATURES

24 Weight Management
What promise does nutrigenetics hold for weight management?

34 Probiotics
Fascinating frontiers for probiotics science. Plus, debunking five common probiotic myths.

42 Men’s Health
Testosterone support is still going strong in the men’s supplement market.

54 Plant Protein
Protein’s trendiest category looks unstoppable, with more plant-based protein options at formulators’ fingertips.

62 Sweeteners
Added sugars are in the crosshairs of FDA’s revised Nutrition Facts label.
UP FRONT

10 From the Editor

12 News
Industry leaders suggest how FDA should update healthy definition.

COLUMNS

14 Global Regulations
There's a new FDA commissioner in town.

20 Business
The global forces influencing the market for vitamins and dietary supplements

30 Weight Management
Delivery-system challenges for weight-management ingredients

RESOURCES

70 Research Update

72 Advertiser Index

73 Classified

74 Last Bite
Algae

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Is Full Traceability Achievable in Today’s Supply Chain?

Over the past few years, we’ve seen traceability initiatives rolling out from more companies in the dietary supplements space. Why? These firms know that investing in traceability boosts brand credibility, consumer trust—and profits.

In March, I wrote about the latest firm to see the light: retail giant Amazon, whose Amazon Elements dietary supplement line debuted this spring with a heavy emphasis on traceability, right down to the QR codes on the products’ packaging that provide access to extensive product information. In April, I also interviewed smaller brands (smaller than Amazon, anyway) to find out how they built their own traceability platforms. The third and final story in my “From the Editor” traceability series asks this question: Can a company really maintain a grasp on traceability throughout today’s complex supply chain?

This question stems from a conversation I had with Ric Scalzo, founder and CEO of Gaia Herbs, whom I interviewed in last month’s column. You could say that Scalzo knows a bit about traceability. In 2010, long before Amazon launched its Elements line, Gaia Herbs introduced its Meet Your Herbs traceability platform, with on-package QR codes that provide the same kind of extensive product information that Amazon is touting only now, including lot-specific information on purity, potency, certificate of analysis, etc. Scalzo notes that Amazon’s model closely follows Gaia’s. More precisely, he says, “they 100% copied the Gaia Meet Your Herbs platform.”

Scalzo says, “They were the first ones to actually duplicate our position, and yet, when you ask yourself whether [traceability] can be translated across the board for [Amazon] and their private-label manufacturer? Probably not.”

Why is Scalzo doubtful it can work? Namely, due to the modern-day supply and manufacturing chain. Scalzo says Gaia’s strength is that it owns its entire supply chain “seed to shelf,” meaning it has full control over its supply and processing, down to the farming and extraction, testing and production. By contrast, he says, more likely than not, most large companies like Amazon (and small companies, too)—or their private-label or contract manufacturers—are purchasing premade extracts from third-party ingredient suppliers. As such, he says, the ingredient supply chain isn’t always fully traceable by the brand, at least not to the extent that Gaia is.

“Any private-label manufacturer might be able to [trace an ingredient] on one, two, three products where they know that they can control the supply chain and control the extraction themselves,” Scalzo says, “but when you try to apply that principle to an entire brand, I don’t think anyone can do it” without a system like Gaia’s, he says.

“That’s where you lose the trail of command, so to speak,” he says. “They can’t control all of the elements that go into supply, nor will they necessarily be able to do it for every ingredient in every product.”

Is it really true that you need to own your entire supply chain before you can achieve full traceability? Or can you rely on a supplier do that work for you—assuming, of course, that you’re vetting that supplier to ensure your own compliance with Good Manufacturing Practices?

Many suppliers, after all, are making great efforts to highlight how their own traceability initiatives guarantee ingredient quality for their buyers. During the Natural Products Expo West trade show in March, for instance, Cargill (Minneapolis) began wielding its longstanding identity-preservation/traceability program under the name KnownOrigins—a program that the company says invokes traceability back to the ingredient producers and through testing in order to verify non-GMO status. Last year, another supplier, Naturex (Avignon, France), began promoting Trace, the company’s five-step program that involves a battery of test methods, including DNA testing, to affirm ingredient authenticity. During Expo West, Lea Buerman, Cargill’s food safety, quality, and regulatory manager, told me that Cargill’s program “gives our customers the confidence and trust that if Cargill says it’s non-GMO, it’s non-GMO and they can feel confident about putting a non-GMO claim on their package.”

Ingredient suppliers with these types of robust programs certainly are playing a role in helping finished-product companies succeed in their own traceability missions. Scalzo himself acknowledges that if a raw-material supplier can indeed track the supply chain in this way, traceability can work. “If,” he says, “a company goes back to the growers and has all of the input specifications for the growers, and then at the raw-material level that can be carried through all of the extraction phase and up to the finished-ingredient phase, and then you can supply that trail of traceability from the seed all the way up, then yes, [traceability] becomes a doable proposition.”

Traceability is a huge undertaking, and that’s one reason why not all companies do it (or do it well). What makes the notion of traceability additionally complicated, too, is that companies define quality differently, as Scalzo points out. Variations become a problem if you’re trying to implement a traceability program involving many parties where everyone—growers, raw-material suppliers, distributors, manufacturers—needs to be on the same page in order to meet an agreed-upon quality standard. That’s another conversation to be had as more companies invest in traceability and as what we define as traceability evolves.

Jennifer Grebow
Editor-in-Chief
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Industry Leaders Suggest How FDA Should Update Healthy Definition

Last September, FDA officially called for public comments about how the agency should define the term healthy as it relates to food labeling. FDA has said its goal is to revise its definition of the word healthy to reflect current findings in nutrition science. The official federal definition of healthy has not been updated for more than 20 years. Industry associations the American Herbal Products Association (AHPA; Silver Spring, MD) and the Council for Responsible Nutrition (CRN; Washington, DC) recently shared their official public comments to FDA.

CRN’s main concern was that “nutrient contribution criterion” should continue to be used to determine whether or not a food is considered healthy. The association pointed out that the 2015–2020 Dietary Guidelines for Americans (DGA) indicate that many Americans do not get adequate intake of some essential nutrients. As such, wrote Andrea Wong, PhD, CRN’s vice president, scientific and regulatory affairs, in the association’s comments, “Foods that are good sources of underconsumed nutrients should bear the ‘healthy’ nutrient content claim to help Americans structure diets that conform to current dietary recommendations”—especially such underconsumed nutrients as iron, protein, potassium, dietary fiber, choline, magnesium, calcium, and vitamins A, D, E, and C.

She also stipulated that foods that are fortified to provide these same nutrients should also be eligible for the “healthy” claim. Finally, she advised that FDA’s definition should allow products that are not necessarily low in fat but rich in healthy fats like mono- and polyunsaturated fatty acids to use the “healthy” claim.

AHPA, meanwhile, proposed that criteria other than nutrient content should also be considered for “healthy” claims. AHPA argued that foods considered to be part of a “healthy eating pattern” should also merit the claim in order to encourage Americans’ intake of healthier foods. It also noted that the latest DGA seem to reflect this sentiment, stating that “rather than focusing purely on reduction, emphasis should also be placed on replacement and shifts in food intake and eating patterns.”

AHPA also noted that, within this framework, herbs and spices that can substitute for salt, for instance, should be considered a healthy alternative. “Such healthy options to reduce sodium intake could allow herb and spice blends or prepared foods that substitute herbs and spices for salt to bear a claim such as, ‘a healthy alternative to salt,’” proposed Michael McGuffin, AHPA’s president, and Anthony Young, AHPA’s general counsel, in their joint comments on behalf of the association. “The ability to make such claims might provide encouragement for food producers to reduce the sodium content in their products and would assist companies that market herbs and spices to help consumers learn more about these as salt substitutes.”

The same goes for added sugar, they wrote. “AHPA suggests that another legitimate option to sugar-sweetened beverages would be unsweetened teas, including black and green teas and herbal teas, and believes again that companies that market teas would be motivated to provide healthier options if regulations allowed a ‘healthy’ claim, such as ‘unsweetened tea is part of a healthy diet.’

Consumers Think Oral Supplements for Skincare Is Normal, Survey Shows

Lycored (Secaucus, NJ), supplier of ingestible skin-health carotenoid ingredient Lycoderm, says that a new survey the company conducted found that two-thirds of consumers now see the concept of taking a supplement for skincare as normal practice.

The survey was conducted in 480 British and French consumers. Of those surveyed, 66% agreed with the statement, “The idea of taking a supplement for skin health or beauty is normal.” Only 14% disagreed with that statement and felt that it was “not normal.”

Millennials were more likely to have used an ingestible skincare product compared to older age groups. Of those surveyed, 43% (one in 10) of consumers in the millennial group (ages 18–35) said they had used an oral skin-health product. By comparison, 39% of 36– to 49-year-olds, 23% of 50– to 69-year-olds, and 14% of those over 70 said they had used an oral skin-health product. The company also asked non-users why they had never taken a pill or a supplement for skin care. Of those, 46% said the main reason was that, “It seems to make more sense to apply a product to my skin.” And the second most common reason, cited by 32% of respondents, was, “I wasn’t aware I could achieve the same skincare benefits by taking a pill or capsule.” Millennials, however, were least likely to cite these as barriers.

Zev Ziegler, Lycored’s head of global brand and marketing for health, said, “Ingestible skincare—once seen as a niche category—is rapidly heading for the mainstream. Consumers, particularly those under the age of 35, are increasingly recognizing the benefits of supplementation for healthy, resilient skin. There’s a very clear generational shift in favor of ingestible skincare, and with further work to inform consumers we can achieve even more.”

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2. Lee, A. et al., (2016). A green and black tea extract benefits urological health in men with lower urinary tract symptoms. Ther Adv Urol. 8(2), 90-96. Recommended Directions of two recommended capsules of one 1000 mg per day of AssurITEA taken as a clinical dose with meals. Suggested Prescriptive Statement: This product contains caffeine. This product is not intended/recommended for children or those sensitive to caffeine, if pregnant, nursing, under physician’s care or taking medications, consult your health care professional before use. The suggested consumption statement is based on statements occurring in the labeling for other plant extracts. Inclusion of this statement or a variation of this statement, will depend on your company’s labeling practices, the composition of the finished product, and its direction for use. © 2017 Herin Industries, Inc. and its group of companies 2017. All rights reserved. ** Trademarks of Herin Industries, Inc. U.S.A.
A New Commissioner in Town

Industry hopes that Scott Gottlieb, the new FDA commissioner, will support existing dietary supplement regulations, ensure consumer access to supplements, and help police bad actors.

BY JENNIFER GREBOW, EDITOR-IN-CHIEF

All eyes are now on Scott Gottlieb, MD, as he takes the helm as FDA’s new commissioner. Based on recent comments Gottlieb has made, leaders of the dietary supplement industry are hopeful that he will maintain existing regulations governing dietary supplements and help to secure consumer access to dietary supplements.

Before the U.S. Senate voted 57–42 to confirm Gottlieb’s nomination in May, Gottlieb underwent a hearing in April of the Senate Committee on Health, Education, Labor, and Pensions (HELP). While much of the committee’s questioning focused on Gottlieb’s former ties to businesses in the pharmaceutical industry, Senator Orrin Hatch (R-UT) asked a question of Gottlieb related to the dietary supplements industry that sheds a promising light on how the new commissioner might approach regulating the dietary supplements industry.

Hatch asked Gottlieb the same question he has asked past commissioner nominees—namely, whether he feels that current regulations overseeing dietary supplements, the Dietary Supplement Health and Education Act of 1994 (DSHEA), provides FDA with adequate authority for regulating dietary supplements. Hatch said, “Every day, millions of Americans safely take one or more dietary supplements. As consumers continue to take greater control of their health, it is important that they have access to safe products that fit their needs. The FDA currently has the oversight authority to remove any product it finds is unsafe and to take enforcement action to remove the product from the market.”

In response, Gottlieb answered: “As someone who uses dietary supplements every day, I believe they serve an important role in health promotion for millions of Americans, and I support consumer access to these products. I believe the regulatory framework established under DSHEA is the right one, and if confirmed, I would commit to enforcing DSHEA, as intended by Congress.”

