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Where’s the Report?

If you’re wondering how seriously New York Attorney General Eric Schneiderman’s crusade against dietary supplements could hurt the industry, perhaps the concern shared at April’s Ingredient Marketplace show will shed some light.

“I’ve been in the industry 10 years this week, and I think in terms of lasting impact, it is the most significant negative event that we have seen,” said Steve Mister, president and CEO, the Council for Responsible Nutrition (CRN).

“In my experience over 41 years in the herbal community, this is the biggest issue that has been on the table,” added Mark Blumenthal, founder and executive director, American Botanical Council. (Blumenthal and Mister are Nutritional Outlook editorial advisory board members.)

Omega-3 sales slippage in recent years showed just how badly negative news, accurate or not, can hurt the bottom line. While the supplements industry won’t know the dollar impact of the NY AG backlash for some time, the case is yet another battle in what looks like a war on the industry. “A very well-coordinated feeding frenzy has descended upon what is perceived by people to be a vulnerable industry,” said attorney Dan Dwyer at Ingredient Marketplace.

“This is a paradigm-changing moment in terms of the way consumers [feel] about the industry,” Mister later told me.

Just a minority of media have questioned the AG’s use of DNA testing during his investigation, and leaders say no outlets have published any of the letters to the editor sent in an attempt by industry members to explain why the DNA testing may be faulty.

Is the dietary supplements industry losing control of its public image? “I think we’re coming to a day of reckoning,” Mister said. “Even if the DNA testing [used by the NY AG] is 100% wrong, there have been enough negative media reports that they start to build on themselves. So somebody is now writing the narrative, and the narrative is not one that we’re going to like.”

Perhaps the only way to stop the train is if AG Schneiderman made his investigation data public and the industry was able to expose any flaws, supplement leaders say. Unfortunately, many, including the media, seem to forget that no one has ever seen the AG’s report nor verified the data his entire case is built on. “People are no longer asking critical questions,” Mister said.

Industry leaders haven’t forgotten about the missing report, however. “The AG needs to release his data. He’s calling on industry to be transparent with the consumer, and as I pointed out this morning, there are lots of flaws in that report,” said Mister. Mister said that CRN again asked for the report in a meeting with AG Schneiderman’s office in mid-April, “reiterated our request in that meeting twice, and we were flatly told that they will not give us any of the background, methodology, or results.” The association is now filing a request for the report under New York’s Freedom of Information Law (FOIL), but Mister said the AG’s office will most likely deny that request by citing a need for confidentiality amidst the ongoing investigation.

At this point, other tactics seem unlikely. If one of the cases the AG has brought against supplement companies proceeded to a courtroom, the accused company could demand to see the full report during discovery. But, Mister said, most companies “don’t want to do that. Nobody wants to go through that.” GNC, for instance, came to an agreement with AG Schneiderman’s office at the end of March without ever having seen the full report. To date, none of the companies accused has seen the report.

“I think the AG’s office knows that this report is very thin ice for them. So they are not going to give us the report if they can find any way to keep from giving it to us, because they know that if we have the actual report, it will confirm all of the suspicions that we have raised,” Mister said. He said CRN will wait to see the fate of its FOIL request before deciding on next steps. And as far as pursuing the AG in court, “We have not ruled that in or out at this point,” he said.

Report or no report, one thing is certain: in the face of such an onslaught, the industry needs to move quickly to determine its next move. Examining quality-assurance procedures company by company to assure GMP compliance is a good start (see page 14), but considering the industry’s eroding image, the answer may need to be more immediate. “I think it does have to be a combination of things that can be implemented quickly to show change, to show movement, and then other things [can be done] that maybe are more longer-term,” Mister said. Meanwhile, he said his group and others will continue trying to get AG Schneiderman to release the report.

“We’re not done with that,” he said. “We’re continuing to push this.”

Jennifer Grebrow
Editor-in-Chief
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FDA Cracks Down on BMPEA

FDA took definitive action in April following accusations that the agency failed to remove dietary supplements from the market adulterated with the stimulant beta-methylyphenylethylamine (BMPEA), despite knowing about the problem for more than a year. The agency sent warning letters on April 23 to five companies listing BMPEA as a dietary ingredient in dietary supplements, stating that BMPEA “does not meet the statutory definition of a dietary ingredient...rendering misbranded any products that declare BMPEA as a dietary supplement.”

Hi-Tech Pharmaceuticals Inc., Tribarvus Enterprises LLC, Train Naked Labs LLC, Better Body Sports LLC, and Human Evolution Supplements Inc. are the five companies who received warning letters for various sports and weight-management supplements.

Some marketers list BMPEA as an extract of the botanical Acacia rigidula; however, FDA states that the agency’s own research in 2013 concluded that “BMPEA is not a constituent or extract of Acacia rigidula.”

FDA’s actions followed a study led by Pieter Cohen, MD, published in April in Drug Testing and Analysis that criticized FDA for failing to pull BMPEA-containing products off the market even more than a year after its presence was discovered in dietary supplements.

The Drug Testing and Analysis study published online April 7 found that more than 52.4% of the Acacia rigidula supplement brands that researchers tested contained BMPEA, which has never been studied for efficacy or safety in humans. There is no evidence that the stimulant can be produced by any method other than chemical synthesis, said the researchers.

“The dosages of BMPEA in supplements strongly suggest that the amphetamine isomer is synthetically produced and placed in the supplement to lead to physiologic effects,” the researchers wrote. Their study included 21 brands of Acacia rigidula supplements, 11 of which the researchers said contained BMPEA in individual serving amounts ranging from 0.97 mg to 32.23 mg. The supplements were analyzed with liquid chromatography-quadrupole time-of-flight mass spectrometry.

Sixteen of the brands analyzed were marketed for weight-loss benefits, three were marketed to improve athletic performance, and one was marketed to enhance cognitive function.

In January 2014, FDA scientists released a study which analyzed 21 Acacia rigidula supplements purchased in 2012, finding that 9 of the 21 products contained BMPEA. But aside from publishing the study (Pawar RS et al., vol. 88) in the Journal of Pharmaceutical and Biomedical Analysis, FDA “has yet to inform the public or take enforcement action to remove BMPEA from dietary supplements,” the Drug Testing and Analysis researchers wrote.

FDA’s April 23 announcement of its BMPEA crackdown says that the agency will keep the public updated on any further actions taken regarding BMPEA or Acacia rigidula.

Omega-3 “No Overall Association” with Prostate Cancer, Says New Study

The omega-3 market has had a rocky last couple of years, caused in part by a slew of negative studies reaching mainstream media audiences. One of the most problematic was a study published in the Journal of the National Cancer Institute (Brasky et al., vol. 105) in 2013 that suggested men with high blood concentrations of omega-3s might be at greater risk of getting prostate cancer. Although the study’s design has been widely criticized, the negative publicity took a severe toll on the omega-3 market. But now, a new meta-analysis published online in Nutrition and Cancer (Alexander DD et al.) on March 31 poses another challenge to that controversial study by finding “no overall association” between long-chain omega-3 polyunsaturated fatty acid intake and prostate cancer.

More than 460,000 total participants were included in the analysis, which looked at 12 self-reported dietary intake studies and 9 biomarker studies that were published through 2013.

Accounting for the bulk of the analysis population with 446,243 participants, the dietary intake studies showed no overall association between omega-3 use and prostate cancer, and some even indicated a small inverse association, said the researchers. The biomarker studies—comprising 14,897 participants—also showed no overall association between omega-3 use and prostate cancer. Although researchers did find a majority of positive associations in the biomarker studies, they were so weak in magnitude as to be statistically insignificant.

The researchers also point out that “a plausible biological mechanism by which [long-chain omega-3 polyunsaturated fatty acids] could facilitate prostate carcinogenesis has not been identified, whereas anti-inflammatory properties of these fatty acids would suggest anti-carcinogenic effects.”
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Which Way to Quality Assurance?

The New York Attorney General wants better quality assurance for dietary supplements. So does the supplements industry. So how does it get there?

BY JENNIFER GREBOW, EDITOR-IN-CHIEF

FDA’s Good Manufacturing Practices (GMPs) for dietary supplements are meant to ensure industry-wide quality, but does the system actually work? Now is a good time to ask, because whether through public scrutiny or regulatory pressure (see page 10), the dietary supplement industry is being forced to take a deeper look.

Spurred by New York Attorney General Eric Schneiderman’s (NY AG) recent dietary supplement industry investigation, Schneiderman and 13 other state attorneys general (AG) asked Congress in April to consider a more “robust” role for FDA in regulating the dietary supplements industry. The AGs asked Congress to address “the extent to which Congress should mandate, or direct the FDA to develop, enhanced, uniform, industry-wide quality-assurance and verification regimes” to ensure ingredient identity and product safety and efficacy.

At the core, the AGs and the supplements industry at large share a desire: to ensure safe, effective, high-quality products for customers. What the industry and the AGs do not agree on is the best way of getting there.

Different Paths to Quality Assurance

Dietary supplement industry leaders say that FDA’s GMP regulations are appropriate and sufficient. In a letter documenting GNC’s March agreement with AG Schneiderman—an agreement that subsequently ceased the AG’s investigation of GNC products—GNC said it disagreed with the AG’s opinions about “the sufficiency of federal rules and testing requirements.” The implication is that GNC, like many industryfolk, feels federal laws are fitting, while AG Schneiderman does not.

FDA’s GMPs are the bare minimum—“the floor”—of what FDA believes a company must do in order to ensure quality. The GMPs, however, leave it to companies to decide how best to meet the minimum, and companies can—and should—do what they can to rise above that floor.

“Where the regulations say you must conduct at least one appropriate test, you have to do that. But if you’re a company that really has a commitment to quality, you’re probably doing more than just one test,” and you’re personally auditing your key vendors, etc., said Steve Mister, president and CEO of the Council for Responsible Nutrition (Washington, DC), at an Ingredient Marketplace trade show panel in April. GNC CEO Mike Archbold said via open letter that his company has “always gone above and beyond to assure compliance with FDA cGMPs.”

But, of course, whether through human error or human deceit, not all companies engage in best practices. Cases of economic adulteration and mislabeling in recent years are enough to confirm that bad practices are indeed happening with dietary supplements. The same is true of any industry. Dietary supplement leaders refer to these lawbreakers as “industry outliers.”

These outliers are what keep the public, regulators, and law-abiding industry members up at night asking themselves whether the dietary supplement industry has the proper framework in place to achieve industry-wide compliance and self-policing. Depending on whom you ask, the rules either are sufficient (and would be even more effective if FDA had the resources to pull more lawbreakers off the market), or we need new rules (such as premarket regulation).