Past FDA commissioner nominees have also said they support DSHEA, but Gottlieb’s answer stands out because the nominee also said that he not only personally uses dietary supplements, but views supplements as playing a role in healthcare.

“I think generally, with regards to supplements, [the response] we get from either commissioners or acting commissioners is more of, ‘Hey, we’re going to uphold the law,’ and he certainly said that, which we’re very supportive of. We want to see the law upheld,” said Dan Fabricant, PhD, CEO and executive director of the Natural Products Association (NPA; Washington, DC), speaking to Nutritional Outlook in April before Gottlieb’s May appointment. “But he also seemed to say, ‘Hey, there may be a role here for supplements to help this country in its healthcare system.”

Fabricant added that this position aligns with NPA’s own priorities of expanding consumer access to dietary supplements through programs like Flexible Spending Accounts (FSA), Health Savings Accounts (HSA), and the federal Special Supplemental...
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Nutrition Program for Women, Infants, and Children (WIC). “There are things like that where we know that supplements can play a role, and we’re encouraged by the fact that there seems to be some receptivity to that” in Gottlieb’s comments, Fabricant added.

Mike Greene, senior vice president, government relations, for the Council for Responsible Nutrition (CRN; Washington, DC), said in April that CRN was also happy with Gottlieb’s words: “We were so pleased to see his response that he uses dietary supplements every day and feels like DSHEA is a good law, that it gives FDA the tools to enforce the dietary supplement industry.” He said that Gottlieb’s support of consumer access to supplements is likewise positive. “It reminds us that over 170 million Americans take dietary supplement products every year. I think that’s something [CRN] has been very good at in terms of sharing information on Capitol Hill, but it’s good to hear it from Scott Gottlieb, as well.”

Both Fabricant and Greene said that Gottlieb’s former experience at FDA is a benefit. Gottlieb served as FDA deputy commissioner in 2005–2007 during the George W. Bush administration. Prior to that, he served as senior advisor to FDA Commissioner Mark McClellan, MD, and as the FDA director of Medical Policy Development. He is currently a practicing physician and a resident fellow at the American Enterprise Institute, a nonprofit, nonpartisan think tank for issues including economics, education, and healthcare.

“We’re very optimistic,” said Fabricant in April. “I think it’s good in general for the agency to have somebody who understands industry and also understands the FDA. This [will] be Dr. Gottlieb’s second trip at FDA. He knows the agency very well. He also has done quite a bit with different FDA-regulated industries. So I think that makes him very unique in that regard but also very good at the balance that needs to be struck.”

When asked whether he feels Gottlieb would seek to impose stricter regulations or greater FDA authority over dietary supplements, Fabricant said, “I don’t anticipate him wanting to see a change in the laws. I just think he may want to see them being actively enforced, which I think we all do.”

In April, Greene answered the question this way: “I think it’s too early to say that. What we know about Scott Gottlieb is that he’s a smart, dynamic leader. He certainly understands dietary supplement issues, but I don’t know that we could be so bold as to say that.”

As promising as Gottlieb’s statements are for the supplement industry, both Fabricant and Greene said the industry has no reason to
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assume that Gottlieb as FDA commissioner will be in any way lenient on the sector.

“Tere’s no free pass here,” said Greene. “We have to work hard here, just like everyone else, to talk about our policy goals and to talk about the things we’re moving forward.”

Likewise, Fabricant said, “His positive statements don’t get rid of our critics, but at the same time, they do. I think, open the door for those discussions.”

When asked what he hopes Gottlieb will prioritize as FDA commissioner, Fabricant said, “I think the biggest things in terms of our industry and probably others is just making sure that the appropriate resources are being used appropriately—you know, that there is X budget allocated for inspections, and are we getting that number of inspections? If X is the amount allowed for re-inspections, are we getting that number of re-inspections? So those are the first things. Let’s really take an accounting of what’s out there, what’s happening. And then from that, go from there.”

Both Fabricant and Greene said the industry shouldn’t assume Gottlieb will be lenient on industry.

Greene said he’d like to see Gottlieb devote attention to the supplements industry specifically. “I think when you look at all the other issues that exist out there and certainly all the priorities that FDA has to focus on, they don’t always spend a lot of time on dietary supplements,” he said. “I’d like to see more activity on enforcement of dietary supplements, particularly for problem products on the market, and potentially see more of a focus on specifically educating inspectors on the importance of dietary supplement GMPs during their inspections.” He said he thinks Gottlieb would work to ensure the recently instituted FDA Office of Dietary Supplement Programs remains in place, despite any potential future budget cuts.

Of course, Greene acknowledged, “I do know that actions speak louder than words. We’re really happy with some of his words.” How Gottlieb will ultimately deal with the dietary supplements industry remains to be seen. In a press release following Gottlieb’s confirmation, Steve Mister, president and CEO of CRN, offered a statement of support for Gottlieb: “His prior experience at the agency, combined with his medical background and his understanding of industry, all bolster our confidence that he is well-qualified to lead the FDA. Dr. Gottlieb will bring the right balance of concern for consumer safety, focus on product integrity, and protection of consumer access to a wide array of dietary supplement products.” Mister added, “We look forward to working with Dr. Gottlieb and his team at the Center for Food Safety and Applied Nutrition (CFSAN) and the Office of Dietary Supplement Programs.”
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Consumers’ growing interest in preventive healthcare, with the aim of avoiding expensive healthcare costs and living healthier, longer lives, is generating growth opportunities for vitamin and dietary supplement (VDS) firms. VDS consumption has increased due to a variety of factors incentivizing prevention, including a global movement away from hospitalization and the search for more affordable healthcare services for a growing aging population. Looking more closely at sales channels, while e-commerce sales are growing at double digits in many markets, health stores and drugstores are also, at the same time, developing wellness spaces and health-monitoring kiosks.

Retailers, manufacturers, and ingredient suppliers are benefiting from the popularity of wellness and are creating diverse and healthier portfolios to match this new scenario. These companies are also adjusting to a newly connected and more informed consumer who is starting to demand clean-label VDS. At the same time, companies are dealing with increasingly stricter regulatory limitations around health claims and ingredients. Regulatory agencies are paying more attention to health claims, and it is expected the industry is becoming more regulated.

Global and Regional Trends
Euromonitor International classifies VDS as an aggregate of general dietary supplements, vitamins, pediatric vitamins/dietary supplements, and tonics. This includes everything from minerals, fish oils/omega fatty acids, protein supplements, probiotic supplements, eye-health supplements, co-enzyme Q10, and glucosamine to herbal supplements like garlic, ginseng, Ginkgo biloba, evening primrose oil, echinacea, and St. John’s wort. It also includes dietary supplements that are sold in the form of liquid concentrates, shots, oral gels, and energy shot boosters and tonics.

Dietary supplements at large are still the leader of the VDS industry, but pediatric VDS products are outperforming general category growth. And, while OTC drugs still hold the largest value share of the global consumer health market, VDS led growth rates between 2011 and 2016, with the U.S., China, and Japan representing the world’s largest VDS markets.

Pediatric VDS products are outperforming general category growth.

Pediatric VDS products showed the fastest growth during that period. Almost 50% of this growth is due to strong sales in China, where the expansion of a new middle class with rising disposable incomes and increased concerns about food safety all influenced parents’ purchasing habits.

Asia Pacific and North America accounted for almost 80% of global VDS value. Growth in Asia Pacific is driven by the rising middle class with increasing purchasing power and who are more educated and concerned about maintaining lifelong health. In
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North America, one key product influencing growth is probiotic supplements, which are increasingly positioned as beneficial not only for digestion but also for immunity, healthy aging, and other conditions, allowing for broader use scenarios for prevention.

Another interesting market outside of the two leading regions is the Middle East and Africa, whose VDS sales are projected to grow at the fastest global pace between 2016 and 2021.

**Innovation Insights**

The VDS industry has seen trends emerge around whole-food and non-GMO ingredients along with interactive packaging. Pill fatigue and a need for convenience are pushing the VDS industry to increase options that are more snack-like, personalized, and easier to swallow.

Drink shots, sticks, and pouches are generating more interest from consumers, especially among Millennials, along with the rise of membership programs that offer monthly product delivery and access to a health and wellness team.

**Beyond 2017**

A holistic approach to health and prevention will continue to encourage consumers to purchase VDS over the forecast period. However, access to more information and constant connectivity is changing both consumers’ purchasing patterns and what they demand, especially among Millennials. Their search for healthier (i.e., clean label) and more “snack-like” and customized products, in tandem with the rise of online sales, is causing strategy disruption in the VDS industry.

Furthermore, stricter regulatory agencies could further impact health claims by demanding pharma-like evaluations to back claims, or by forcing companies to improve ingredient traceability and transparency. But there is a silver lining here: while this could challenge the industry, it could also increase consumer trust.

Moving forward, technology will continue to influence the whole VDS industry due to developments in medical devices, personalized VDS products, mHealth apps, artificial intelligence, and an empowered mConsumer (mobile consumer) who is more informed by the Internet. At the same time, interest in ancient traditional medicine (e.g., Ayurvedic) will continue to rise and drive this category forward.

These insights are explored in Euromonitor’s new Vitamins and Dietary Supplements (VDS): Trends and Prospects 2017 report.

**Carolina Ordonez** is a consumer health analyst at Euromonitor International, where she provides global insights on the latest trends in vitamins, dietary supplements, sports nutrition, and weight-management and well-being products.
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Could knowledge of our individual genetic variants guide us in making better, more personalized lifestyle choices, including the foods we eat and the dietary supplements we take? And could we leverage this information to mitigate our individual risk of obesity and other conditions? Experts in the fields of genetics, microbiology, the “omics” (including metabo-omics, proteomics, and more) and nutritional science generally say yes—but their opinions differ on what conclusions we can draw now with the information we currently have in this field, and how and when the science will be translatable into meaningful, scientifically sound commercial applications.

“Much more than a trendy buzzword, nutri-genetics “has as its main goal to understand the gene-based differences in response to dietary components and to develop recommendations that are the most compatible with the health status of individuals based on their genetic makeup,” explains José M. Ordovás, PhD, director, Nutrition and Genomics, and professor, Nutrition and Genetics, at the Jean Mayer USDA Human Nutrition Research Center on Aging, Tufts University (Boston). Another way of putting it? “Nutrigenetics is about how individual responses to food are driven by genetic differences.”

Hooman Allayee, PhD, professor, Departments of Preventive Medicine & Biochemistry and Molecular Medicine, at the Keck School of Medicine, University of Southern California (Los Angeles), and president-elect, International Society of Nutrigenetics/Nutrigenomics, adds, “Nutrigenetics asks, ‘Do the DNA differences between any two people make them respond differently to nutrients?’ The concept is based on relating genetic differences at the DNA level to the response to nutritional components.”

This science is poised to disrupt the nutrition field and its blanket public-health guidelines as we now know them, and the potential applications hold tantalizing appeal for industry and consumers alike. “The ultimate personalized nutrition comes, of course, from nutrigenetics,” Ordovás says.

Characterizing the field as “extremely complex,” Ordovás explains that while he and his colleagues have been studying nutrigenetics for decades, it is, in his opinion, “still in its infancy” from a practical perspective.
Early on, progress was limited by more-primitive technology and poor knowledge of the human genome, Ordovás says. Since then, technology has “vastly improved,” and our knowledge of the human genome is better—“though rather incomplete.”

“Still,” Ordovás says, “we have to integrate nutrition and genetics using very solid scientific approaches if we want the field of nutrigenetics to mature and yield meaningful solutions and applications.”

**Nutrigenetics & Weight Management: What We Know, What We Have Still to Learn**

The question, “What do we currently know about nutrigenetics, particularly related to obesity and weight management, and what can we do with that knowledge?” yields varying answers depending on whom you ask. A portion of an American Heart Association statement published in the journal *Circulation: Cardiovascular Genetics* in 2016 and to which both Ordovás and Allayee contributed reads, “Nutrigenomics has the potential to identify genetic predictors of disease-relevant responses to diet, and this potential and its applicability in the context of personalized nutrition have popular appeal. However, nutrigenomics has also been the subject of much hyperbole and has been ascribed much promise, particularly in the arenas of personalized nutrition, functional foods, and nutraceuticals. Unfortunately, the science has not yet fully delivered on this unrealized potential.” The statement does acknowledge “enthusiasm about possible clinical applications” but maintains that “the evidence base remains limited.”

While the tone of that particular statement is one of cautious optimism, Tufts’ Ordovás does, in comments shared with *Nutritional Outlook*, point to “promising findings related to nutrigenetics and weight management,” including research performed at Tufts University that concluded that limiting saturated-fat intake may help promote healthy body-mass index (BMI) especially in people whose genetic makeup increases their risk of obesity.1 (For this study, researchers identified 63 gene variants related to obesity and used them to...
calculate a genetic-risk score for obesity for more than 2800 white adults. Participants with a higher genetic-risk score who also consumed more of their calories as saturated fat were more likely to have a higher BMI, the researchers found.

"Genetic-risk score could be useful in identifying people who are predisposed to obesity and could ultimately lead to personalized dietary recommendations," reads a Tufts press release about the study, which was published in 2014 in the Journal of the Academy of Nutrition and Dietetics.

**All Eyes on FTO**

Several genes associated with risk of obesity have been found in large studies, including FTO, MC4R, TMEM18, KCTD15, GNPDA2, SH2B1, MTCH2, and NEGR1, USC’s Allayee says. The FTO gene in particular is the subject of some studies cited by Ahmed El-Sohemy, PhD, professor and Canada research chair in nutrigenomics, Department of Nutritional Sciences, at the University of Toronto, in comments e-mailed to Nutritional Outlook.

In one of these, "FTO genotype and 2-year change in body composition and fat distribution in response to weight-loss diets: the POUNDS LOST Trial," a randomized, controlled study published in the journal Diabetes in 2012, the authors wrote, "We found that dietary protein intake might modify the FTO variant’s effect on changes in body composition and fat distribution." Specifically, "a high-protein diet may be beneficial for weight loss in individuals with the risk allele of an FTO variant."

El-Sohemy, who founded a company called Nutrigenomix, which provides customers with genetic testing and subsequent lifestyle advice based on test results, says that FTO in particular has also been shown to determine whether a person is more or less likely to lose weight by altering the amount of saturated and unsaturated fat in his or her diet.

"And another factor that has been linked to the FTO gene is metabolic response to physical activity," he adds.

El-Sohemy acknowledges that "the FTO gene alone is not a very strong predictor of whether or not a person will become obese," an opinion with which USC’s Allayee agrees.

"There are just too many factors—social, environmental, genetic, et cetera—that affect a person’s risk. But knowing which version of the FTO gene a person has can help determine whether they are likely to benefit from certain dietary changes, or whether they need to focus on another aspect of their diet," El-Sohemy contends.

Knowing one’s FTO status could also be useful simply as a behavioral motivator for those seeking to lose weight, according to a finding published in the American Journal of Clinical Nutrition this year. Results from the randomized, controlled Food4Me European trial showed that when an individual is provided information about his or her FTO-gene status (specifically, whether he or she carries the obesity-risk allele) in addition to dietary advice, that individual loses more weight than someone provided dietary advice alone.

"That study," explains Allayee, "showed that if you inform people that they are genetically susceptible, and if you give them the genetic info, it makes people more aware, and they are more likely to stick to dietary recommendations," whatever those recommendations may be.

**Beyond FTO: New Research Begins on a Liver-Fat Gene**

Turning their attention to a potential nutrigenetic association within a segment of the pediatric population, Allayee and colleagues are currently recruiting participants for a study that examines whether reducing sugar consumption in children at genetic risk for developing fatty liver decreases their amount of fat in the liver at the end of six months.

"Fatty liver is a big problem in Hispanic children who tend to be overweight or obese," Allayee explains. "We found that if you carry the genetic variant that increases liver fat [GG genotype of gene PNPLA3], it was especially bad for kids who had a lot of sugar in their diets. That’s another nutrigenetic association."

If the researchers’ hypothesis (that reducing sugar will reduce liver fat in children who carry the risk allele) is correct, there could be valuable clinical applications in terms of personalizing dietary recommendations for these children and their families. "That’s where the field has to go," Allayee says.
Industry Participation

While leveraging existing nutrigenetic findings for the creation of commercial personalized-nutrition and lifestyle products and recommendations is not condoned by some in academia, others disagree and are doing just that.

El-Sohemy’s University of Toronto–based biotech startup, Nutrigenomix, offers a genetic test (made available through participating healthcare providers) that analyzes an individual’s DNA through a saliva sample and tailors personalized dietary and lifestyle recommendations based on the results. The Nutrigenomix test includes 45 genetic biomarkers, including those related to FTO variants and weight management.

El-Sohemy stands behind his company’s product and maintains that there is currently “plenty of evidence to show that we can give specific recommendations for those with the FTO risk variant.” He cites the previously referenced POUNDS LOST Trial as well as another study published in the *Journal of Nutrigenetics and Nutrigenomics* in 2015 that connects a low-carbohydrate, high-protein diet with better weight-management results in individuals with the FTO risk allele. A *Diabetes* piece published the same year analyzed 16,000 children and adolescents from 14 studies and reached the same conclusion, El-Sohemy adds.

Another industry player who is already applying nutrigenetic findings to a commercial personalized-nutrition program is Amway, the direct-selling business based in Ada, MI, that was worth $8.8 billion in 2016. Amway offers a genetic test and subsequent lifestyle recommendations and related food and supplement products as part of its BodyKey by Nutrilite line. BodyKey was launched in the United States in 2013.

Nick Wasmiller, PR lead, Global Media Relations at Amway, explains that the genetic test that is part of the BodyKey Jump Start kit in the United States and Europe is provided by Inherent Health (an Interleukin Genetics brand) and includes gene testing related to weight management. Based on an individual’s test results, BodyKey recommends a particular dietary plan (such as reduced carbohydrates or reduced fat) plus BodyKey food products (such as snack bars) and Nutrilite supplements (such as Nutrilite CLA 500). Forty-nine percent of Amway’s 2016 sales were in the nutrition category, up 3% from 2015, and its Nutrilite line of supplements is one of its top-selling brands.

On the supplier side, BASF Corp. is paying close attention to the field of personalized nutrition and the science behind it, including nutrigenetics. The company offers its Newtrition line of ingredients for supplement brands. The Newtrition line includes, among other ingredients, Tonalin CLA, which the company states on its website is “clinically shown to help reduce body fat up to 10%, while increasing lean muscle mass and preventing fat regain.”

John Helfrick, director, Human Nutrition, BASF Nutrition & Health, North America (Florham Park, NJ), says that BASF “realizes the importance personalized nutrition will have on demand and will continue to innovate with [companies ranging from] startups to major brand owners to support the science and develop novel ingredients to meet evolving needs.” He continues,

Patented extract from black pepper fruit, significantly “improves the gastrointestinal absorption and systemic utilization of nutrients”* that are supplemented. BioPerine’s bioavailability enhancement effect has been well studied with several nutrients such as curcumin, resveratrol, coenzyme Q10, vitamins such as B6, vitamin C and beta carotenes. Optimizing nutrient delivery can go a long way in enhancing the dosage efficiency and health benefits obtained from your formulation.

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"Personalized nutrition offers tremendous opportunities for marketers and manufacturers, and BASF will continue to work with them to differentiate their health-enhancing products."

**Moving Forward**

Opinion is mixed on how much nutrigenetic evidence is required to personalize an individual’s diet and supplementation for weight management, cardiovascular health, and other concerns. “I certainly think there are personal-nutrition recommendations one can give for obesity or heart disease or cholesterol, et cetera,” says Allayee. “But we haven’t figured out which ones those are yet.” Certain recommendations “are not yet ready for prime time,” he adds.

Ordovás says of nutrigenetics in general and weight management in particular, “FTO is one of many genes involved. We need to pool the information from different genes in order to achieve practical solutions.”

And Allayee concludes, “I would say to supplement makers and functional-food brands that clearly there could be very important clinical applications for this field. We’re not at that point yet, but if you are interested in it, then please get involved. Support the academic teams studying nutrigenetics and nutrigenomics; invest in advancing the science.”

El-Sohemy offers a different, perhaps less-conservative perspective: “There’s always the need to say that we need to learn more, and we need to do more research. I agree. But, there comes a time where we need to ask, ‘How much more evidence do we need?’ We currently give advice on what to eat, which is based on ‘old’ science from ten to twenty years ago. If we now have science that enables us to provide better advice for individuals—not just one-size-fits-all for the entire population—then shouldn’t we do that?”

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**Weight Management**

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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Weight management remains a key category of the U.S. dietary supplement market. Recent data from Nutrition Business Journal indicate that weight-management supplements are still among the top 10 of top-100-selling dietary supplements in the United States. As the demand for weight-management products rises alongside a growing obese and overweight population, manufacturers would be wise to understand that product-delivery formats can appeal to consumers as much as the weight-management ingredients themselves. The ease of use and appeal of a dosage form not only influences whether a consumer will regularly use a product; it also greatly affects a supplement’s efficacy and outcomes.

Of the 78 new weight-management supplements Mintel reported launching globally between January 2015 and May 2016, 46% were formulated in capsules. Brand companies are relying on capsules as their delivery form because they are a simple and clean-label approach to supplement delivery. The consumer mega-trends of transparency and authenticity are influencing buying in this category. Claims on some of the major new products speak to naturally nutrient-rich ingredients, non-GMO verification, and minimal processing—promises that capsules can help products make thanks to innovation and technological advancements.

In addition to providing vegetarian and non-GMO consumer choices, hard-capsule technologies can also help manufacturers meet delivery challenges of stability, bioavailability, and taste-masking presented by some of the most popular weight-management ingredients. Ahead, we look at some of the delivery-system dilemmas implicit in weight-management formulating today and how hard capsules provide solutions.

**Resveratrol (Red Wine Extract)**

Resveratrol is a molecule found in the skin of red grapes and in red wine. Researchers have been investigating resveratrol’s potential effect on weight management and its ability to enhance exercise endurance. The resveratrol molecule, however, is prone to degradation if exposed to oxygen, heat, or light, all of which...
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can compromise the supplement’s stability over time.

But stability can be achieved when the extract liquid is encapsulated in a hard gelatin capsule that is flushed with nitrogen before it is fused shut with a hermetic seal in order to reduce oxidative action. The capsule’s opaque shell can also protect the contents from light. Furthermore, because resveratrol has a bitter taste, consuming it via a hard capsule that opens after ingestion eliminates the unpleasant taste if resveratrol is swallowed in straight liquid form.

**L-arginine**

A building block of protein, L-arginine is a precursor of nitric oxide, which causes blood vessels to relax for a positive cardiovascular effect. L-arginine is thought to stimulate protein synthesis when combined with weightlifting and a hyper-caloric diet, and might promote weight management by reducing body fat and increasing lean mass.

L-arginine can be micronized (broken down into extremely small particles)—as well as solubilized—in a free-flowing liquid with a high concentration of active ingredient so that the active is more easily absorbed. Encapsulating this liquid formulation in a hard-shell capsule in a nitrogen-flushed environment and then hermetically sealing it has been shown to maintain stability of this product compared to other forms of L-arginine.

**HMB (β-hydroxy β-methylbutyric Acid)**

A naturally occurring metabolite of leucine in the body, HMB has been shown to increase the synthesis of proteins in skeletal muscle and reduce muscle damage and breakdown post-exercise, helping to support regular exercise and muscle health. HMB in a calcium salt form or a free-acid (FA) form is often formulated into a liquid for drinking.

For greater convenience and bioavailability, however, the HMB-FA form can be encapsulated at a much higher dosage level than the HMB salt form. A dose of up to 500 mg in a colorless, readily absorbable liquid can be stabilized for long-term integrity—even despite the ingredient’s acidic nature—in a hard-shell capsule made of a low-moisture hydroxypropyl methylcellulose (HPMC) vegetarian polymer.

**White Kidney Bean Extract**

Used in weight management as a carbohydrate blocker, this extract has been studied for its ability to inhibit the action of the body’s amylase enzyme, which otherwise breaks starches into sugars for absorption in the body. Supplement manufacturers can maintain vegetarian claims by encapsulating this natural extract of white kidney bean in a HPMC hard capsule as a powder fill or liquid fill.