Answers to these questions don’t come easily. But as the fire grows hotter, the industry needs a concrete response—“a grand gesture,” Mister said—to reassure the public at large whether existing dietary supplement regulations can protect consumers.

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Prescribing Specific Tests Isn’t the Answer

By using DNA testing as the sole test method in his investigation, and by furthermore requiring GNC to adopt DNA testing per their agreement, AG Schneiderman seems to believe that DNA testing should be an integral part of the “uniform, industry-wide quality-assurance regime” the AGs asked Congress to consider. Today, companies are able to chart their own course for how best to meet FDA’s GMPs, but AG Schneiderman now aims to make that course more specific—at least from what can be inferred from the GNC settlement. “The GNC settlement tries to articulate a specific set of testing standards, whereas FDA’s GMPs just focus on the general concept of what needs to be done in order to come into compliance with FDA’s concept of GMP,” said another Ingredient Marketplace panelist, attorney Dan Dwyer.

FDAs GMPs decline to dictate the exact quality-assurance tests a company must perform, only requiring that the test be valid and fit for purpose. There’s a good reason for this, and that is that the testing needs of supplement manufacturers will range broadly depending on what type of ingredient or product a company is dealing with. When you

SHOULD FDA PROVIDE MORE GMP GUIDANCE?

By law, quality assurance for dietary supplements means meeting or surpassing FDA’s GMP requirements. While 21 CFR 111 only instructs that manufacturers “conduct at least one appropriate test or examination” that are “appropriate, scientifically valid methods” (21 CFR 111.75), in certain scenarios, it may behoove FDA to in fact be more specific, said Steve Mister, president and CEO of the Council for Responsible Nutrition.

Mister suggested that perhaps FDA can take a heavier hand in guiding companies operating in some supplement categories that are known to be at high risk of adulteration (sports nutrition, weight loss, and erectile dysfunction). FDA could, for instance, suggest that these companies go beyond the GMP “floor” of one test; perhaps companies in those high-risk markets need to do more than a few tests to ensure they are testing for known adulterants, if they aren’t doing so already. “I think they could provide more clarity to the industry for certain kinds of products what is appropriate and what is sufficient,” he said.
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take a minute to consider the scope of the supplements industry, this makes sense. “The breadth of the industry is so broad” that an ingredient like fish oil requires a completely different set of quality-assurance procedures than does, say, an ingredient like chondroitin sulfate, said CRN’s Mister. Even a market sub-segment like botanicals comprises “a huge spectrum” of products, different plant parts, and different formulations, added fellow panelist Mark Blumenthal, founder and executive director of the American Botanical Council (Austin, TX). This makes finding a singular test method that works “very challenging,” he said. “I have no indication as to how certifying organizations would propose [a single solution] because it’s not simple.”

“We’re not just one industry; we’re a group of different industries,” Blumenthal said. Take DNA testing. Blumenthal outlined real-world examples of when DNA testing alone would fail to catch some of the most common cases of herbal product adulteration. (Blumenthal isn’t anti-DNA testing, either. He called DNA barcode technology “a perfectly reasonable tool in the analyst’s toolbox.”)

“A have no indication as to how certifying organizations would propose [a single solution] because it’s not simple,” said ABC’s Blumenthal.

In cases of known ginseng adulteration, DNA tests will not detect adulteration of ginseng root extract with ginseng leaf extract (done to raise ginsenoside levels). This is because DNA testing does not differentiate plant parts. This kind of differentiation “can only be done through proper chemical analysis by looking at different ratios of the different ginsenosides,” Blumenthal said. The same is true for ashwagandha, whose root extracts are often adulterated with leaf extract. In these cases, DNA testing as a sole solution would certainly not meet FDA’s GMP requirement for fit-for-purpose testing.

“There is no ‘one size fits all’ testing methodology when it comes to analyzing dietary supplement ingredients and finished products,” says Lisa Thomas, general manager, dietary supplement programs, NSF International (Ann Arbor, MI), which provides third-party GMP testing for dietary supplement companies based on standards of the American National Standards Institute (ANSI). “Methods vary depending on the ingredients of interest and the product matrix or form.”

Is There an Industry-Wide Solution?

Amending the GMPs to dictate specific test methods may not be the right way to better
## ANTIOXIDANT (ORAC) PROTECTION COMPARISON CHART

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>ORAC Value (µmole TE/100g)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sumac, Bran, Raw</td>
<td>312,400</td>
</tr>
<tr>
<td>Acai Berries</td>
<td>102,700</td>
</tr>
<tr>
<td>Cocoa Unsweetened</td>
<td>55,653</td>
</tr>
<tr>
<td>Blueberries</td>
<td>9,621</td>
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<tr>
<td>Pomegranate</td>
<td>4,479</td>
</tr>
</tbody>
</table>

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<table>
<thead>
<tr>
<th>Antioxidant Type</th>
<th>ORAC Value</th>
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</thead>
<tbody>
<tr>
<td>Peroxyl Radicals</td>
<td>1,571,000</td>
</tr>
<tr>
<td>Hydroxyl Radicals</td>
<td>2,410,000</td>
</tr>
<tr>
<td>Peroxynitrite</td>
<td>83,100</td>
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<tr>
<td>Superoxide Anion</td>
<td>2,544,500</td>
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<tr>
<td>Singlet Oxygen</td>
<td>249,000</td>
</tr>
</tbody>
</table>

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quality assurance, but the dietary supplement industry still can and should endeavor to improve industry-wide quality assurance in other ways. With adulteration, pharmaceutical spiking, and general safety issues still happening, even dietary supplement industry leaders acknowledge that. "I think there's enough going on in this industry that warrants improvement," Blumenthal said. "We have problems here."

Existing tools—such as U.S. Pharmacopeia public standards—are available for many ingredients, and if everyone in the industry were to abide by publicly created, broadly accepted testing standards, quality assurance would find an even playing field. "We have real tools that can deal with these issues," said Steven Lukawski, whose company Fruit d’Or Nutraceuticals (Notre-Dame-de-Lourdes, QC, Canada) sponsored the Ingredient Marketplace panel session.

Lukawski pointed out that industry advances, including technology, mean the industry has greater means of product testing than it did 20 years ago. "The correct test methods are certainly available; the problem is that many dietary supplement companies do not have the in-house expertise or instrumentation necessary to perform all proper purity and identity testing in compliance with GMPs," NSF’s Thomas adds. Third-party certification is one solution, and Thomas says that NSF International is seeing "more manufacturers...stepping up to fulfill this expectation" of product quality by increasingly using third-party verification.

Good tools do exist, but the challenge is in getting everyone in the industry to use them. To that end, increased criticism and scrutiny of industry will have one positive effect: dietary supplement manufacturers have no choice now but to improve.

Scrutiny Down the Line
If public confidence in dietary supplements erodes, the impact will hit all members of industry where it hurts the most—the bottom line. As such, "What I’ve heard is that people are having a very serious conversation internally," said Mister. "This has taken the [conversation] out of the QA/QC departments, and it's going all the way to the executive suites of the companies. They are now asking, 'What are we doing to assure the identity of our products? What are we doing to assure that we're providing a pure and quality product?'

Scrutiny will work its way through the supply chain. Already, Mister said, recent conversations he's had with marketers and retailers lead him to this conclusion: "I think the retailers may start to put pressure on the industry. They are going to want to know more about the products they put on their shelves, both their store brands and even the national brands. They, as much as the end-consumer, may be what puts the pressure on industry."

At least that's the hope, industry leaders say. "I don't think you will get an industry initiative that has 100% buy-in, no matter what you have," said Mister. "But I think what you get is an agreement among the majority of companies as to where they should go, and then what happens is the companies who don't agree get left by the wayside—either that, or consumers move away from them."

The industry might see more proposals for industry solutions in the coming months. Mister said industry leaders are definitely discussing strategies internally. But with quality assurance at the heart of the publicity storm supplements face today, taking a look at one's own QA procedures is a smart place to start.
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How the Healthcare Professional Evaluates Supplements

Sorting through the fads and pitches

By Dave Foreman, RPh, ND

As a healthcare provider, it’s of course imperative to do my homework on what supplements to use and recommend. Back in the early 1990s when I began to integrate natural products in my pharmacy, I undertook the task of selecting quality products for my patients and for personal use—a responsibility not to be taken lightly. Even though I retired from being a traditional pharmacist, I still utilize the same criteria in selecting the natural medicines I recommend on television and radio programs. Recommending products that are truly efficacious and safe is even more important these days, as I have gone from reaching hundreds of people to reaching millions of people.

Having been in radio for over 16 years and television for another 10, I now get bombarded with solicitations. Companies either want me to mention or put my seal of approval on their products and services. Even in the days of owning my pharmacy, I would get solicited by network marketers, upstart companies, etc., to sell or mention their products. They wanted to be able to say “pharmacist recommended,” which holds a lot of credibility to the end consumer.

Of course, it would be much easier to just accept the marketing stories these companies tell me or to listen to a sales pitch and come away with the conclusion that the product is great, but in the end, protecting my credibility and a person’s health is more important than helping someone sell more product. As such, it takes time and due diligence before I will get behind anything. Just because you—seller or marketer—say that something is good for me doesn’t mean it is. When someone’s health is on the line, fancy marketing, websites, and skyrocketing sales aren’t enough to convince me to jump on the bandwagon. Instead, here are some of the red flags I look for before I even begin to dig:

1. Is the company following proper FDA/FTC guidelines regarding structure/function claims and advertising?

This is one of the biggest barometers of credibility in my book. If a company is making outrageous claims like “eat more, exercise less, and still lose the weight” or “stops cancer in its tracks” or “works better than XYZ drug,” it shows me they don’t know the law and are most likely “cheating” somewhere else.

2. Does the product’s Supplement Facts panel list simply “proprietary blends,” or does it list the actual amounts of each ingredient in the product?

Labeling is key, even on the side or back of a package. Following guidelines in labeling makes a bigger impression on me than product names and structure/function claims. Also, to me, the words proprietary blend beg caution. How much did you really use?

3. Is the company using therapeutic amounts of key ingredients, or is it just “pixie dusting”?

Too many times, I see a label listing only a miniscule amount of an ingredient contained in a serving. This is an old trick used to fool or confuse consumers who may know that selenium is good for them but who don’t know how much selenium is good. One of my favorite examples is eye health products that contain only a whiff of lutein (sub-therapeutic dosing based on research), yet boast about lutein content on the front label. The consumer is led to believe there is ample lutein within the product for their eye health, but may not realize the dosing is sub-therapeutic.