**Creatine**

Creatine is a compound naturally synthesized within humans and stored in muscle tissue. Creatine restores adenosine triphosphate (ATP), the energy source that the body uses at rest and especially during strenuous exercise. Creatine supplementation has been used to increase the body’s concentration of creatine, with increased creatine consumption linked to the increase of lean body mass over time.

Creatine is highly bioavailable after ingestion, but because a portion of the compound is extremely prone to degradation by stomach acids and enzymes, delayed delivery closer or within the intestines is preferred. An optimized delivery solution is an acid-resistant hard capsule that delays the onset of opening until 52 minutes after ingestion as the capsule is about to leave the stomach.

**Combination of CLA (Conjugated Linoleic Acid) and L-carnitine**

Conjugated linoleic acid (CLA), usually derived from safflower oil, has been studied as an aid in fat loss for the obese and has been shown *in vitro* to inhibit the transformation of nonfat food materials into fat. L-carnitine, in the meantime, is a naturally occurring amino acid–like nutrient essential for fat metabolism and energy production. In combination, it is thought that these ingredients can promote energy production in those deficient in L-carnitine, including the aging population, while supporting fat loss over time.

**BCAA**

Protein, when digested, is broken down into amino acids that the body then absorbs, thus contributing to the anabolic process of muscle building, which is relevant to active exercisers for building muscle mass and for mitigating muscle loss during the aging process. The branched-chain amino acids leucine, isoleucine, and valine are essential amino acids that the body cannot synthesize and that many consumers ingest by way of supplementation.

Manufacturers typically flavor BCAA powders to mask their less-than-desirable taste. An alternative delivery form is lipid multiparticulate (LMP) technology that incorporates the BCAA in a spherical lipid that effectively masks the taste because it dissolves after ingestion, not in the mouth. These LMP microspheres can then be included in a powdered blend in capsules and be included in “sprinkle” capsules designed to be opened up by the consumer, with ingredients then sprinkled onto food such as yogurt.

**Use It to Lose It**

Capsules deliver a host of benefits for the weight-management category: convenience, easy consumption, ingredient enhancement, and clean-label values. Don’t forget that in the eyes of consumers, dosage forms can be just as important as the ingredients themselves.

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Probiotics are a genuine supplement success story. Popular with consumers and clinicians alike, they offer a case study in how foundational science and public health both benefit when researchers work collectively—and exhaustively—to tease out what makes these good gut bugs work. And the more we learn about them, the more they surprise us.

The latest eye-opener: Not only do probiotics have a proven track record of promoting digestive and immune health; emerging findings associate some strains with marked improvements in cognition and cardiovascular wellness, to boot. Though research on the ties linking probiotics with the heart and the head remains in its early stages, the notion that there’s a real “there” there is gaining traction.

And as David Keller, vice president of scientific operations for probiotic-ingredients firm Ganeden Inc. (Cleveland), points out, it makes sense that there would be.

“The digestive tract is considered a main hub in our bodies and has an effect on almost every other vital bodily function—making it crucial that we keep it in balance,” Keller observes. “As interest and awareness around probiotics increases, more extensive research is being done not only on their effects on the health of our digestive systems, but also on their correlation with other functions—including cognitive and cardiovascular.” As the scientific community starts exploring these benefits in greater depth, the heart and the head will be two areas worth keeping an eye on.

Healthy Balance
In fact, the probiotic space already merits attention in general. In a report released last year, Transparency Market Research forecast the global market for probiotics to expand at a compound annual growth rate (CAGR) of 7.40% from 2014 to 2020, rising from a value of US$62.6 billion to US$96 billion over that same time frame.

Yet much of probiotics’ growth remains driven by a focus on gut health, the report concludes. And it’s true that probiotics’ most convincing—and extensively researched—story lies in the gastrointestinal (GI) tract. In particular, the therapeutic use of probiotics in treating diarrhea has significant support, with controlled trials showing that *Lactobacillus GG* can shorten the duration of infectious
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If probiotics promote gut health partly by maintaining a healthy balance between beneficial and harmful microorganisms in the gut, it stands to reason that they may do the same elsewhere among our bodies' ecosystems.
in omega-3s or a decrease in consumption of products rich in omega-6s,” Jager says. But for consumers fond of processed foods made with omega-6-rich oils from the likes of corn, soy, and safflower, that’s easier said than done.

So it’s heartening to learn that a systematic screening of Bifidobacteria present in the GI tract has recognized a number of probiotics capable of converting the omega-6 linoleic acid (LA) into conjugated linoleic acid (CLA), a fatty acid associated with a host of health benefits including those related to cardiovascular disease, high blood pressure, and insulin resistance. Specifically, Jager explains, “B. longum and B. breve were identified to convert LA into CLA very efficiently, with B. longum BL04 DSM 23233 being best in class, with a 93% LA-to-CLA conversion rate.” Probiotic ingredient supplier Probiotical (Novara, Italy) has even patented the use of CLA-producing probiotic strains, Jager notes.

Metabolic Measures
In the first in a series of white papers evaluating the state of science surrounding unconventional probiotic use, the International Probiotics Association (IPA) has also examined probiotics’ role in attenuating the effects of metabolic syndrome, which ropes in a number of cardiovascular conditions, including hypertension, dyslipidemia, obesity, and diabetes. And while the evidence for probiotics taken as a whole remains equivocal at this point, some findings look promising.

Consider, as the IPA’s white paper1 notes, that fermentation with probiotics can produce both milk and soy peptides capable of inhibiting angiotensin-1-converting enzyme (ACE) activity—a key step in controlling blood pressure. The same study found strong evidence supporting probiotics’ ability to lessen hypertension by way of mediating phytoestrogens, too.

The sheer number of research findings mentioned in the paper gives readers an idea just how active an area of inquiry this is—and how probiotics may become another tool in the kit for addressing metabolic syndrome. But again, science takes time, and researchers are still at the start of this and other probiotic journeys. As the IPA states in the paper, metabolic syndromes “reflect a complex tangle of interfaces with the microbiota representing only one part of the multiple factors at play.” With time, those and other probiotic factors may start sorting themselves out.

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

References

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Probiotic health products have never been more popular. Probiotics were the highest-selling ingredient in the U.S. natural channel last year, according to SPINS, and were the second-best-selling supplement in the mainstream channel. According to Euromonitor, probiotics will be the fastest-growing supplement in North America through 2021. Nutritional Outlook named probiotics a 2017 Ingredient to Watch.

With so much hype around these beneficial microbes, it’s all the more critical that probiotic makers cut through the clutter with information that is accurate, truthful, and substantiated by solid science. With this in mind, we asked probiotic-ingredient leader Ganeden (Cleveland) to share five of the most common myths associated with probiotics.

**MYTH #1: FERMENTED FOODS ARE PROBIOTIC**

Given the popularity of probiotics, many fermented foods are touting themselves as “probiotic” and “cultured.” But are consumers getting true probiotic benefits when they consume fermented foods? Not necessarily, Ganeden says, for two reasons:

First, while many of these foods do use naturally occurring live cultures to begin the fermentation process, often these products are pasteurized for a longer shelf life. Pasteurization requires heat that will kill almost all living bacteria, even the good guys.

Secondly, even if the fermented product is raw, meaning it was never pasteurized, it will contain bacteria—but not necessarily bacteria that can be called “probiotic.” The World Health Organization says that in order to be a probiotic, a product must contain “live microorganisms which, when administered in adequate amounts, confer a health benefit on the host.” The organisms used to produce the fermented food most likely have not been studied to show that they provide a health benefit to the consumer, Ganeden says.

**MYTH #2: MULTIPLE PROBIOTIC STRAINS ARE BETTER THAN A SINGLE STRAIN**

Is more better when it comes to probiotic strains? Not necessarily, Ganeden says. The number of strains in a product doesn’t mean much if those strains are not proven to be effective. A studied, single-strain product proven to be effective and viable through its shelf life could outperform an unproven multi-strain blend.

Ganeden adds: “What’s truly important is not the number of strains but rather the quality and safety of a strain in a product. It’s also vital to know how strains interact when blended—some can cancel one another out, for example. Therefore, it is important to use the same level of diligence reviewing blends as it is reviewing a single strain.”

**MYTH #3: PROBIOTICS WORK WHEN APPLIED IN TOPICAL BEAUTY PRODUCTS**

Does a probiotic antiaging topical face cream confer the same kinds of benefits that taking an ingestible probiotic supplement does? “There are a number of challenges to making an actual probiotic beauty product, and it is highly unlikely that any company will be able to produce and legally market any such product,” says David Keller, vice president of scientific operations, Ganeden. According to Keller, here is one important reason why probiotics and topical skincare don’t always mix.
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Probiotics

With so much hype around these beneficial microbes, it’s all the more critical that probiotic makers cut through the clutter with accurate information.

“You need data to ensure that this specific strain survives at adequate levels until the end of shelf life and that it will grow on the skin after application. Dead bacteria are not probiotics!” he says. “Most probiotics are susceptible to the rigors of manufacturing and shelf life, particularly in a topical cosmetic product, and will not survive throughout the long room-temperature shelf life required of these products. Even spore-forming bacteria that may survive will not germinate on the skin to create cells that will have a benefit on the skin. To date, I am not aware of any strains that have been shown to meet these criteria that have been included in a beauty product.”

Another reason relates to FDA itself. According to Keller, a recent FDA warning letter stated that “FDA’s guideline is that the Aerobic Plate Counts (APC) should not be greater than 500 Colony Forming Units (CFU)/g for eye-area cosmetics, and 1,000 CFU/g for all other products.” He says, “Considering that most probiotics require billions of CFUs to be effective, if FDA applied this guideline, it is highly unlikely that the low levels of allowable bacteria above would offer any probiotic activity or skincare benefit.”

According to George Paraskevakos, executive director of the International Probiotics Association (IPA), “The truth is in the science. We have seen published articles and clinical trials with probiotics that vary in range of total CFU. Bigger isn’t necessarily always better, albeit I do feel there is use for larger CFU applications than we have seen in published studies—but I can say the same for the lower CFU counts as well.”

When it comes to determining the ideal number of CFU, science is your best guide, he says. “Ultimately, it is what can be scientifically justified on a strain-by-strain basis and supported by peer-reviewed clinical trials.”

The “Live & Active Cultures” seal is a trademark owned by the nonprofit trade group the National Yogurt Association (NYA). According to NYA, “all manufacturers of refrigerated yogurt whose products contain at least 100 million cultures of Lactobacillus bulgaricus and Streptococcus thermophilus per gram at the time of manufacture, and whose frozen yogurt contains at least 10 million cultures per gram at the time of manufacture” can use the seal.

According to Ganeden, however, products bearing the “Live & Active Cultures” seal may not necessarily be probiotic because it’s uncertain whether probiotic bacteria are guaranteed to be viable by the time the consumer eats the product. The NYA’s criteria is “at the time of manufacture,” meaning that those bacteria were present at the time the yogurt was made. Ganeden points out, however, that depending on the probiotic strain, the beneficial microbes may not survive depending on storage conditions, post-fermentation heat treatment, and other subsequent processing and storing procedures. In addition, it says, not all of these ingredients will have been proven to confer a health benefit on the host—which is the very definition of a probiotic.
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Testosterone support is still a stronghold of the men’s supplements market.

BY JENNIFER GREBOW, EDITOR-IN-CHIEF

“Low T,” a term popularized by commercial TV, has become one of the most successful modern ad campaigns for men’s health. If you believe those “Low T” commercials, the inability to produce sufficient levels of testosterone (a condition also known as hypogonadism—or, in the case of lower production related to natural male aging, as andropause) is likely responsible for a number of men’s present-day health woes, with decreased energy and suboptimal libido among the most advertised.

Research focus around testosterone is gradually moving beyond just energy and libido alone. According to those specializing in the men’s dietary supplements market, attention around testosterone support may be slowly—slowly—extending to the role that healthy testosterone levels play in areas less sensational, but nevertheless extremely important, to male health overall.