4. Does the company cite science or historical use in its literature, and how do they do it?

Granted, historical use can go a long way, but this is still an area that warrants a red flag. If you are unaware of the actual historical use, then you need to do the research. Find out how the supplement was historically made, what plant parts were used, how often people used it, etc. One of my favorite examples today is soy. Soy has long been sold for numerous disease-state prevention
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programs. It is sold in all forms—milk, beans, supplements, tofu, etc. As substantiation, some marketers refer to the historical fact that certain cultures that consumed soy as part of their daily diet had less incidence of certain diseases. What these marketers fail to mention, however, is that in those cultures, soy was consumed as fermented soy and not in all of the other ways soy is sold and consumed today. Show me the science that soy milk will decrease my risk of developing cancer, and maybe I will consider it—but it’s more likely that you need a history lesson or a lesson on regulatory claims.

On the Flip Side…
What about negative press? How does negative coverage in the popular press inform or influence my decisions? Simply put, look beyond the headlines.

My favorite example is the negative press circulating a few years ago stemming from a negative study about St. John’s wort being ineffective at treating depression. The media jumped all over the information in this study, and thousands of people stopped using the herb—and even, in some cases, decided that “natural medicine” wasn’t worth it. Taking a close look at the study, there were numerous important facts left out of the information sent to the media. The biggest omission to me—and what should have been the easiest for reporters to debunk—was that the patient group involved had severe depression. The science on St. John’s wort indicates that St. John’s wort is only effective in people with mild to moderate or seasonal depression, not those with severe depression.

I never take the original headline at its word. I always want to know things like 1) Did they use the proper dose? 2) Did they use the right type of patient? 3) Who funded the study? 4) Were there any financial interests that would have influenced the results? Again, just because someone says something is or isn’t good for you doesn’t mean that should be gospel.

Besides the quick red flags mentioned, here is the evaluating approach that I take that has worked for me for several decades.

Look for Branded Ingredients
My experience is that patented or branded ingredients will have studies performed on the ingredient. These studies usually examine mechanism of action, dosing requirements, and safety profiles. Branding is done when someone has either a unique ingredient or technology that makes his or her product stand out from the rest. These unique ingredients may start with the same herb as other products, but due to their technology (extraction process, manufacturing techniques, farming, specific species, etc.), the final ingredient is often significantly different and more effective.

Here are some great examples: The ingredient Phase 2 Carb Controller comes from a specific type of white kidney bean. The technology used to make the final ingredient ensures the end product is unique from powdered white kidney beans. Another favorite is Maitake mushroom extract. The only Maitake extract I am aware of is Maitake D-Fraction. I am not willing to take a chance using someone else’s Maitake until they can show me the scientific benefits like D-Fraction has. Carnitine is another great example. Carnipure (the pure L-carnitine versus other salts or DL-carnitine) is branded and has numerous clinical trials showing its benefits; yet, I am unaware of other forms showing the same or similar benefits in studies. Meriva (a curcumin extract) is not just another turmeric extract. The ingredient has studies showing its improved absorption and impact due to it being technologically different. It is examples like these that drive me to look for branded ingredients.

Look for Reference to Third-Party Testing
This is another one of my favorite pieces of advice, since the actual seller of the product is generally not verifying the product—i.e. ingredient(s)—but a third-party laboratory is. NSF International (Ann Arbor, MI) and the United States Pharmacopeia (Rockville, MD) are two popular labs. Each company has a website that lists products that have passed their tests.

Reputation
To many, this may sound strange, but I feel that longevity goes a long way. I feel that if a company has been in business for numerous years, it means that its products must be working. This doesn’t mean that a new company doesn’t provide satisfactory products, either, but the longevity and reputation someone has adds to the credibility of the end products they produce.

Price
If something seems too cheap, it usually is. Quality ingredients, manufacturing practices, testing, etc., come at a price. This often leads to something costing more. This does not mean that a more expensive product is better. It means that if you have two similar products and one is extremely inexpensive, that would give me a yellow flag of caution when evaluating the purchase. More due diligence is needed in this case.

One last note for the above section: I often look for the studies done on ingredients I am approached with. I prefer human studies with significant p-values. Yes, this may lead to flashbacks of statistics, but it’s well worth the time invested. We are humans, not rats, mice, or any other animal and therefore do not often accept science done in animals.

Lastly, keep in mind that each product and ingredient needs to be evaluated on all of these levels. Making sure you take the proper steps to evaluate a product will go a long way towards achieving the health benefit(s) we are seeking. Your health matters!

“I feel that if a company has been in business for numerous years, it means that its products must be working.”

Dave Foreman, RPh, ND, is a pharmacist, author, television commentator, radio host, and practitioner of natural living and holistic approaches to better health. His weekly radio program is broadcast throughout the United States. Visit www.herbalpharmacist.com.
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Ask any chef, and he or she will say that the first step to any tasteful creation is to utilize quality ingredients that provide consistent, expected characteristics. The same can be said for the production of those ingredients: knowing that the quality and stated characteristics will be consistent from batch to batch is the best way to maintain the production of a high-quality food ingredient. FDA requires food manufacturers to have detailed documentation of the components of their product, some of which can only come from ingredient suppliers; therefore, both manufacturers and ingredient suppliers need to keep in constant communication in order to stay compliant with increasingly stringent FDA regulations.

From a quality-assurance standpoint, maintenance of quality and consistency, along with continued analysis for potential contaminants, is a critical part of the production of a safe ingredient. An ingredient supplier must meet criteria necessary for the production, verification, and stability of the final ingredient during shipment, including a valid and complete certificate of analysis (COA) and certification and documentation meeting all Food Safety Modernization Act (FSMA) and Good Manufacturing Practices (GMP) requirements.

**Certificate of Analysis**

When assessing the ability of a supplier to provide the necessary ingredient in a timely fashion, a food manufacturer should first begin with obtaining a COA of the ingredient to be supplied. A COA is defined as “an authenticated document, issued by an appropriate authority that certifies the quality and purity of pharmaceuticals, and animal and plant products being exported.”\(^1\)

In order to certify quality and purity, the COA must also have a description and limits for substances, such as fiber, antioxidants, or certain phytochemicals, that define the product. A vague COA lacking endpoints that define the ingredient is not very useful; it may be nice to look at, but not provide much else. Specification sheets or COAs should contain the following information:\(^2\)

1. The ingredient statement and information on any allergens present
2. Microbial limitations (as necessary)
3. Nutrition Facts for labeling purposes
4. Shelf-life statement
5. Packaging information
6. Traceability code and how to read it
7. General product description
8. Key quality attributes (e.g., % fat, % protein, refractive index)
9. Physical characteristics
10. Heavy-metal analysis

A well-detailed COA will also help in addressing oncoming needs that the manufacturers are facing with the continued implementation of 2011’s FSMA regulations.

**FSMA Regulations**

FSMA is the most sweeping food-safety reform law passed in over 70 years. This new law shifts the U.S. government from simply responding...
to contamination to preventing contamination. As a part of FSMA, facilities that manufacture, process, pack, or hold human food are required to register with FDA as food facilities. In addition, FSMA includes a Preventive Controls rule, which requires food facilities to both prepare and implement hazard analysis and risk-based preventive controls. It also revises the existing current GMP requirements. Although these requirements are not yet final, and changes to the current language are anticipated, the proposed rule provides a good indication of the final language.

As a part of the Preventive Controls rule, the facility must prepare a written food-safety plan that includes the establishment and implementation of a risk-based supplier program for raw materials and ingredients that the facility identifies as a significant hazard. The supplier typically controls information concerning the composition of ingredients. Also, the rules state that a supplier approval and verification program must be implemented for both domestic and foreign ingredient suppliers. Also, as a part of the Bioterrorism Act of 2002, domestic and foreign facilities that manufacture, process, pack, or hold food or food ingredients must register with FDA, and FDA must be given advance notice on shipment of imported food.

**GMPs**

For dietary supplement ingredient suppliers, FDA first introduced regulations in 2007 on GMPs for dietary supplements. In comparison, GMP regulations for food-processing facilities were first instituted in 1969 and were revised in 1986. Processed food and dietary supplement facilities that fall under FDA’s GMP regulations must meet guidelines for all phases of manufacture, from raw-material control (e.g., valid and complete COA information), facility design, and structure information to product traceability, qualification, and validation of operating procedures for testing equipment and methods to analyze different phases of production.

The implementation of the GMP requirements for dietary supplement production has a direct impact on the actions of ingredient suppliers because the ingredient suppliers are now subject to the specification or purchasing requirements of the companies that source their ingredients. A dietary supplement manufacturer must meet a "supplier qualification" GMP guideline, which may include verification of the supplier’s reliability, test results for batch analysis and identity parameters of each ingredient, as well as a consistent auditing program established for each ingredient supplier. Methods and equipment used for identity testing should undergo a validation process to ensure that the results are consistent with national or international standards (e.g., AOAC, AOCS, and ISO). For suppliers, records management also includes verification that any substances used in the manufacture of the ingredient, such as solvents, carriers, and processing aids, are also approved for food use if specified by the food-manufacturing qualifications.
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When first working with a new supplier, the manufacturer should request a sample of the ingredient shipped under typical packing conditions. Once the manufacturer receives the ingredient, the batch of ingredient should again be sampled and analyzed to confirm that it meets the specification parameters. Any variations between the manufacturer’s results and the supplier’s COA should be immediately discussed and rectified; if parameters critical to the safety or quality of the ingredient are not met, the batch should be rejected.

Suppliers will need to maintain detailed recordkeeping, ingredient identity, and batch consistency, and overall reliability to manufacturers in order to remain competitive when FSMA is fully implemented. Upcoming federal regulations aim to increase both the safety and quality of food that reaches U.S. consumers; for this reason, suppliers and food manufacturers will need to work together in order to sufficiently meet these new FDA requirements. Communication is key.

Ray A. Matulka, PhD, is the director of toxicology at Burdock Group, a leading food safety and regulatory consulting firm headquartered in Orlando, FL.

References

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Creature Feature

Pet products look more like human goods these days, from alternative- and high-protein treats to increasingly condition-specific formulas.

BY INNOVA MARKET INSIGHTS

With the rising disposable income of pet owners and a tendency to regard pets as part of the family, it’s not surprising that specialized trends for prepared foods for humans, led by interest in health, snacking, and indulgence, are also increasingly apparent in the pet foods sector. The number of pet food launches recorded globally by Innova Market Insights has risen consistently in recent years as more households take on pets of various kinds, the use of prepared pet foods rises, and the market segments and focuses increasingly on added-value options.