Paul Clayton, PhD, chief scientific advisor to ingredients firm Gencor (Irvine, CA), describes the evolving interest in testosterone...
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Men's Health

support. "Interest in testosterone fell back a little after the initial articles (e.g., see TIME magazine's "Manopause?!" cover from August 2014), but then stabilized and has recently seen an uptick due at least in part to the publication of various scientific articles showing that low testosterone is bad for men’s health in a variety of ways, and that returning testosterone in low-testosterone males to physiological levels does not cause adverse effects." He continues, "Male performance is still interesting to a section of the market and likely always will be, but now we see a larger number of men who are more interested in improving their general well-being."

And, increasingly, science continues to support the notion that testosterone does play an important role in general well-being. As Clayton says, "Testosterone exerts multiple effects on the body, and libido/anabolic effects (where the market started) are not necessarily the most important ones."

Testosterone, for instance, is intrinsic to men's bone health. In a recent International Journal of Endocrinology paper reviewing the link between testosterone deficiency and bone structure, researchers explained, "Testosterone has a clear, direct effect on bone health. Testosterone signaling stimulates osteoblasts to form trabecular bone and helps osteocytes prevent trabecular bone loss. This leads to the decreased [bone mineral density] and increased fracture risk seen in men with both primary and secondary hypogonadism."

Testosterone is also increasingly being noted as important to heart health and brain health, Clayton says. It's a theory supported by ongoing research. "This trend is likely to increase," he adds, "as recent work at the University of California, Los Angeles, has shown that restoring testosterone in middle-aged and elderly males is also neuro-protective and likely to find a role in protecting against dementia."

Emerging markets like bone, brain, and heart health are certainly areas where dietary supplement companies will want to lay their bets in the future. For the present time, however, dietary supplement makers report still seeing most success in the market-proven categories of testosterone supplementation—namely, sexual health. Ahead, we take a look at some of the ingredients with new science in this area.

Sexual Health and Vigor

Fenugreek (Trigonella foenum-graecum) remains a leading ingredient in the sex-health category. Gencor’s branded fenugreek ingredient, Testofen, is said to increase energy, sex drive, and general feelings of well-being. Clayton describes how Testofen works to raise testosterone levels.

"There are at least two mechanisms," he says, "I should start by making it clear that Testofen is not a testosterone analogue, but it has been shown to increase free testosterone levels by dislodging a fraction of testosterone in the bloodstream that is bound
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Men’s Health

to serum albumen [a protein in the blood] and hence inactive. This is a novel and very interesting mechanism, which you can describe as ‘re-partitioning.’

The second way in which Testofen and its active constituent—furostanolic saponins—work, he says, is by inhibiting the enzyme 5-alpha-reductase. In doing so, he says, “this second mechanism not only increases free testosterone but also reduces dihydrotestosterone (DHT) in some tissues, providing a second benefit—namely, the alleviation of benign prostatic hyperplasia.”

The company’s latest study published on Testofen backs its testosterone-raising effects. Published in the journal Aging Male last year, the double-blind, randomized, placebo-controlled study was conducted in 120 healthy middle-aged men between the ages of 43 and 70. Researchers found that subjects who took 600 mg/day of Testofen for 12 weeks saw a significant increase in the Aging Male Symptom questionnaire (AMS), a measure of possible androgen deficiency symptoms—that is, low levels of testosterone.

Testofen subjects also saw improvements in sexual function and serum testosterone (both total serum testosterone and free testosterone), leading researchers to conclude that “Trigonella foenum-graecum seed extract is a safe and effective treatment for reducing symptoms of possible androgen deficiency, improves sexual function, and increases serum testosterone in healthy middle-aged and older men.”

According to Clayton, “This trial showed, for the first time, that the negative symptoms of the viropause, another word for andropause, ‘could be effectively managed using a safe and botanical product.”

Ingredients supplier Cepham (Piscataway, NJ) also offers a proprietary Trigonella foenum-graecum extract under the brand name Furosap, which has been shown to boost healthy testosterone levels, sperm profile and morphology, sexual health, mood, and mental alertness in humans, the company says.

The most recent study on Furosap was published this year in the International Journal of Medical Sciences. The 90-day, one-arm, open-label multicenter study was conducted in 50 male volunteers ages 35 to 65. Subjects were given 500 mg of Furosap daily. Researchers found that free testosterone levels improved by up to 46% in 90% of the study population. Also during the study, 85.4% of the study population showed improvements in sperm counts, with sperm morphology improving in 14.6% of volunteers.

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Attention around testosterone support may be slowly shifting from a primary focus on sexual function to the role of healthy testosterone in overall health.

The study findings also extend to other areas of testosterone interest, with researchers noting improvements not only in libido but also in mental alertness and mood in a majority of the subjects, as well as improvements in cardiovascular health.

Overall, the researchers concluded, “the results demonstrate that [Furosap], enriched in 20% protodioscin, is safe and effective in attenuating testosterone levels, healthy sperm profile, mental alertness, cardiovascular health, and overall performance in human subjects.”

In addition to Furosap, Cepham is now supplying BlaMus, a black-musli extract (Curculigo orchioides). The company says it has animal data showing that BlaMus may help boost testosterone levels.

In a recent rat study, researchers found that a 50-mg dose of BlaMus effected significant increases in serum free testosterone after 28 days of supplementation (but no significant increases in serum total testosterone levels). “These data demonstrated that BlaMus may serve as a safe and novel natural testosterone booster and provide broad-spectrum applications in sports nutrition, muscle building, and exercise pathophysiology,” researchers concluded. Cepham says the study (Chopra K et al., “Safety and free testosterone boosting efficacy of a novel Curculigo orchioides extract in male rats”) will soon be published in The FASEB Journal.

HP Ingredients (Bradenton, FL) is another company whose ingredient—LJ100, a studied tongkat ali (Eurycoma longifolia) extract—is assisting men with flagging libido. Standardized to 40% glycosaponins, more than 22% eurypeptides, 30% polysaccharides, and 1% eurycomanone, the ingredient is patented for its ability to combat sexual dysfunction and male infertility. The company says LJ100 is extracted using patented technology that the firm describes as a high-temperature, high-pressure, reverse-osmosis water extraction method.

In the ingredient’s most recent study, in 2014, researchers found that LJ100 (which also markets under the trade name Physta by the company Biotropics Malaysia) was effective in enhancing sexual performance in
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NUTRITIONAL OUTLOOK • JUNE 2017

We Can...But Should We?

Age-related testosterone declines are a normal part of the aging process for men. Critics of today’s testosterone-boosting marketplace argue that instead of using supplemental products to elevate testosterone levels, we should let those declines happen as nature intended. We asked those we interviewed for this story; if declining testosterone levels are a normal part of male aging, should we—either through dietary supplementation or drug/treatment interventions—be attempting to restore testosterone levels to youthful levels? Here are their responses:

Chase Hagerman, brand director for ingredients firm Chemi Nutra (Austin, TX): “Absolutely. Testosterone, libido, and lean body mass aside, I think most people would agree that more vitality is a welcome thing.”

Annie Eng, CEO of HP Ingredients (Bradenton, FL): “Absolutely. ‘Younger’ levels of testosterone promote a healthy outlook via improved or sustained quality of life. Everything in healthy moderation, and that includes dietary supplements such as LJ100; we do not advise our marketing partners to print dosages more than 600 mg per day for men.”

Paul Clayton, PhD, chief scientific advisor to ingredients firm Gencor (Irvine, CA): “This is a profound question and goes to the philosophical heart of modern medicine. There are multiple answers. To begin, how natural is the aging process as it is experienced today? The answer is that it is not natural at all. For example, studies done in the so-called ‘Blue Zones’ [parts of the world where people live the longest] show that the diseases we think of as age-related (heart disease, cancer, dementia, osteoporosis, etc.) do not occur at anything like the rates we see in our society, and are not so much to do with aging per se as the profoundly toxic aspects of the modern lifestyle and the resulting burden we carry of chronic inflammation. Then, if we take another tack, how natural is it to use modern technologies ranging from immunization to dentures and glasses, to motor cars and jet airplanes, to freezers and microwave ovens? There is change, and there is progress, depending on your own values and definitions.

But if we revert to an overall health perspective, the case is simpler. Restoring testosterone levels in males with subnormal levels makes them feel better and is associated with multiple health benefits. And there is a time-specific factor that should be considered here—namely, very good evidence published last year that male testosterone levels are falling and are probably linked to the very significant increase that has been recorded in male sub-fertility and infertility. This is probably due to the same toxic lifestyle factors that have made us so vulnerable to the ‘diseases of civilization,’ and so the debate about what is natural and what is not natural becomes very complex.”

healthy male volunteers in combination with another Malaysian herb, Polygonum minus.

The 12-week, randomized, double-blind, placebo-controlled, parallel-group study was conducted in 26 men aged 40-65 years. The supplementation group received a 300-mg combination of LJ100 and Polygonum minus. Outcomes were measured via validated questionnaires evaluating erectile function, satisfaction, sexual intercourse performance, erectile hardness, mood, and overall quality of life.

“...and an ability to increase energy, enhance sports performance, increase fat-free mass, improve mood state and maintain healthy cortisol levels, and support healthy immunity.

Focus on Energy/Sports Nutrition

Aside from sex health, testosterone boosters are, of course, famous for increasing energy and supporting muscle mass.

“Energy and better maintenance of musculature are two predominant areas of health that benefit from increasing testosterone,” says Chase Hagerman, brand director for ingredients firm Chemi Nutra (Austin, TX). “Lesser-known benefits of testosterone include aiding in recovery following exercise.”

Hagerman says early data from a sports-related study indicate that his company’s SerinAid phosphatidylserine ingredient may help to “normalize” healthy testosterone levels in men.

“In addition to age-related testosterone impairment, testosterone levels can be decreased from physical stress like that of exercise,” he says. He notes that “phospholipids in general, and here phosphatidylserine, are involved in the hypothalamic-pituitary-adrenal (HPA) axis, as is cortisol and testosterone.”

Jeff Lind, vice president, sales and marketing, for ingredients firm Natreon Inc. (New Brunswick, NJ), says his company is focusing on how testosterone’s anabolic effects also relate to muscle mass and strength, supporting a growing role for testosterone-supporting products in the heavy-hitting sports nutrition market. (Gencor’s Clayton points out that testosterone’s role in muscle building also lays ground for a role in combating sarcopenia, or age-related muscle mass.)

“The testosterone market is extremely large, as it plays a significant role in both the men’s health/sexual health segment as well as the sports nutrition segment,” Lind says. Given the continued growth of both the sexual health and sport nutrition markets, he says, “you can see that the testosterone market is healthy and growing.” During the Natural Products Expo West trade show this March, Nutrition Business Journal reported 7.8% and 7.1% year-over-year growth in 2016 of U.S. sports/energy/weight loss and sexual-health supplements sales, respectively—healthy growth indeed.
In fact, in a sort of reversal, Lind’s company, Natreon, is now proposing one of its ingredients originally targeting the sports nutrition and anti-aging market for the male sexual health market. The ingredient is PrimaVie, made from purified Himalayan shilajit, an ingredient used in Ayurvedic medicine. As Lind says, “PrimaVie increases both total and free testosterone in oligospermic [low sperm] subjects as well as in healthy volunteers. Additionally, PrimaVie increases mitochondria, energy, and improves endothelial function.”

In 2016, a 75-subject, randomized, double-blind, placebo-controlled study published in the journal *Andrologia*. The study was performed in healthy male subjects. Researchers found that 250 mg of PrimaVie twice daily for 90 days increased total testosterone, free testosterone, and dehydroepiandrosterone compared with placebo. According to Lind, “This study, along with the previous study in oligospermic males as well as the performance-in-exercise study of healthy volunteers, positions PrimaVie as a leading dietary supplement ingredient for male sexual health as well as sports performance.”

And, further coming back to the concept of overall well-being, Lind says that a recent study published in the *Journal of Medicinal Food* showed that PrimaVie “upregulates the genes responsible for collagen synthesis, making PrimaVie an excellent ingredient in healthy-aging formulations” as well.

**Staying Power**

As of now, interest in testosterone-supporting ingredients continues to keep the men’s supplement industry on a straight course. “Based on our experience, we would say the interest in testosterone-supporting supplements has been steady for the past five years—that is, there has been no notable increase, but no decrease either,” says Chemi Nutrís Hagerman. “Perhaps the most prominent change has been the increase in products that have become market leaders in this category.”

In the long term, Gencor’s Clayton says, shifting attention away from “sensational” positioning and moving toward an overall-health-benefits positioning may in fact be good for the supplement category; for, while it means the increase in product sales may not be as “sensational” as they once were following the “Low T” hype, sales may ultimately be more sustainable down the road.

Testosterone support will always remain a key focus of the men’s supplements market, of course. After all, Hagerman points out, “you could argue it is the only health focus that differs from women’s health.” As such, he says, “testosterone support is certainly one of the essential focuses of health that makes up the men’s health category.”

How that focus around testosterone continues to evolve remains to be seen, but one thing is for sure: its importance to overall male health can’t be underestimated. “Testosterone has versatile functions,” says Cephæ’s Bagchi. “It plays a major role in prenatal development, as well as development of brain, prostate glands, and sex organs. During childhood, testosterone is instrumental in developing brain, hair, and muscle. During adulthood, testosterone plays an important role in sperm development and sexual health.”

Eng of HP Ingredients adds that all of the commercial advertising may in fact have helped men feel more comfortable in ultimately seeking out dietary supplements to support drops in libido. Giving the condition a name like “Low T,” she says, “eases the discomfort or embarrassment previously associated with age-related declines in testosterone (the idea of losing one’s virility or masculinity).”

“The current generation of middle-aged men does not appear at all to be embarrassed because they are overall more aware and understand that their sex hormone levels tend to decline—naturally,” she says, “and, therefore, they are more willing to try products that help them regenerate their own testosterone-producing mechanism,” such as the array of supplements waiting to serve them.

### References


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BY KIMBERLY J. DECKER

In 2013, the 68th UN General Assembly declared that 2016 would be the International Year of Pulses (IYP 2016). And boy, did they call that one. The global pea-protein market alone was set to surpass 12,598.2 MT in volume with a value north of $34.4 million in 2016, per Future Market Insights (FMI) data. And looking ahead, FMI says the pea-protein sector should expand at a CAGR upwards of 11.8% in value and 12.0% in volume as we move toward 2026.

So even as 2016 recedes into the rearview mirror, there’s scant reason to believe that IYP’s time is up. Or, as Jon Getzinger, chief marketing officer, World Food Processing (Minneapolis), says, “It’s probably wise not to crystal-ball this too much, but let’s just say that the year of the pulse is turning into the decade of the pulse.” Yet even that may be too limiting a view of the coming wave. For when you take into account that the global value of the plant-protein market writ large may hit $10 billion and a CAGR of 5.7% by 2020, according to Mordor Intelligence data, the near future might better be called the golden age of plant proteins, period—with room for pulse, soy, wheat, and even algae to establish beachheads. As Getzinger says, “It would certainly appear that this isn’t a short-term trend.” With ingredient options improving dramatically, “The use of plant proteins will continue to gain support among all types of consumers,” he says.
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“The year of the pulse is turning into the decade of the pulse,” says John Getzinger, World Food Processing.

Planet Plant
Plant-derived or not, protein isn’t slowing down. A raft of factors keep it humming, including an increasing global population, rising incomes—which tend to correlate with increased protein consumption,” says Amandas Donohue-Hansen, business development manager, Cargill (Minneapolis)—and a keen awareness of protein’s health benefits. Each is “leading consumers to incorporate more protein into their diets,” she says.

Fortunately for the planet and its inhabitants, plant-based options are increasingly their choices. Notes Neelesh Varde, PhD, senior product manager, Roquette (Geneva, IL), the task of feeding the two billion additional people projected to occupy the planet 30 years from now will put “tremendous strain” on its natural resources. “Since animal-based proteins require much more land and water to produce than do plant-based proteins,” he says, “we’ll have to shift to more plant-based options globally.”

Consumers are getting the message, and the growing ranks of “flexitarians” are leading the shift. As recently as 10 years ago, Varde notes, those flexitarians were dismissed “as vegetarians who cheated or lacked willpower to stick to a purely veggie diet.” Now, he says, they outnumber American vegetarians by more than three-to-one. Their diet, which makes room for both animal and plant protein, “offers a nice alternative for those who want to embrace health but not give up entirely on meat consumption.”

And that embrace of health cannot be discounted as a factor nudging consumers toward plant proteins.

Yes, Peas!
As is the current crop of plant-based proteins, the quality and palatability of which leave its predecessors in the dust. “More options in the plant-based market have emerged,” says Julia Linhart, assistant marketing manager, Cyanotech Corp. (Kailua-Kona, HI), “and that gives consumers more choices that weren’t there before.” Even better, she adds, “Plant-based proteins can taste really good!”

Donohue-Hansen agrees. “Plant proteins continue to improve as producers refine their processing conditions to minimize ‘off’ flavors.” In addition, she says, “by leveraging flavor maskers and through formulation expertise, we’re able to further mask off flavors in the final product.”

Pea protein—premier among pulses—is a principal beneficiary of these improvements. Though “there are vast organoleptic differences among manufacturers,” Getzinger says, “with profiles ranging from incredibly smooth and clean to something akin to a fresh-mown field, the bar is moving up on many plant proteins, and especially pea.”

Varde is bullish on pea, as well. By his reckoning, the raw ingredient doesn’t require fertilizer and actually fixes nitrogen into the soil; and peas “are among the stingiest in their need for land and water compared to other pulses and cereals,” he adds. On the nutrition side, pea protein has a relatively high PDCAAS (protein digestibility-corrected amino acid score) and “has been shown to produce similar results to whey in terms of muscle growth,” he notes.

Even its functionality is a draw, suiting it to a wide variety of applications. Pea “can be extruded into a cereal crisp for use in snacks or nutrition bars, or into a textured meat alternative,” Varde says. “It works well in beverage applications, both RTD and powdered drink mixes. It can function in gluten-free baking mixes or in spreads like peanut butter.” All told, he says, “it makes sense for formulators and consumers alike.”

Give Wheat a Chance
So, too, does wheat protein—which, despite the reputational beating it’s suffered at the hands of gluten-phobes, remains a go-to protein for effective formulation. True, formulators serving a celiac, hypoallergenic, or reflexively anti-gluten market won’t find much use for wheat protein. But product developers not bound by those limits will find it plenty useful, indeed.

After all, says Ody Maningat, PhD, vice president and chief science officer, MGP Ingredients Inc. (Atchison, KS), functional and physicochemical properties are the top attribute that developers look for in proteins—and here, wheat protein has an advantage. Wheat gluten, he says, is “the only plant-based protein capable of exhibiting the unique elasticity and extensibility properties—or viscoelasticity—that are crucial in breads and other bakery products.”

His company makes wheat protein isolates that span the viscoelastic spectrum, with options ranging from those displaying less extensibility (e.g., able to serve as dough strengtheners) to more-extensible proteins fitting the needs of tortillas, pizza crusts, and flatbreads. Textured wheat proteins are classic choices in vegetarian meat analogues, he adds, “and dominate other textured-protein sources in terms of taste and texture.” Their granules, chips, and shreds can be colored to match different animal protein sources and “take on a meat-like appearance and resilient fibrous texture when hydrated,” he says. When unhydrated, they can top sweet goods like cookies or serve as crunchy, protein-dense components in nutritional and protein bars.

And in ready-to-drink protein beverages, Maningat says, lightly hydrolyzed wheat proteins stand out for their water solubility and protein quality—delivering about two times the peptide-bonded glutamine concentration of soy or whey. That gives wheat protein an edge in reducing muscle soreness and in
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Plant protein aiding muscle recovery post-exercise, Manningat says, citing Kansas State University research. Moreover, lightly hydrolyzed wheat proteins are functional, too, reducing mixing times in flour-based doughs.

**In with the New**

There’s something deliciously “old school” about wheat proteins, which—like soy and rice—have never truly left the scene. But with wheat, soy, rice, and even pea nearing or even reaching their “saturation points,” says Rikka Cornelia, product manager, BI Nutraceuticals (Long Beach, CA), alternative plant proteins like fava bean, lentil, and pumpkin-seed “are on the upswing.”

Rillorta adds sacha inchi, hempseed, and cranberry seed proteins to that list. He notes that with brands “looking for ways to give their protein formulations a complete nutrition profile from a variety of sources rather than relying on just pea and rice,” including such up-and-coming options “allows for a way to stand apart from other formulations on the shelf.”

Donohue-Hansen has “definitely” noticed some customers “investing in and seeking unique proteins largely for their novelty and ability to differentiate their products from competitors on the shelf.” In other cases, “the formulator or marketing department is targeting protein claims and fortification, which will require selecting proteins with the best nutritional profile.”

Cecilia Wittbjer, vice president of marketing, Parabel (Melbourne, FL), points to her company’s concentrated water-lentil protein as just such an ingredient. It’s higher in essential and branched-chain amino acids than other plant proteins, she notes, which should be “interesting for formulators.” And with minimal processing taking it from harvest to finished ingredient in 40 minutes, it’s “definitely a farm-to-table product.”

Another minimally processed plant protein, and one that’s squarely on the cutting edge of plant sources, is spirulina, a microscopic blue-green algae. Cyanotech has been cultivating a select strain of this tiny plant, *Spirulina platensis*, for decades and markets it as a protein source providing 2 g of protein per 3-g serving. “Once the spirulina is ready for harvest,” says Gerry Cysewski, PhD, Cyanotech’s CEO and founder, “we send it to be washed with high-pressure fresh water, then to our unique Ocean Chill Dryer, and finally to be turned into a powder or tablet. The whole process from pond to powder takes only 30 minutes and uses no chemical processes. It’s about as clean and pure as you can get for a protein source.”

“Clean and pure” certainly scores points with plant-protein partisans. But there’s a “very real technical motivation to minimize processing of proteins,” Donohue-Hansen notes. Too much can damage the proteins, she says, “adversely impacting their nutritional and functional properties. Finding the right milling, heat, pressure, time, and drying conditions is critical to extracting the plant’s inherent functional and nutritional properties.”

Of course, that’s easier said than done, Cornelia concedes, “especially when it comes to plant-based protein concentrates, which require some processing to concentrate the protein to a useful level.” Her solution: “Switching from a harsher solvent like hexane to water or ethanol can sometimes ‘clean up’ the process and make it more consumer friendly.”

**Putting Protein to Work**

Those aren’t the only tips that protein experts have for optimizing plant-based formulations. Bill Gilbert, certified master baker and principal food technologist at
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Cargill, notes that when proteins hydrate, they compete for water, “increasing the density of puffed cereals, snacks, and baked products.” Years of experience with varying protein sources have given his team a deep understanding of their water-absorption rates, enabling them to “keep the rheology the same so that formulators don’t have to dramatically change the amount of water in their formulas,” he says.

Beyond water management, he notes that proteins can inhibit a dough’s development, “making it stiff and difficult to stretch and sheet, and causing headaches on the production line.” And some plant options still have “unique” flavors that confound efforts to mask, he says. In these cases, “finding the right blend is the real key.”

Cornelia also sees flavor as “the biggest issue” with plant proteins. “Picking a good source with a mild, clean flavor—like fava bean protein—is a great starting point,” she says. “But a good flavor system is paramount, too.” And when it comes to texture, she says that “it’s often helpful to incorporate a fiber or stabilizer to help with mouthfeel” when proteins turn finished products thick, chalky, or powdery—which they sometimes do.

The upshot: “Even the best plant proteins aren’t drag-and-drop solutions,” Varde concludes. “Formulators have to consider the matrix in which the protein’s entering and understand the nutrition and functionality it’s expected to deliver. In a powdered drink mix, you’d need to consider dispersibility and solubility. In RTD, you’d have to look at viscosity increase over time. How do other ingredients affect these parameters? And remember: what works on the benchtop may not work on the plant scale, so there’s a lot of science and craft going into producing a final product.”

Some plant options still have “unique” flavors that confound efforts to mask, says Cargill’s Bill Gilbert.

References

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

IT ALL ADDS UP

Added sugars are in the crosshairs of FDA’s revised Nutrition Facts label.

BY KIMBERLY J. DECKER

Consumers already know that everything from baked goods and barbecue sauce to dressings, desserts, and deli meats can be sugar delivery vehicles in disguise. What they may not know, however, is that some of their favorite functional foods and beverages—products designed expressly to be “good for you”—may be packed with plentiful added sugars, too.