In line with the food and drinks market as a whole, the pet foods market is becoming increasingly diverse with many products, particularly premium and super-premium lines, now targeting very specific nutritional requirements—everything from foods for puppies and kittens to foods for senior dogs and cats, obese dogs, indoor cats, and even neutered cats.

Optimizing pet health is now of particular interest, to the point that three-quarters of the global pet food launches recorded by Innova Market Insights in the first 11 months of 2014, including 85% of 2014 launches in North America, were marketed on a health platform of some kind. The interest in naturalness and clean-labeling evident in the food market as a whole is also reflected in pet foods, with 35% of global launches using natural, additive-free/preservative-free, and/or organic claims, and with more than 50% of launches in North America making such claims.

There is also a high level of activity in grain-free and high- and alternative-protein lines, reflecting current trends in the human food and drinks market. Interesting launches in the United States include Louisiana Dog Biscuits and Louisiana Dog Jerky chews from Delca, all made with alternative protein sources. Ingredients include alligator, crab, crawfish, and shrimp, all sourced from sustainable family farms and fisheries in the Louisiana bayou. Over in the UK, launches include a grain-free range from holistic pet foods supplier Goodwyns, marketed as “non-allergenic” and “easily digestible,” as well as the Gloriously Grain Free range from Laughing Dog, marketed as “suitable for dogs with sensitive stomachs.”

Other key areas of interest in pet foods include claims relating to joint health, used on over a quarter of global launches in the first 11 months of 2014, particularly products formulated for older pets. This is reflected in U.S. launches such as Dogswell’s Happy Hips and NaturVet’s Overby Farm Hip Flex range for joint mobility, with the latter marketed as “high in anthocyanins from natural tart cherry and dark berry bioactives, plus glucosamine and omega-3.”

While dogs were once the key focus of this kind of product, there is now also evidence of growing levels of activity in joint health for cats, such as the Natural Wellness Joint Care for Cats supplement featuring glucosamine. Over in the UK, Mars’s market-leading Whiskas cat food brand entered this market in 2014 with the launch of the Whiskas Healthy Joints pet treats range.

Claims relating to the use of omega-3 fatty acids or DHA are also relatively popular in...
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the pet foods market, used in 18% of global introductions and rising to well over 20% of launches in the United States. Many products do not attribute specific benefits to omega-3; those that do most often cite joint health and maintaining skin health and a shiny coat.

Pet snacks is one of the fastest-growing areas of the pet foods market, as consumers increasingly look to treat their pets with healthy and/or indulgent options. These options not only take the established form of sticks, chews, and tablets, but may also mirror growing human-snacks formats, such as Wellpet's Wellness Core Superfood Protein Bars for dogs. These are all grain-free and feature added ingredients like blueberries, sweet potato, pomegranate, and kale. Wellpet launched the product at the same time as its Kittles crunchy cat treats, which count cranberry as an added ingredient.

Growing use of snacks and treats has also raised concerns about the growing level of obesity among cats and dogs. As a result, healthy treats and treats with added functional benefits (joint care, dental care, anti-hairball, etc.) are showing some of the best growth rates. There is also rising demand for pet foods with weight-management benefits, with just under 7% of pet food launches recorded by Innova Market Insights in the first 11 months of 2014 using “low fat” or “low calorie” claims, or both, and just over 7% leveraging a more specific weight-management platform.

Humanization is undoubtedly now a key feature of the pet foods market, reflecting the high level of emotional attachment that many owners have with their pets. They tend to treat pets like family members or even children and therefore provide only the best in terms of food and care. This has created considerable opportunities in the pet-care market, where we are seeing an increasing emphasis on branding, segmentation, and adding value in a relatively concentrated market. The result? Huge investment pouring into product and promotional activity by the major players.

Innova Market Insights is your source for new-product data. The Innova Database (www.innovadatabase.com) is the product of choice for the whole product-development team, offering excellent product pictures, search possibilities, and analysis. See what food manufacturers are doing around the world: track trends, competitors, ingredients, and flavors. In today’s fast-moving environment, this is a resource you cannot afford to be without.
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Pea protein is on a winning streak with customers these days—and not just among sports enthusiasts. (Turn to page 44 for more on protein’s growing role in weight management.) With demand coming from everywhere, ingredient sources of all kinds are now jockeying for a piece of the market. And while animal and soy proteins continue to dominate, pea protein is now breaking into the mainstream as a serious plant-based contender.

“Pea protein has the strongest message right now” among all other legume-source proteins outside of soy, according to Frost & Sullivan’s Christopher Shanahan, global program manager, food and agriculture. Shanahan spoke on the expanding protein market at April’s Ingredient Marketplace trade show. Frost & Sullivan predicts an 11.3% CAGR for pea protein through 2020, an estimate that Shanahan says may even be somewhat conservative. If all pans out well for pea protein, he says, that number could even go as high as 15%–20% through 2020.

What’s driving pea protein upward among plant proteins? With its combination of non-allergen, non-GMO, and vegan appeal, pea protein can compete with soy and even go places soy can’t. Couple that with pea protein’s low environmental impact and versatility, and you’re looking at a protein source that both consumers and manufacturers can find reasons to root for.

**Pea Protein’s Rising Star**

Don’t get us wrong; soy is still the undisputed champion of the plant-protein world. In 2014, soy-protein products accounted for 38% of the global protein-product market, compared with 26% for all other non-soy plant-protein products, according to a Frost & Sullivan analysis. But soy may be reaching market maturity and leaving room for fresher options—like pea protein.

A little less than 5% of all protein products were formulated with pea protein in 2014.
“Pea protein has expanded from a niche to a mainstream product,” says Varde.

according to Frost & Sullivan. But among the segment of non-soy plant proteins, pea protein presents serious competition. Within the global non-soy category, legume-based proteins were used in 34% of products, and within that legume segment, pea protein was formulated in fully 55% of products. Compare that with the next most popular legumes—beans (16%) and chickpeas (15%)—and there’s no doubt that pea protein is now the legume-protein heavyweight.

What’s most remarkable about the market for pea protein is how quickly it’s anticipated to grow. In a recent survey released by Global Food Forums (Saint Charles, IL), 78 “protein-knowledgeable food technologists” were asked to answer the following question: “Do you see the use of the following protein types (as a powdered ingredient within formulated products) as decreasing, increasing, or remaining the same in the United States in the next two years?”

A striking 89% of the respondents said pea protein use would increase in the next few years—the highest mark given to any protein source in the survey. Only 36% predicted an increase in the use of proteins from soy.

Of all the possible alternatives to soy in the plant-protein market—rice, potato, microalgae, and wheat gluten proteins—pea may also be the most cost-effective, said Shanahan.

“There’s a lot of peas grown already in the world, so it would be pretty quick to increase capacity, availability, and make it price competitive, even though now it’s still a little bit more expensive than soy,” said Shanahan. He added that prices will likely come down as pea protein suppliers gain capacity.

Beyond just the predicted rise in sales, pea protein can also be found in more products than in the past, says Neellesh Varde, PhD, senior product manager, Roquette (Lestrem, France), supplier of Nutralys pea protein.

“The last three to four years has seen a growing consumer demand for pea protein to the point where pea protein has expanded from a niche to a mainstream product,” says Varde.

Between 2013 and 2014, the number of global food and drink product launches featuring pea protein increased by 49%, according to a report by Stephanie Mattucci, global food science analyst, Mintel. Snacks, baked goods, desserts, and processed fish, meat, and egg products were the top four categories using pea protein in global food and drink launches in 2010–2014, says Mattucci. She also mentions the wide range of products that include pea protein, including mayonnaise, granola bars, pasta, and meat-substitute products.

One major driver of the growth is likely that pea protein is free of two features that have been problematic for soy: GMO and allergens. Consumer concerns around soy allergies and genetically modified soybean have led many in search of a plant-protein alternative.

“Many proteins have problems with either allergenicity or non-GMO status, and pea protein is an exception on both accounts. It’s not one of the seven major allergens, and it is non-GMO,” says Varde.

There’s another reason why pea protein may get a boost—the sheer number of soy-based products that saturate the market. Quite simply, pea protein is a fresh face that may attract consumer attention for its sheer novelty.

**Pea vs. Whey**

Aside from the unique factors that set pea protein apart, how effective is it where it actually matters—for instance, in the sports nutrition industry where protein is so prized? And how does it stack up against the efficacy of the sports industry’s undisputed leader, whey protein?

From a plant-protein standpoint, Nutralys has a comparable amino acid profile to soy and exceeds the FAO/WHO 2008 suggested amino acid profile for all but one of the nine essential amino acids—methionine—according to Roquette. Ingredients supplier Cosucra (Warcoing, Belgium) promotes a similar amino acid profile for its pea protein ingredient, Pisane.

Whey protein still outpaces pea protein when it comes to content of most essential amino acids, but the difference isn’t all that dramatic, says Roquette’s Varde. According to Roquette, Nutralys has significantly more phenylalanine than whey, significantly less threonine than whey, and comparable if slightly lower levels of the other amino acids.

A clinical trial published in January in the *Journal of the International Society of Sports Nutrition* also speaks to the potential of pea protein to promote muscle thickness and strength. The study compared the effects of Nutralys pea protein, whey protein, and placebo supplementation on increasing muscle thickness in young men.

For 12 weeks, 161 men aged 18–35 underwent resistance training on upper limb muscles three times per week and were given either pea protein, whey protein, or a placebo to take twice daily. Training exercises involved the elbow flexor and extensor muscles, including arm curl, lateral pull-down, and bench press. The three supplements all came in the form of 45-g sachets of banana-flavored cocoa powder that were identical in appearance, texture, and taste. The powders were then diluted in 300 ml of cold water. The study was randomized and double-blinded.

At the 6-week and 12-week mark, participants were measured for right-side biceps brachii muscle thickness with an ultrasound machine to determine muscle thickness. Parameters of muscle strength, including
Plant Protein

right-arm circumference, maximal voluntary torque, and the maximum load that could be lifted during an arm curl, were also studied at the same intervals.

Based on the muscle thickness increase of the participants who were weakest at inclursion, researchers discovered a statistically significant difference between participants who took the pea protein and the placebo. The thickness increase for the pea group was +20.2 ± 12.3%, compared with +15.6 ± 13.5% for the whey group and +8.6 ± 7.3% for the placebo group.

Although muscle strength improved over time in all three groups, with no statistically significant difference between the three protein interventions, researchers said that when it came to muscle thickness, they did observe a statistically significant difference between the muscle-thickness gains from pea protein over placebo. (Between whey protein and pea protein, however, researchers said there was no statistical difference in muscle-thickness gains.)