Yet if consumers have been enjoying their protein bars, energy beverages, and even their chewable vitamin gummies in a sort of ignorant-of-the-added-sugars bliss all this time, the scales may fall from their eyes once FDA’s new “added sugars” line starts appearing on Nutrition Facts panels next year.

When it does, fans of functional foods and drinks may be in for an unpleasant surprise. For while sugar levels in functional products “vary widely,” notes Jonathan Hopkinson, PhD, senior applications scientist, DuPont Nutrition & Health (New Century, KS), beverages can be as much as 15% sugar and higher; energy bars are often 30% sugar, or 16 g per 50-g bar; and protein bars and energy shots have sugar levels that regularly top 23% and 30%, respectively, Hopkinson says.

Of course, functional formulators don’t use all this sugar just to trick their loyal consumers. And many brands have been hard at work bringing levels down. But it’s no easy task. In functional formulations and elsewhere, “every ingredient is in there for a reason,” says Andy Estal, technical manager, NAFTA region, Beneo (Morris Plains, NJ). That’s especially so with sugar. “So when you’re trying to reduce the amount of sugar in these formulations, you need to replace it with something, or a combination of ingredients, that has the same attributes as sugar,” he says. And that’s a search that will keep functional formulators busy for some time.

Regulatory Recap

In case you, too, had been blissfully ignorant of the coming changes to the Nutrition Facts panel, let’s recap: Last May, FDA announced that by July 26, 2018, said panels “will require the declaration of the gram amount of ‘added sugars’ per serving, establishing a Daily Reference Value, or DRV, for added sugars, as well as providing the percent daily value,” says Satya Jonnalagadda, director of nutrition, Kerry (Beloit, WI). And lest supplement makers breathe a sigh of relief at having missed the new requirement by that much: they haven’t. “The final FDA Nutrition Facts label rules apply to both conventional foods and dietary supplements,” Jonnalagadda says.

You can’t blame FDA for making the change, as scientific consensus holds that Americans really should reduce their caloric intake from added sugars—a consensus supported by groups as diverse as the American Heart Association, the American Academy of Pediatrics, the Institute of Medicine, and the World Health Organization. And considering that about 13% of the average American’s calories come from sugars, FDA hopes that knowing where those sugars lurk will make it easier for consumers to avoid them.
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Sweeteners

What’s in a Name?
But when you dig into what FDA actually defines as ‘added sugar,’ you realize that such sugars are well-nigh inescapable, even in functional formulas. To wit, FDA deems as “added sugars” those “that are either added during the processing of foods, or are packaged as such,” including “sugars (free, mono- and disaccharides), sugars from syrups and honey, and sugars from concentrated fruit or vegetable juices that are in excess of what would be expected from the same volume of 100% fruit or vegetable juice of the same type.”

While this excludes 100% fruit or vegetable juice concentrate sold to consumers, as well the lactose naturally present in milk, falling within the definition’s scope are brown sugar, corn sweeteners, invert sugar, malt sugar, and molasses, as well as “natural” sugars like turbinado, cane-juice extract, brown-rice extract, agave nectar, rapadura, barley malt extract, sucanat, and palm and coconut syrups.

Such a big-tent classification “has been both a surprise and a source of confusion in the interpretation of the guidance,” Jonnalagadda concedes. “It’ll be very important to provide some clear guidelines for product developers to maintain consistency in how added sugar contents are determined, since there are no analytical methods to determine added sugar content in foods and beverages.”

Wasting No Time
Nevertheless, brands aren’t idly waiting for FDA to provide clarity. And neither are their sweetener suppliers. “With the new guidelines taking effect in 2018, we’ve been inundated with requests for samples and reformulation services,” says Thom King, president and CEO of Stevia Ingredients (Portland, OR). In addition to building out a second lab and purchasing a new facility in July, his company is even completing the development of a direct-compression form of its clean sweeteners for use in chewables and gummies. “There’s been a mass exodus from added sugars to clean-label sweetening systems,” he says, “and we feel this is going to be a huge market for us.”

Pam Staufer, global marketing programs manager, Cargill (Minneapolis), would agree. The coming label change “will shift the paradigm for consumers, and that’s something our customers understand,” she says. Though calories will remain top-of-mind, “the inclusion of ‘added sugars’ to the panel will also have an impact on consumer perception and purchase decisions. More functional food and beverage makers will likely explore reformulations aimed at either targeted levels of added sugar or calories.”

One Ingredient, Many Functions
They’ll have their work cut out for them, As Hopkinson previously mentioned, functional formulations can be hot spots for added sugar. Asked why, he wagers “it could be that sugar has traditionally provided low-cost functionality.” For instance, in bars, “sugars help hold the nuts, chocolate chips, fruits, and seeds together in a coherent bar,” he says. Sugars may also be inherent to the bar’s ingredients—think dried fruits and dehydrated fruit purees, which he says “are very high in sugar.” Sugar can also add gloss or shine to a bar, and helps hold protein bars together while also making them more palatable.

Indeed, as Estal notes, “Sugar is a very functional ingredient in most all food systems where it’s used.” And how.

Its sweet taste is an especially sought-after quality in functional formulations, where “many ‘good-for-you’ products contain ingredients, such as vitamins, minerals, fiber, or protein, which traditionally have associated off notes,” says Teresa Polli, senior marketing communications manager for taste at Kerry. “By adding more sugar, these off notes can be minimized, making the products more palatable and appealing.”

And yet, notes Wade Schmelzer, principal food scientist at Cargill, “sugar is much more than sweetness. In baked goods, it plays critical roles in texture, browning, spread, and preservation. In bars, it aids in binding. In frozen dairy, it plays critical roles in ice-crystal formation and freezing-point depression. And in beverages, it contributes to mouthfeel.”

Particularly important in functional products designed for performance nutrition, “sugar is a rapid source of energy to support physical endurance,” Jonnalagadda adds. And King even notes that sugars “can push supplements into the bloodstream faster.”

The new added-sugars line of FDA’s revised Nutrition Facts label tells consumers how much sugar has been added to a product. This line will appear under the listing for total sugars, which represents both natural and added sugar. Photo credit: Mock-up of label provided by FDA. Label pictured is purely for illustrative purposes to depict how the new Nutrition Facts label might look. Label represents a fictional product.
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Big Shoes to Fill
Given its job description, “We never really talk about completely replacing sugar,” Estal says. “Depending on the application, reducing sugar is a better goal to set.”

And yet even that’s a tall order. Notes Larry Davis, commercial director, food and beverage, Prinova USA (Plano, TX), “It’s an extremely difficult task for a formulator to replace sugar while maintaining the same sensory appeal for the consumer and the same functionality in the finished product.”

Consider sugar’s contribution to bulk and mouthfeel. In a beverage, it may appear as a “macro-ingredient” at 8%–10% of the formula, explains John Buckley, vice president for taste innovation at Kerry; by contrast, the high-intensity sweetener that replaces it “is usually added at less than a percentage.” By simply substituting the high-intensity option for the sugar, “you might be able to replicate the sweetness intensity level,” Buckley says, “but the mouthfeel would be affected and the final product would taste thinner or more watery.” Though formulators may try to adjust the mouthfeel with hydrocolloids or gums, “when used alone these oftentimes fall short of matching the original mouthfeel and can come off as being slimy,” he says.

High-intensity sugar replacements “often have flavor challenges of their own,” Hopkinson adds, which “the developer will need to address along with the original challenges” posed by less-than-delectable functional ingredients. Indeed, getting the flavor to check out may be the paramount challenge of added-sugar reduction.

As Buckley notes, “Taste is very complex, and when you remove a significant piece of that formula—sugar, in this instance—it’s rare that you can add back just one ingredient or flavor to replace it.” This is why working with a seasoned flavorist is key. “There’s an art to being able to balance the ingredients to make something taste great,” he says. “Similar to conducting an orchestra, you can have many different instruments playing together, but if they’re not in tune, it just sounds like noise. Tune them properly and they create a beautiful and memorable performance. The same goes with building a great taste experience in a food or beverage.”

No One-Size-Fits-All
In the end, says Estal, “the aim is to achieve parity” between a reduced-sugar product and its antecedent already on the shelf. “A product’s taste, texture, appearance, or the overall appeal should be maintained to ensure a product’s appeal and attraction to consumers. So the big challenge is finding an ingredient or a system of ingredients that will maintain what consumers are used to, while still trying to remove the sugar.” (And don’t forget: ‘Pretty much any ingredient you use to replace sugar is going to cost more than the sugar did,’ he says.)

That’s why “sweetener-system components must be tailored to meet the needs of the specific product in development,” Schmelzer says. “To achieve sugar-reduction goals in functional foods and drinks, developers need to recreate its functionality by leveraging other ingredients, such as starches, hydrocolloids, or fibers.”

So which ingredients get the job done? “This is a very difficult question,” Hopkinson says. “What could be the best choice in one product could be horrible for another.” Consider a protein bar formulated with antioxidant fruit and nuts. He says it would need a sweetener system “that helps hold the product together by forming a glass or near-glass—a hard, taffy-like consistency.” A combination of intense sweetener and polydextrose could do the trick, binding and sweetening the bar, and, as a bonus, “if the intense sweetener had any ‘off’ flavor, it would probably be covered by the fruit,” Hopkinson adds. Yet this same system would founder in a delicately flavored vanilla protein beverage, “where a sweetener with a strong aftertaste wouldn’t be appropriate” or as easily masked, he says. The lesson: “In each case, the alternative sweeteners or structural carbohydrates must be evaluated for appropriateness for the functional formulation intended.”

Discovering Your Roots
One ingredient that’s received positive attention for its multiple functionalities is chicory.

Added sugars account for almost 270 calories (more than 13%) of most Americans’ daily calories, according to the 2015–2020 Dietary Guidelines for Americans. Beverages account for almost half (47%) of all added sugars consumed by the U.S. population. Other major sources are snacks and sweets, dairy desserts, candies, jams, and syrups.
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Sweeteners

root fiber, a clean-label, naturally occurring soluble fiber extracted from the chicory root. Key to its appeal is its ability to replace sugar's bulk in formulation on a one-to-one basis. As Estal explains, when replacing sugar with the same weight of chicory root fiber, "you end up not altering the ratio of ingredients in the final formulation. So that helps preserve sugar's functionality as a source of solids." And because chicory fibers have a mildly sweet taste of their own, thanks to their molecular structure, significant sugar replacements are possible with "no statistical difference in the liking, appearance, or overall sensory experience," he says.

For example, a dairy-based chocolate nutrition drink may carry up to 32 g of sugar per 8-oz serving—most of it added—to lend body, mouthfeel, sweetness, and flavor enhancement, and to "help create that overall sensory experience," Estal notes. Yet Beneo’s sensory testing showed that because a beverage sweetened to this degree is already so far above our sweetness-perception threshold, replacing 25% to 30% of the sugar with the same weight of chicory fiber not only leaves the body and mouthfeel unchanged, but maintains the perceived sweetness, too. "The fiber works synergistically with the remaining sugars because you haven’t altered the mouthfeel," Estal explains. "Body and mouthfeel are such a part of the sweetness-perception experience that you need to be able to replace that.

As if that weren’t enough, reformulating with chicory root fiber both removes considerable sugar and adds a soluble dietary fiber that clocks in at 2 kcal/g—half sugar’s caloric density. "So in essence," Estal says, "you’re making your product much healthier."

Another innovative ingredient is a sprouted whole-wheat powder that Briess Malt & Ingredients Co. (Chilton, WI) makes as InnoSweet. The powder "offers all the whole-grain nutrition of the raw wheat," explains Shawn Kohlmeier, product line manager for the company’s food division, "but through our patented sprouting, cooking, and drying processes, we’re able to unlock the natural sweetness of the grain while maintaining all the elements of the initial material." That makes it a true "whole-food" solution that delivers not only whole grain,

fiber, and protein, but a level of sweetness "that doesn’t count against ‘added sugars’ and that can be labeled as 'sprouted whole wheat,'" he says. In applications testing, the ingredient has successfully replaced up to 50% of a formulation’s refined added sugars, with typical starting use rates at around 25% of refined sugars, Kohlmeier says.