They concluded: “In addition to an appropriate training, the supplementation with pea protein promoted a greater increase of muscle thickness as compared to placebo and especially for people starting or returning to a muscular strengthening. Since no difference was obtained between the two protein groups, vegetable pea proteins could be used as an alternative to whey-based dietary products.”

The researchers hypothesized that the lack of statistical difference between the pea and whey protein results may have been due to the similar amino acid content of the two sources. Also, they noted, the Protein Digestibility Acid Corrected Amino Acid Score (PDCAAS) for Nutralys closely corresponds to the values for whey or casein.

A More Sustainable Protein

Another reason to get excited about pea protein is how environmentally sustainable the ingredient is. Most pea proteins are made from the Pisum sativum L. yellow pea, which

2014 GLOBAL PROTEIN USAGE IN PRODUCT FORMULATION (% OF TOTAL COMMERCIALIZED PROTEIN PRODUCTS)
BASED ON DATA PROVIDED BY FROST & SULLIVAN IN APRIL 2015

SOURCE: FROST & SULLIVAN ANALYSIS

- Plant Soy 38%
- Dairy 35%
- Non-Soy Plant (Not Pea) 21.14%
- Pea Protein 4.86%
- Algae 1%

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Plant Protein

is grown throughout the world and requires relatively minimal resources to produce.

“Fifteen acres of land are needed to produce one ton of beef protein,” says Roquette’s Varde. “It only takes about two acres to produce one ton of pea protein.” He adds that pea doesn’t need much fertilizer either because it adds nitrogen to the soil itself.

Pea is also less water-intensive than many other protein crops. According to a presentation from Cosucra, it requires 3200 liters of water to produce 1 kg of pea protein, far lower than the 5882 liters for the same amount of soybean protein, 6923 liters for the same amount of wheat protein, or 588,235 liters for the same amount of beef protein.

Based on an estimated 9880 kJ of energy required to produce 1 kg of pea protein, pea needs slightly more energy than the 8853 kJ necessary to produce 1 kg of soybean, but still far less than the 62,570 kJ necessary to produce 1 kg of milk protein, according to Cosucra.

With a growing population worldwide and water already a limited resource, pea’s relatively low environmental impact could prove to be another factor driving consumer and manufacturer interest, especially with lower resource costs than soy or whey.

Pea protein requires less water to produce than soy or beef protein.

Formulating with Pea

So pea may look good on paper, but when it comes down to it, how easy is it to formulate with?

One of the challenging aspects with pea protein is that it can be fairly viscous, according to Alan Rillorta, director, branded ingredient sales, AIDP (City of Industry, CA). AIDP offers PeasiPro pea protein as well as Advantein, a combination of rice and pea protein. Rillorta says that the combination of the grainier rice with the viscous pea can make for a more balanced texture. The combo also addresses some of pea’s taste issues.

“When working with pea proteins, often the taste and smell are an issue,” says Rillorta. “Some products have a very strong beany taste and almost a shrimp smell. Some also note a salty taste.” By combining rice with pea, AIDP’s Advantein avoids some of these taste issues, and the pairing also results in a touch of sweetness, says Rillorta.

Another reason to combine pea protein with rice or other proteins is to create a more complete protein profile and to maximize PDCAAS values. For instance, while pea protein is high in lysine but low in methionine, rice is actually the opposite and is therefore well suited to balance out the amino acid profile of pea protein, according to Rillorta.

Pea protein is similar to soy protein in that it coagulates and thickens when added to water, but it differs from soy in that it has limited foaming, according to Axiom Foods (Los Angeles), supplier of Vegotein pea protein.

Digestion Speed

Pea protein’s unique digestion speed is another aspect that formulators and marketers may want to consider when deciding what type of consumer may be most interested in using pea protein as a sports nutrient.

Roquette’s Varde describes Nutralys pea protein as an “intermediate/fast-digesting protein,” compared with whey’s fast digestion speed and casein’s low digestion speed. Roquette describes soy as a fast/fast-intermediate protein.

“Nutralys behaves similar to casein until it coagulates and thickens and is added to water, but it differs from soy in that it has limited foaming, according to Axiom Foods (Los Angeles), supplier of Vegotein pea protein.”
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Plant Protein

Cascadian Farm Organic Protein Bars began including pea protein in 2014.

potential uses: for consumers who want a slower release of protein for possibly increasing satiety, for endurance athletes who need a steady and long-lasting source of protein for activity, and even for senior citizens who need a steady source of protein to aid against sarcopenia."

The versatility of a medium-burning protein may also appeal to mass-market consumers who aren’t as savvy about different digestion speeds, suggests AIDP’s Rillorta. Even bodybuilders and devotees of animal and milk-based proteins should consider including pea protein in their diet to take advantage of the different digestion speeds, he says.

"The real answer is to diversify your protein consumption," says Rillorta. "It’s like somebody who’s saying, ‘I want to become vegan,’ and all they eat is broccoli all day. Is that necessarily healthy? You want a broad range of protein."

Frost & Sullivan’s Shanahan reported that manufacturers are increasingly tapping into this idea of diversified protein by incorporating more than one protein source into final products. In 2014, 76% of commercial protein products had only one protein source, while 23% combined two sources and 1% combined three sources, according to Frost & Sullivan. Shanahan expected this trend toward combining protein sources to continue in coming years.

Going Mainstream

As pea protein continues to gain traction for its many appealing aspects, major manufacturers are beginning to incorporate the ingredient into their products. One such company is General Mills, manufacturer of the Lärabar ALT protein bars with pea protein since May of 2013. In 2014, General Mills also rolled out Cascadian Farm Organic Protein Bars and Granola with pea.

“We are always looking for ways to offer our consumers great-tasting products that meet their needs, and we’re hearing from our consumers that they would like more protein options,” says Julia Wing-Larson, marketing manager, Lärabar (Denver). "We chose the pea due to its taste, texture, and low allergenicity. Plus, it is also a sustainable product, which is very important.”

But for pea protein to continue its rise, or any emerging protein source for that matter, it will take a “big consumer education campaign” to compete with the market dominance of soy and milk, said Frost & Sullivan’s Shanahan. Fortunately, pea protein may already be on the right track.

“I think pea protein is a testament of effective communication to consumers on the benefits," said Shanahan. "Using green packaging, leveraging the organic/natural claim, talking about the vegetarian claim—I think that’s really a key driver.”

Shanahan also advised that companies should think about moving beyond protein powders and bars, instead focusing on ways to incorporate protein into "attractive food products that people can easily consume and that [are] recognizable to what they’ve always eaten."

"I know you can only do so much as an ingredient supplier, so they’re going to have to rely on partnerships with brand owners willing to invest a lot of time and R&D to get those new ingredients formulated, new products, but it will be worth the investment if it can get pulled off. And we’re already seeing evidence of pea making inroads in that direction," he said.

References

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Protein: Weight Management’s Good News

Whether from plants or animals, protein lends the weight-management sector some much-needed credibility.

BY KIMBERLY J. DECKER

In a national conversation that sometimes seems to bristle with bad news about the American diet—too much sugar, not enough fiber, and a whole lot of disagreement about everything else—one topic that reliably serves up good news is protein. Alone among macronutrients, protein has escaped the demonization that, for some critics, landed carbs and fat in the doghouse. Even better, whereas the wholesale rejection of sugars and fats is misguided, the positive energy surrounding protein—from consumers, health professionals, and industry alike—is refreshingly reality-based. Whether strengthening bones, maintaining muscle, increasing energy, or easing how we age, protein, evidence continues to suggest, plays a constructive role.

Such is the case in managing weight, as well. And for a weight-management category that’s taken its lumps from increased regulatory scrutiny and shifting consumer expectations, protein’s potential to bring scientifically substantiated legitimacy to functional foods and beverages is good news, indeed.

Food First
Protein is sitting pretty as its renown spreads beyond its initial advocates—strength trainers and athletes. “It’s become the most popular ingredient at the moment with both consumers and product developers,” says Julian Mellentin, director, New Nutrition Business (London). Consumer awareness of protein is very high in the United States, he adds, and the success of everything from protein-powered granola bars to Greek-style yogurt shows that “Americans at a mass-market level are embracing protein in all its forms.”

To the extent that consumers are embracing protein to help control weight, their decision makes sense. After all, protein is “a recognizable ‘food-based’ ingredient that people are already used to consuming in things they like: dairy, meat, etc.,” says Chris Schmidt, consumer health analyst, Euromonitor International (Chicago). This food-like positioning, he believes, gives protein an advantage over “the myriad newer ‘flavor-of-the-month’ diet ingredients.”

When those flavors-of-the-month—think raspberry ketones and green coffee extract—hit shelves in the form of weight-loss supplements, sales tend to spike, Schmidt says, and then “die off fairly quickly” thereafter. In
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the meantime, sales of what he describes as meal-replacement “slimming” products like shakes, bars, and their functional kin that count protein as a key ingredient “outstrip weight-loss supplements by a wide margin in both the United States and across the world.”

That wouldn’t surprise Anne Poulsen, business development manager for performance health & nutrition, Arla Foods Ingredients (Sønderhøj, Denmark), who observes that the bad press aimed at weight-loss supplements tainted with the banned prescription drug sibutramine—the subject of FDA warnings in November 2012, January 2013, and February 2013—leaves consumers “increasingly suspicious of products that seem too good to be true.” For them, she says, protein offers an easier, more convenient, and “more sociable” approach to watching food intake. 

Revving the Engines

Moreover, protein actually appears to work. “There really is a lot of scientific evidence supporting the fact that a high proportion of protein in the diet increases weight loss and prevents weight gain and regain,” Poulsen says.

The theory rests on the understanding that protein helps stanch appetite by promoting satiety better than carbohydrates or fats, naturally amps up the body’s calorie-burning thermogenic engines, and aids in glycemic regulation—the combination of which ultimately leads to improved body composition, Poulsen explains. “Improved body composition means the preservation or gain of muscle mass and the concurrent loss of fat mass, so it’s a highly desirable benefit for consumers who want to look and feel good.”

Consumers have gotten the memo. According to a 2014 Consumer Whey Protein Tracker survey of U.S. adults conducted by San Francisco–based market research firm GfK for Dairy Management Inc. (DMI; Rosemont, IL), 43% of respondents attested to actively changing their food and beverage choices to ensure adequate protein intake—a 36% increase from 2011—and 52% agreed that “protein plays a role in weight management.”

Notes Erin Coffield, RD, LDN, vice president, strategic communications and integration for health and wellness at the National Dairy Council (NDC; a DMI-managed program), ”Consumers are most likely to identify ‘building and maintaining muscle’ and ‘providing sustained energy’ as protein benefits, but significant numbers also attribute benefits to protein linked directly to weight management, such as ‘helps speed up metabolism and burn more calories naturally’ and ‘helps keep you from feeling hungry between meals.’” And they want more.