High Intensity Goes Next-Gen

Chicory root fibers have their fans, but according to Prinova’s Davis, "The leading product now is stevia." Although early iterations of the natural high-intensity sweetener were notorious for their “challenging” taste profiles, "major improvements have been made over the past couple years to address this," Davis says.

The trick lies in identifying the combination of steviol glycosides—the compounds responsible for stevia’s sweet taste—that "create the most optimized custom stevia ingredient," says John Martin, senior director of technical development, PureCircle (Oak Brook, IL). That’s the path his company has taken to developing its line of stevia sweeteners. As Martin explains, "Each glycoside has widely different performance characteristics—in terms of taste, modifying properties, solubility, and more." "The key is leveraging the positive aspects of these different glycosides to optimize the overall taste profile." They’ve done this on what he calls an "application basis," whereby individual ingredients "deliver taste breakthroughs based on the specific food or beverage type," he says. "The ingredients are unique in that they get to the root of many of the challenges developers have with using stevia at the category level, and they allow developers to accelerate formulation times and eliminate unnecessary guesswork."

Similarly, Cargill’s line of stevia sweeteners arose from the company’s "proprietary taste-prediction model," Stauffer says, "which can precisely predict which combination of steviol glycosides deliver optimal taste and sweetness." And this is important, Schmelzer says, because "when exploring sugar reduction, the sweetness dynamics of the sweetener system, including sweetness onset and linger, are just as important in developing a great-tasting product."

And it doesn’t hurt that stevia is "clean," which is no small matter these days. "We’ve seen an increase in customers actively avoiding or even banning the use of artificial sweeteners like ace-K”—acesulfame potassium—as well as an increased demand for natural sweeteners, such as stevia, monk fruit, erythritol, coconut sugar, and agave," Buckley says. And suppliers are coming through with options.

King notes that his company is ramping up production of an ultra-purified monk fruit extract developed using a two-stage ion-exchange (IX) resin bead filtration system. The IX process allows the monk fruit solution to essentially "swap" ions with the natural resin beads as it passes through the exchanger—essentially removing all aftertastes and ‘off’ notes from the resulting sweetener. King says. The IX product line, named PuRefine, will include straight monk fruit sweeteners as well as blends with stevia and the sugar alcohol erythritol and, he hopes, will "set the bar for quality and superior taste in the natural, high-intensity sweetener category." The company even hopes to implement the process in producing some of its stevia extracts, with the products ready for introduction onto the ingredient market in early third quarter, 2017.

They’ll likely be a boon to functional formulators as they attempt to turn the lemons of FDA’s added-sugars declaration into reduced-sugar lemonade. And James S. Tonkin, founder and president, Healthy Brand Builders (Scottsdale, AZ), believes the reformulations may be good not just for the industry but for public health as a whole. That said, "It’ll take years to wean consumers off generally sweet or too sweet products," he says. And yet "time is not on our side. The epidemics of overeating, obesity, high blood pressure, high cholesterol, poor gut health, colon cancer, and heart disease are all promoted by eating or drinking too much of the wrong foods"—and too much sugar. "Sugar is a killer for sure," he says, "and too much of it can kill eventually."
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Polyphenol-Rich Extract May Enhance Mind-Body Wellbeing

Romain C et al., "Regular consumption of HolisFit, a polyphenol-rich extract-based food supplement, improves mind and well-being of overweight and slightly obese volunteers: a randomized, double-blind, parallel trial." International Journal of Food Sciences and Nutrition. Published online ahead of print February 23, 2017.

Health-and-wellness ingredient developer Fytexia (Vendres, France) has announced the publication of a clinical study demonstrating that its HolisFit polyphenol supplement ingredient improves measures of mental and physical wellbeing in overweight and slightly obese volunteers.

The double-blind, randomized, placebo-controlled clinical study—conducted in collaboration with the Research Center in High Performance Sport-UCAM Universidad Católica de Murcia, Spain, and funded by Fytexia—involved 33 otherwise healthy male and female subjects aged 30 to 50 years with body-mass indices (BMIs) in the overweight to slightly obese range.

After four months of daily supplementation with 1 g of HolisFit—which comprises green tea, yerba mate, vitamin B3, and extracts of grapefruit, black carrot, and grape—or a placebo control, the supplement cohorts’ scores on the Athens Insomnia Scale (AIS) improved 43%, indicating a significant increase in overall sleep quality. Those improvements in sleep markers appeared to translate to waking hours, as subjects reported a 67% improvement in wellbeing and 80% increase in functioning capacity during the day, too. Responses to the validated SF-36 health questionnaire reflected a 10% increase in perception of general physical health among the HolisFit group. As for measures of physical health, a 7.4% rebalancing of body composition within the experimental group signified improvement in body tone.

According to a press release, HolisFit emerged when Fytexia applied its polyphenol and sports nutrition knowledge to the growing demand for mind-body wellness. A company survey of more than 50 participants found that 96% of sports-nutrition product formulators believe that mind-body exercise products must benefit both physical health and mental wellbeing to achieve body-mind balance.

Notably, the press release added, growth in holistic activities such as yoga, Pilates, and tai chi is considerable, with 36.7 million American adults choosing to join the yoga community in the prior four years alone—an increase of 79%. Fytexia sponsored and helped to conduct this study.

CRANBEREX CRANBERRY EXTRACT DISPLAYS ANTI-ADHESION IN TWO NEW STUDIES

Two recently completed studies are said to corroborate the anti-adhesion activity of Cranberex, Ethical Naturals Inc.’s (ENI; San Anselmo, CA) branded cranberry extract. According to the company, both studies, not published, were conducted at Rutgers University using peer-reviewed and published methods.

Cranberries are known to support urinary-tract health through the action of their proanthocyanidins (PACs), polyphenolic compounds that inhibit E.coli’s adhesion to urinary-tract walls. Notably, ENI points out in a press release, Cranberex is standardized per the BL-DMAC method to contain 15% A-type PACs, which are unique to cranberries and responsible for their anti-adhesion activity (AAA).

The first of the two studies employed an in vitro model to compare the AAA of Cranberex with those of nine other raw-material and finished cranberry extracts. The company says researchers found that Cranberex met the study’s anti-adhesion criteria at a much lower concentration (0.23 mg/mL) than was required of the other extracts tested, demonstrating the extract’s excellent anti-adhesion activity.

The second study, a small human clinical trial, tested Cranberex’s actual AAA in 10 participants who consumed two doses of the extract, one in the morning and one in the evening. Three to six hours after consumption, all participants exhibited increased AAA response, with half achieving 100% significant bacterial AAA and the remaining half achieving 50%.

“We’re very pleased with the results of these studies,” Cal Bewicke, ENI’s CEO, noted in the press release. “These two studies confirm the activity of Cranberex and further open the door to the therapeutic use of high-grade cranberry extracts.” With estimates putting the number of U.S. doctor visits triggered by urinary-tract infections at up to 10.5 million annually—and with perhaps as many as 800,000 of those cases proving to be antibiotic resistant—this space is worth watching.
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Algae ingredients are turning heads in food and drinks.

**BY JENNIFER GREBOW, EDITOR-IN-CHIEF**

Algae ingredients have found some success in food and drinks, most notably among them Life’s DHA vegetarian DHA omega-3 and TerraVia's algal protein and lipid powder. Other algae ingredients, meanwhile, are still gaining footing in this promising market.

Nutritional Outlook checked in with a handful of algal-ingredient suppliers on how formulators can best take advantage of their ingredients in food and drink formulating.

**Algae's Time**

Algae’s appeal has everything to do with how algae address today’s demands for plant-based, sustainable ingredients.

"Consumers want to purchase products that are healthy for both them and the environment," says Greg Berthomieu, vice president, strategic partnerships, Stauber (Fullerton, CA). "You see them shopping at prime natural retailers, back to farmer’s markets, or via farm-to-fridge services for products that are unprocessed, organic, fair trade, eco-friendly, animal- or dairy-free, or vegan. Algae’s cultivation and harvest are, in most cases, sustainable, and algae typically provide very interesting nutritional profiles, so algae and algae-based ingredients fit right in with these new consumer trends."

His company, Stauber, distributes a unique, “clean-tasting” mineral-complex ingredient called Aquamin that is derived from *Lithothamnion* red algae and is rich in calcium and trace minerals.

David O’Leary, commercial manager at Marigot (Cork, Ireland), Aquamin’s creator, says the ingredient’s “unique, open, porous physical structure” provides food formulators numerous benefits. “With its unique structure, clean taste, and large surface area, it delivers a superior organoleptic profile in certain foods and beverages when compared to other calcium salts,” O’Leary says. Aquamin is suited for everything from bakery products to confectionery, snacks, smoothies, fruit juices, and vegetable drinks. (Dairy products are a lesser focus for now, he says, because “dairy producers already have dairy-based minerals immediately available, so there is less of a need to fortify with other sources.”)

Astaxanthin (primarily from *Haematococcus pluvialis* algae) is also expanding its food-and-drink footprint. In particular, confectionery products are a growing business, say the suppliers we spoke to.

Golan Raz, vice president, health and nutrition, LycoRed (Be’er Sheva, Israel), says her company sees growth for its astaxanthin in chewable confectionery products. And Karen Hecht, technical marketing specialist for AstaReal Inc. (Burlington, NJ), says AstaReal’s astaxanthin is doing business in chocolate bars such as Good Superfoods’ Superfood Chocolate Cocoa Mocha Coffeebean bar.

Technical advancements are making it easier to formulate with astaxanthin. Hecht says AstaReal is now working to improve solubility and increase astaxanthin’s concentration in beverages and foods. Raz says that Lycored uses its proprietary microencapsulation technology to create 2% water-soluble starch beadedts enveloping Algatechnologies’ (Kibbutz Ketura, Israel) astaxanthin, which improves water solubility, stability, and temperature- and pH-resistance.

As for astaxanthin’s trademark red color, Hecht says the ingredient naturally “plays well with red or darker foods and beverages.” And while this may be a setback for some, others may like it, she says. “Consumers can look for the signature red hue of AstaReal natural astaxanthin and trust that they are getting nature’s strongest antioxidant.”

Finally, Raz points out another challenge for algae ingredients in food and beverage: “Price is the key challenge. The nutraceutical space isn’t as sensitive to price as food and beverage.”

**If the Branding Fits...**

As of now, algae are still distinctive enough in the food and beverage market to command attention. Take it from one who knows.

Tom Costa is the president and founder of craft beer brand Dr. Jekyll’s. The company’s Beer Attack Irish-Style Red Ale boasts some “peculiar” ingredients (the brand’s word) not commonly seen in beer, including maqui berry, hawthorn berry, cinnamon oil, flaxseed oil, and garlic. Also? *Schizochytrium* algal oil, which makes the beer heart-healthy thanks to the DHA and EPA omega-3 fatty acids from algae.

Costa says these functional oils are encapsulated before being added to the brew, ensuring the beer tastes great. "People care about taste first," Costa says. "When they learn [the beer] has algal oil in it, many do not know what algal oil is. The ones who do absolutely love it! They appreciate what we are trying to do."

Sometimes algae ingredients are also just the right fit with a brand’s image. Renowned surfer Laird Hamilton chose Aquamin’s mineral complex for his Laird Superfood Creamer. “This is a creamer that will be mixed with coffee, tea, or other beverages,” says Stauber’s Berthomieu. “Therefore, taste and dispensability of the ingredient are essential.”

Aquamin not only checks both those boxes, but as Berthomieu points out, “The ocean origin of the ingredient and its sustainability are an excellent fit with Laird Hamilton’s affection for the big waves and respect of the environment.”

Nutritional Outlook
† Results compared to baseline


5. Kalman D, Perez Ojalvo S, Komorowski J. Comparison of cellular nitric oxide production from various sports nutrition ingredients. *J Int Soc Sports Nutr.* 2016;13 (Suppl 1):P33. ©2017 Nutrition 21, LLC. Nitrosigine® is a registered trademark of Nutrition 21, LLC. Nitrosigine is protected by a number of patents and pending patent applications on compositions, their manufacture, and/or their uses, including, but not limited to: U.S. Patent Nos.: 5,707,970; 6,156,735; 6,344,444; 6,803,456; and 7,576,132. DRA951032317

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