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“It’s important not to fall into the trap of believing all proteins are equal,” says Arla Foods’ Poulsen.

larger category. “The surge in interest in protein has inevitably resulted in a huge number of new protein sources coming onto the market as ingredients,” Poulsen notes. “But it would be a mistake to consider the protein market as a single category. Instead, it’s a series of subcategories, each with its own specific attributes. It’s important not to fall into the trap of believing all proteins are equal. In fact, proteins can vary enormously in terms of nutritional quality, taste, and ease of processing.”

Whey to Go

Consider whey’s track record. “In recent years, whey protein has emerged from niche to mainstream,” Poulsen says. And for good reason. “The use of whey protein to improve body composition is supported by 14 randomized clinical trials, including one that involved 627 adults who consumed protein either as a supplement combined with resistance training or as part of a weight-loss and -maintenance diet.”

It’s especially effective at jumpstarting caloric combustion. The energetic cost of metabolizing proteins in general tops that needed to burn either carbohydrates or fat, Poulsen says, yet even within the protein category, whey generates greater diet-induced thermogenesis than either soy or casein protein, per a 2013 study published in The Journal of Nutritional Biochemistry.

That same study found that whey stimulates the secretion of satiety hormones like cholecystokinin, peptide YY, and glucagon-like peptide 1, while reducing secretion of the hunger-promoting hormone ghrelin. It’s also replete with branched-chain amino acids—valine, isoleucine, and leucine—which aid muscle growth and, in leucine’s case, “exerts a direct central effect on reducing appetite,” Poulsen says. Finally, while milk proteins broadly stimulate insulin secretion, whey elicits “the highest insulinotrophic response, thereby assisting blood-glucose regulation that translates into long-term improvements in insulin sensitivity,” she says.

Vegetative State

But whey isn’t the only game in town; increasingly, consumers are investigating vegetarian protein options. While dairy proteins still get the majority of media attention, Schmidt says, “soy protein is fairly ubiquitous in packed foods, and there’s been growing interest in plant sources like pea, rice, and others, particularly within the general health-and-wellness and healthy-weight areas.”

Data from SPINS (Chicago), an information provider for the natural and specialty products industries, illustrates the rise of plant protein in the “Health Focus” sector comprising vitamins, supplements, herbs, and homeopathic remedies, says Kimberly Kawa, SPINS content development. While conventional-channel sales of animal-based protein combination products within the Health Focus market represented the highest dollar value for the 52 weeks ending February 2015—$126 million-plus—they were up only 6.8% over the previous year; by contrast, Health Focus products with a plant-based protein combination may have raked in a more modest $9.6 million-plus in natural-channel sales during the same period, but were up a whopping 92.1% over the year prior.

In any case, “I think pea protein is one of the top plant-based proteins of interest,” Kawa says, crediting its popularity to its GMO-free supply chain, allergy friendliness, easy digestion, and promotion of muscle growth. “Since ‘grain-free’ is also a trend now, pea protein falls into that category, as opposed to rice protein, which has been a common base for plant-based protein powders,” she suggests. No wonder, then, that bars with a pea-protein boost are appearing more frequently, and that items across all products and departments formulated with pea protein grew by 56.5% in the natural channel compared to the year before, she adds. (Turn to page 36 for more on pea protein.)

Still, a protein’s animal or vegetable origin may be a deal breaker for only the closest of label readers and those with dietary restrictions, Mellentin says. He contends that “there is a subset of more health-aware consumers in the United States who are showing a preference for vegetable-source protein. But there’s no science behind this, as dairy protein is the most effective and bioavailable. It’s just a question of people picking up on ideas about plant-based diets being somehow ‘better.’” Ultimately, “Most consumers don’t know the difference between different protein types,” he wagers. “They just know, ‘I want protein.’ or, maybe, ‘I want X grams of protein.’”

Protein in the Pantry

What consumers know is that they want protein to provide an appealing experience. As Poulsen says, “Increasing numbers of ‘ordinary’ health-conscious consumers are now demanding food and beverage products that help them stay fit, toned, and looking and feeling good, but which are convenient to integrate into their everyday lives. The key to tapping into this growth opportunity is to offer ‘lifestyle’ protein-based products that are delicious and easy to consume, since these shoppers aren’t willing to make the taste and convenience sacrifices that niche protein consumers, such as bodybuilders, accept.”

And with contemporary lifestyles being what they are, ready-to-drink (RTD) beverages, shots, bars, and snacks may be just what
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Weight Management

these shoppers are looking for. “Consumers have a growing appetite for protein-rich snacks,” Poulsen points out. Per Innova Market Insights data, sales of such products grew 25% from 2012 to 2013, she says, which “reflects people’s busier lives and limited time for enjoying sit-down meals.”

On the beverage front, Kawa notes that although they don’t exhibit overt weight-management messaging, Orgain’s high-protein plant-based vegan and filtered-milk drinks, Organic Valley’s Fuel and Balance high-protein filtered-milk products, and Mayesa’s plant-based pea-protein beverages are good examples of the latest in RTD meal-replacement and protein beverages that support both plant-based and animal-based trends.

Euromonitor’s Schmidt adds that the weight-management category is shifting from a “diet” focus toward what he calls “healthy/active nutrition.” In other words, “A lot of companies are positioning protein products as meal replacements not so much in the sense of losing weight for bikini season, but as a more nutritious option with on-the-go benefits.” Both niche products like Premier Nutrition’s Premier Protein and Optimum Nutrition’s Protein Energy, as well as packaged-food giants like Kellogg’s Breakfast on the Go and PepsiCo’s Quaker Oats Breakfast Shakes, are cases in point, he says.

Just what weight-loss results these products can claim to deliver, however, remains a subject that manufacturers should approach with prudence. FDA has approved no health claims linking protein and weight management, but structure/functional claims “based on the nutritive value of the ingredient or food and that are truthful and not misleading” are okay, Cofield says. That said, she continues, “Care should be taken when making weight-loss claims. A higher-protein diet can be incorporated into a weight-loss plan, but weight change results when there’s negative energy balance.”

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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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How Big a Threat Is Plant Protein to Dairy Protein?

Plant-protein hype aside, don’t forget that animal protein, especially dairy, still dominates.

BY JENNIFER GREBOW, EDITOR-IN-CHIEF

Plant protein may get a lot of attention these days, but marketers shouldn’t forget that animal protein, especially dairy, is still the heavy hitter. Frost & Sullivan’s Christopher Shanahan, global program manager, food and agriculture, gave a significant overview of today’s burgeoning protein market at April’s Ingredient Marketplace trade show, including how plant proteins are facing off against their animal-source brethren.

Animal Kingdom

Shanahan did not mince words: “Animal proteins still dominate. Dairy still runs this market.”

What continues driving dairy? Infant formula. With growing demand from developing economies like China, India, Southeast Asia—even Sub-Saharan Africa in the next 10 years, Shanahan said—infant formula will continue to be a mainstay of animal protein. Add medical nutrition, milk-based nutrition-al drinks, and sports nutrition and weight-management goods to the mix, and demand is strong. So while plant protein, especially soy, does threaten some of dairy’s market share, especially in markets like sports nutrition, the threat isn’t as big as you’d think, Shanahan said.

Here’s how Frost & Sullivan sees the pie divided. Global 2015 animal-protein ingredient sales are projected to be 61.2%, compared to plant protein (13.8%) and amino acids (25%). (See figure on page 54.)

Plant protein may be trendy, but Shanahan said that dairy marketers are also thinking forward. “Even within the dairy space, we’re seeing a lot of dairy companies looking at their core ingredients and trying to make it a little different, using different feed stocks,” he says. “You’re getting a lot of new entrants into the marketplace with new products, new innovations, and new launches.”

Plant Kingdom

Still, dairy can’t completely kick back. Although it will dominate sports nutrition through 2020, “plant-based and algae proteins will cut into this lead,” Shanahan predicted.

Sports nutrition is a hot spot for plant protein. In 2013 within sports ingredients, while dairy protein still commanded the lead (59.3%), plant protein followed at 22%. (Other sports-nutrition ingredients included creatine at 8.2% and amino acids at 5.7%.) As more sports marketers use plant protein, especially in combination-protein products, “we expect that pie to be much different next year and the year after, as well,” Shanahan said.

And what about soy, the leader in the plant protein market? Soy commands the number-two spot in protein overall, behind animal protein, but it is heading towards maturity, Shanahan said. Other plant alternatives are now eyeing the ladder, and marketers are finding more consumers willing to cross over. Of all non-soy plant proteins on the market, pea protein is the strongest challenger to soy. (See page 36 for more on pea protein.)

Soy—“probably the biggest superfood there was to date” 10 or 15 years ago—is today “under threat in multiple categories, whether it’s the dairy-free milk category or in the protein space where we see significant rise in plant-based proteins—potato, canola, pea, rice, even wheat gluten, which is
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somewhat similar and being looked at again as a potential substitute. Really any legume besides soy is either being commercialized or in R&D right now as a potential disruptor,” Shanahan said.

A lot of plant protein’s global promise stems from one key mega-trend, Shanahan said: emerging markets. As economies develop, rising income correlates with a higher demand for meat. “With China, India, Sub-Saharan Africa going into the emerging middle economy space demanding more protein ingredients and more packaged foods, there will be a significant strain on the ability of animal-based proteins. Which is why plant-based proteins are expected in the very long run—10-plus years—to be a very important nutritional part of the diets in these emerging markets.”

And plant proteins of course also benefit from their “ethical and green” story (sustainability), as well as the ability to take advantage of natural, organic, non-GMO, and other rising claims.

**Protein Wins**

The main takeaway from the protein sector is that there are huge opportunities and demand for almost everyone. In the nutrition space, “protein is the big gorilla in the room,” Shanahan said. Among the global health ingredients market in 2015, protein will still be the leader at 44%, compared to vitamins and embraced functional foods and beverages in general, “protein tends to be one that’s actually not as important relative to where protein ranks in the United States.”

“What’s key here is that this is a very dynamic space—a lot of ingredient categories compared to the vitamins and minerals or even the omega-3 space that have a smaller number of industry participants and a relatively small number of feedstocks,” he continued. Conversely, “the entire world is a feedstock” for protein, “from plants and animals to algae and insects, and the various types of products make this a very dynamic and highly competitive market.”

With so much competition, manufacturers must quickly identify and address opportunities and threats, he advised. For now, many alternative protein sources lack an “effective communication message” convincing consumers why they should switch over, he said. “It’s going to take a big consumer education campaign to really offset the gains of soy and milk.”

Luckily, animal-protein suppliers today may also be friendlier to plant proteins, even looking to partner up. “There’s been increasing tendency for partnerships for the dairy industry—even possibly considering partnerships with these vegetarian-based alternatives and creating value-added combinations,” Shanahan said. “Increasingly, the dairy guys are seeing this as a possible product line extension or partnership opportunity. Maybe they’ll cannibalize some of their sales, but they won’t 100% lose them as a consequence.”

New product applications will drive growth beyond the consistent mainstays like infant formula and sports nutrition. It’s a market that is highly innovative, with Frost & Sullivan tracking more than 2500 new product launches with protein ingredients last year (not counting Asia-Pacific).

“There’s a lot of new product innovation around ingredient innovation throughout the entire value chain, which again really substantiates how dynamic this market is,” Shanahan said.

For a market that shipped nearly $35 million worth of protein ingredients to end-users last year, and with a 5.8% CAGR expected overall through 2017, the answer is clear: With protein, you can’t lose. [1]
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Digestive Enzymes for the Protein Punch

High-protein products are only as effective as the enzymes that optimize them.

BY MELISSA KVIDAHL

Once the territory of bodybuilders and other extreme athletes, sports nutrition products are now immensely popular among mainstream consumers, from amateur athletes and hobbyists to weekend warriors and beyond. Couple this with the ever-rising demand for functional foods—often taking the shape of protein bars and shakes—and the result is a whole lot of protein circulating among athletes and convenience seekers alike.

The problem is that the body is not equipped to naturally break down and optimize the large amounts of protein arriving via these foods and supplements, explains John Deaton, PhD, vice president of technology at Deerland Enzymes (Kennesaw, GA). “Excess protein that goes undigested in the small intestines could move into the colon where bacteria will break it down, creating ammonia that is difficult to neutralize and may build up over time,” he says. And while the body can handle small amounts of ammonia, large amounts of protein can produce more ammonia than the body can handle on its own, leading to a compromised immune system and even cell damage. Other unpleasant symptoms associated with undigested protein include gas, bloating, and diarrhea.

A Need for Enzyme Supplementation

The solution, of course, lies with enzymes that can break down food particles into an appropriate size for digestion. The problem, explains Amy Pereira, national educator at Enzymedica Inc. (Venice, FL), is that enzymatic activity naturally decreases with age. “To further matters,” she adds, “today’s diet is largely devoid of enzyme activity since enzymes are typically destroyed by food preparation and processing techniques that involve temperatures above about 118°F.”

Supplementation with protease enzymes is one way to meet the digestive demands of high-protein foods and drinks. “For those consuming an average amount of protein per meal, protease enzymes hydrolyze the protein consumed, breaking it down to be more easily digested and maximizing nutrient absorption,” says Deaton. “In addition, the body spends a lot of energy on digestion, and an enzyme supplement that assists in breaking down proteins helps the body conserve energy used for other physiological functions.”

Protease Enzymes

When formulating a protease enzyme supplement, there are many considerations at hand. First, explains Bret Wyant, vice president of sales at American Laboratories Inc. (Omaha, NE), the individual protein must be examined. Is it pre-hydrolyzed? Plant-based? The pH range must also be considered. At National Enzyme Company (Forsyth, MO), the recommendation is to include a range of several different proteases optimized at different pH levels to achieve desired results, says director of marketing and formulations Melony Fuller.

“Enzymedica recognizes the need for formulas that would be able to perform throughout the entire tract, regardless of what pH they encounter,” agrees Pereira. “We...
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Enzymes

also recognize the limitations of formulas built with single enzymes. For example, single protease can ordinarily only function in an acid environment or an alkaline environment, but rarely ever in both.”

Plant Protein

Complicating matters is plant protein, which continues to gain traction in the mainstream. While animal proteins such as chicken and steak are single protein molecules that can be broken down by protease enzymes alone, plant proteins are much more complicated, says Deaton. “Plant proteins such as soy and rice are glycoproteins, meaning the protein molecule is bound to sugar molecules,” he explains, which means they’re more difficult to break down via protease enzymes alone. Instead, they must be treated additionally with amylases to break down the carbohydrates. Also falling into this category are quinoa, barley grass, pea, and other grain grasses and legume sources.

For plant protein formulas with a higher fat content—like those stemming from hemp or flax—a higher lipase content would be appropriate, explains Pereira. “Each enzyme is manufactured using a particular raw material or strain organism,” agrees Wyant, “and each can perform slightly differently on the various proteins available.”

As such, finished product manufacturers would be wise to consult with suppliers on the range of enzymes available, to ensure that both formulators’ and consumers’ needs are properly met.

Melissa Kvidahl is a freelance journalist and copywriter specializing in the health and wellness industry. View her portfolio at www.melissakvidahl.com.

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Thinking Inside the Box

How paper cartons moved in on the water market

BY KIMBERLY J. DECKER

From added flavors, bubbles, and vitamins to, quite simply, pulling off the marketing coup of selling consumers something they could get from the tap for free, water marketers have captured consumers' interest by continually presenting them the world's most widely consumed beverage in an attention-grabbing new light. Only in recent years, however, have they presented it in a new package: the paperboard carton.

Barriers to Entry

Actually, water is somewhat late to the paper-packaging party. "It's true," says Andrew Reynolds, president of operations, Icebox Water (Cold Spring Harbor, NY). "You see milk, juices, and, a little farther afield, soups in boxed packaging." So why no water until recently? He cites two driving forces that kept the carton closed, so to speak, until around 2007—when his company's product debuted.

First was the engineering challenge. "Juices, milk, and dairy are much more viscous fluids, meaning that they're thicker and cannot permeate the paper used in box containers," he explains. Not so water, which easily soaks through paper, "creating a soggy mess," he says. And though earlier generations of cartons incorporated wax liners to prevent leaking, that layer hampered, or even prohibited, recycling. Newer package designs like the one his company uses helped square that circle. "It's paper lined with a very thin aluminum barrier and binding layer," he says, which not only holds water with no threat of leakage or package disintegration, but is readily recyclable with the right facilities, too.

"It's paper lined with a very thin aluminum barrier and binding layer," says Icebox Water's Reynolds.

But beyond the engineering hurdle lay conceptual barriers to drinking water from a box, as well, he says. "Consumers just haven't been accustomed to it," he says. Their resistance, however, is beginning to crumble.

Danilo Zorzan, product director for packaging supplier Tetra Pak (São Paulo, Brazil), senses the shift, although he notes that in the economy-water market, "the role of packaging in attracting consumers is relatively low" and that the norm is still PET (polyethylene terephthalate) bottles. Even for premium products, the need "to show the purity of the water within" dictated packaging transparency. But at long

Continued on page 62
GOING COCONUTS

Taking measure of the coconut-water phenomenon

We know: It may be hard to imagine a time before coconut water. (Call it the “B.C. era,” if you like.) But Steve Siegel, vice president, Ecuadorian Rainforest LLC (Belleville, NJ), can, in fact, recall that bleak span of years before the biggest beverage trend to hit beverage aisles since Evian first broke.

“It wasn’t that long ago that sales of coconut water were dragging,” Siegel reminisces. And yet when category pioneers hit the scene—often in aseptic paperboard cartons, if not reliable old cans—the waters, which are actually the clear liquid tapped from young green coconuts, “had only a meager following” among dedicated health-and-wellness consumers, he says.

How things have changed. “Today,” Siegel muses, “the industry is more alive than it’s ever been.” Citing Euromonitor reports, he predicts that the market for coconut waters will top $1 billion “in the very near future,” he says.

And it’s no mystery why. Today’s beverage space is a battleground, with everyone from celebrity chefs to city councilmembers to public-health sages pointing their fingers at sugary sodas, sports beverages, and pseudo-juices as culprits in what some call a national obesity epidemic. Coconut water, with its low caloric content, naturally sweet taste, and rich supply of electrolytes, is a nature-made alternative fit for health-conscious consumers desperate for drinks that “quench thirst while also delivering vital nutrients,” Siegel says.

So what does coconut water offer? One cup can pack up to 2.6 g of fiber, Siegel says, which works out to about 10% of the daily amount recommended for healthy digestion. “Coconut water may also offer a number of essential nutrients, including magnesium, copper, and potassium,” he continues. “In an age when consumers want both nutrients and convenience, coconut water makes it easy to have both.”

Even better, it pleases the palate with its sweet, nutty profile. And for manufacturers worried about processing challenges and shelf-life issues, rest assured: formulation-friendly formats await. “For manufacturers who need coconut water with a long shelf life,” Siegel suggests, “the powdered form would be their best bet.”
last, he says, cartons “are making inroads into the water sector.”

Paving the Way

Many credit carton-borne coconut waters with paving the way for “plain” boxed waters. (Read more on coconut water on page 61.) And it’s hard to ignore the influence that coconut water has had. “Worldwide, the number of product launches in the coconut-water sector has more than quintupled,” Zorzan says, rising 540% in the past five years alone. Globally, estimates place the market’s value at about €220 million, with Brazil and the United States accounting for most of the consumption and growth.

Zorzan says that Tetra Pak was the first company to introduce aseptically packaged coconut waters capable of withstanding long-term storage and of being packaged without losing their native texture or nutritional value. And as coconut water has evolved from a niche product to an increasingly popular drink, he says it’s moved boxed packaging along with it.

That’s spread the medium’s advantages across the water category, Zorzan says, and he lists product differentiation as principle among the benefits. “Carton packaging is relatively novel in the water market,” he points out. “It provides good branding opportunities, stands out on the shelf, and offers an excellent drinking experience for on-the-go consumption.” Add to that its improved ergonomics, light-barrier properties, and its reliance on a main resource—paperboard—that’s renewable and what he calls “an innovative alternative to the default of glass or plastic bottles,” and you have a winner.

So with companies like Icebox having cleared the ground for paper cartons within the water sector, other water marketers are following their lead. But far from seeing the new entrants as nibbling away at his company’s slice of the market, Reynolds believes they’re expanding the whole pie. “We welcome the likeminded companies and believe this is more than a trend,” he says.

Socially Conscious Cartons

That said, what’s in the carton for consumers, other than the novelty factor? For one, Reynolds says, “Without changing their behavior,
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they get to consume a product with a much smaller carbon footprint compared to plastic bottles.

Part of that reduction comes from distribution efficiencies. Namely, his cartons ship flat, allowing 1.05 million empties to fit a 53-foot trailer. By contrast, that same trailer could carry only 95,370 empty plastic bottles, “meaning it would take 11 trucks to get the same amount of material—empty 500-ml plastic bottles—to the co-packer for filling compared to one truck of our flat shipped cartons,” he says. Even better, while bottles and cartons often require shipment to just such a co-packer for filling, Icebox fills its cartons at the water’s source—True North Springs in Canada’s Notre Dame Bay—“so there’s no additional transportation of the water,” Reynolds says.

The cartons are also revolutionary in being 100% recyclable where facilities exist—a quality that’s as important to Reynolds as it is to mindful consumers. “Plastic pollution is a major problem,” he says. “Too much is used and not enough is recycled.” Paperboard cartons help correct that imbalance by reducing the quantity of plastic that enters the waste stream in the first place.

Embracing Change

With so much going for paper, then, what are we waiting for? The barrier, Reynolds believes, is consumer education. “Consumers as a whole are unfamiliar with the product and may require education as to the importance of sustainable packaging solutions,” he says. And once we can get them on board, the incentive will be there for marketers not only to serve their consumers, but to put a dent in what he calls the “plastic pollution problem” at the same time.

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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Yaupon’s Comeback

The only caffeine source native to the United States has potential to explode.

BY MICHAEL CRANE, ASSOCIATE EDITOR

From a glance at the U.S. caffeine market, it might seem like all the great energy ingredients come from other parts of the world. Coffee is thought to originate in the Middle East, tea comes from Asia, and even alternative energy ingredients like guarana, guayusa, and yerba mate hail from South America.

There is, however, one local contender looking to break onto the scene. Yaupon holly, the only naturally occurring caffeine-containing plant in the United States, has the potential to become the next hyped alternative to coffee. Celebrated for its combination of homegrown appeal, pleasant taste, and possible health benefits, yaupon tea has plenty going for it. But will consumers be put off by its unflattering history?

The “American Yerba Mate”

“If you’re looking at trends in caffeinated beverages, the thing I think that is the most interesting right now, and the one that’s got the potential to become the next hyped alternative to coffee. Celebrated for its combination of homegrown appeal, pleasant taste, and possible health benefits, yaupon tea has plenty going for it. But will consumers be put off by its unflattering history?

Yaupon holly, the only naturally occurring caffeine-containing plant in the United States, has the potential to become the next hyped alternative to coffee. Celebrated for its combination of homegrown appeal, pleasant taste, and possible health benefits, yaupon tea has plenty going for it. But will consumers be put off by its unflattering history?

Yaupon and its cousin, yerba mate, have roughly the same amount of caffeine.

A History to Reckon With

Which brings us to yaupon’s cultural history and rather unfortunate scientific name, *Ilex vomitoria*. The plant was named in 1789 by William Aiton, a Scottish botanist, as a reference to its use in a Native American ceremony during which men would drink huge amounts of the yaupon-filled “black drink” in order to induce vomiting and gain energy.
The purification ritual often preceded wars or marriages, with yaupon holding an important place in the culture of Timucuan Native Americans and later Seminoles, according to Francis Putz, professor of biology and forestry, University of Florida (Gainesville, FL). Indeed, even the name of the famous Seminole leader Osceola is an Anglicized version of "Asi Yahola," meaning "black drink singer," says Putz.

Yet in spite of its name, several studies have shown no such emetic effect in yaupon leaves. It may have been that the "black drink" contained other ingredients that induced vomiting or it was simply the massive amount the men consumed that made them purge.

There is also another, more sinister theory behind *Ilex vomitoria*’s name, says Putz. It’s possible that Aiton was bribed by Ceylon tea merchants working in England to give yaupon its unattractive name as a way to shut down competition. Although this early case of corporate espionage lacks proof, Putz believes it to be true.

For companies like ASI Tea (Savannah, GA), which launched the first ready-to-drink (RTD) yaupon tea a little over six months ago, that history may still be working against them. Lou Thomann, founder, says that yaupon’s legacy is the company’s "biggest challenge."
“Anyone trying to commercialize this is going to have to deal with that story,” says Thomann, adding that his philosophy is “don’t hide it, celebrate it. It’s an amazing story. If anyone wants to root for the underdog, this thing has been the underdog.”

Building from the Ground Up

Yaupon’s distinctly American heritage is a big part of the appeal, but it can also make things more difficult for suppliers. For one, labor costs are considerably higher in the United States than in developing countries where many other caffeine ingredients originate.

“There is the financial challenge of American labor rates throughout harvesting and processing, in contrast to lower internationally sourced coffee and tea production costs, which means yaupon tea will be a more expensive specialty,” says Abianne Miller Falla, cofounder, Cat Spring Tea. Cat Spring Tea currently wild-picks its yaupon leaves.

Yaupon’s relative newcomer status as a commercial ingredient also means there are no established methods or supply chains to tap into, but Falla says this has given Cat Spring Tea the freedom to experiment with a variety of techniques in improving its treatment of the yaupon leaf.

Although several companies have plans for RTD yaupon teas in the future (and one yaupon moonshine), ASI Tea is the first company to offer a line of RTD yaupon teas, which debuted in late 2014. Other native Southern ingredients, such as muscadine grapes, aronia berries, local wild mints, and wild yaupon honey, are combined with yaupon in the RTD teas, says Thomann, which each contain around 30 mg of caffeine.

“We’re selling a really healthy, native, local, wild-picked American treasure,” says Thomann.

After hundreds of years of obscurity and undeserved stigma, yaupon’s time on the commercial caffeine market may have finally arrived.

References


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It’s difficult to think of any word to describe the U.S. caffeine industry besides “booming.” As of 2014, U.S. coffee market retail sales were around $12.8 billion, with skyrocketing energy drink sales close behind at $9.8 billion, according to Ashley Sellers, communications executive, Euromonitor International. Even regulatory scrutiny around energy drinks and alcohol/caffeine combinations hasn’t slackened America’s thirst for caffeine.

Although FDA has been relatively silent on the topic of caffeine recently compared to years past, the first months of 2015 have already offered the agency several possible opportunities to comment or take regulatory action on caffeine. Whether it’s powdered caffeine, safe usage thresholds, or caffeine products aimed at children, here are a few of the possible targets for FDA action this year.

Safe-Limit Guidelines

In April, the European Food Safety Authority (EFSA; Parma, Italy) adopted its safety assessment of caffeine, including the opinion that 400 mg of caffeine per day is a safe threshold for adults. This 400 mg recommendation is in line with FDA’s stance, says Bill Frankos, PhD, former FDA director, division of dietary supplement programs, and currently the senior vice president for global product science, safety, and compliance at Herbalife International.

In the past, FDA has cited 400 mg of caffeine per day as “an amount not generally associated with dangerous, negative effects” for healthy adults, but the agency has not released anything as official or broad as EFSA’s safety assessment of caffeine. However, Frankos points to a 2013 caffeine report supported by the International Life Sciences Institute (ILSI) as a likely indicator of FDA’s thinking on the issue.

The ILSI report suggests, fortunately, that most Americans consume caffeine within that safe range—a finding that Frankos thinks FDA may look to as evidence of why further broad action on caffeine is unnecessary. Based on the caffeine habits of 37,602 Americans surveyed, the report found that the 90th percentile of caffeine intake for all ages was 380 mg/day, or within the recommended threshold.

“Based on this apparent lack of a widespread health hazard, Frankos says “it’s unlikely FDAs going to limit use of any specific beverage type.”

Frankos. “Those were primarily what are called shots, small shots, where you could get as much as 480 mg, up to 550 mg, in one shot. Something like that, that very specific type of product, I could see that they could say that you cannot sell a product like that when it has such a high level of caffeine, since its single use would be above the 400 [mg threshold].”
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Even in drinks with a single serving below the safe threshold, large cans may contain multiple servings of caffeine that total more than 400 mg. Frankos sees these products as another possible target of FDA action. For instance, the agency might say that such beverages have to come in a resealable container so consumers won’t be as likely to drink all that caffeine at once.

FDA guidance or proposals have already indicated the agency’s thinking in this area. In February 2014, FDA proposed to update the Nutrition Facts label to better reflect contemporary serving and packaging sizes. Under the change, a beverage that is likely to be consumed entirely in one sitting would feature nutrition information for the entire bottle’s contents regardless of whether it contains 12 oz or 20 oz. Additionally, in January 2014, FDA issued final guidance on how it distinguishes liquid dietary supplements from conventional beverages. The product name, packaging, graphic representations, recommended daily intake, and composition were a few of the criteria FDA said it would consider in determining whether a product is a supplement or a beverage.

**Powdered Caffeine**

Perhaps the greatest pressure FDA currently faces is around the availability of powdered caffeine direct to consumers. In January, six U.S. senators wrote to FDA and urged the agency to immediately ban direct-to-consumer marketing and retail sale of pure caffeine. The Council for Responsible Nutrition (CRN; Washington, DC), the American Herbal Products Association (AHPA; Silver Spring, MD), and the United Natural Products Alliance (UNPA; Salt Lake City, UT) have also spoken out against selling powdered caffeine to consumers and strongly discouraged their member companies from doing so.

“Consumers have no reason to purchase pure caffeine and would be unable to properly measure it into doses containing safe levels of caffeine,” said Steve Mister, president and CEO, CRN, in a press release dated January 27. “Direct-to-consumer sales of pure caffeine present an unreasonable risk to public health.”

A single teaspoon of pure caffeine contains roughly the same amount of caffeine as 25 cups of coffee, according to FDA. In 2014, two young men died after ingesting too much powdered caffeine, which has been a major factor behind the outcry.

Unlike a run-of-the-mill grocery store coffee product, “when you have a product that has labeling and dosage that could be really confusing and almost impossible for a consumer to discern, that obviously raises some issues,” says Rend Al-Mondhiry, CRN’s regulatory counsel. She adds that powdered caffeine sales to supplement manufacturers are not currently a subject of concern because manufacturers have a better understanding of how to properly handle powdered caffeine.

Last December, FDA did warn against the sale of powdered pure caffeine direct to consumers, but the sales still continue. By and large, Al-Mondhiry does not anticipate any major FDA movement on caffeine this year, but she does view powdered caffeine as one of the most likely targets of potential action.

“I know that they [FDA] are really concerned about the availability of that specific type of product to consumers,” said Al-Mondhiry.

**Caffeinated Kids**

Another aspect of caffeine FDA has yet to fully address is what is a safe level of ingestion for a young child, and especially because there seems to be a proliferation of these products that would be consumed as foods by children, such as putting caffeine in a cereal or in a waffle or in a pancake,” says Frankos.

Yet, even if FDA finds that food products marketed to children are leading to adverse health reactions, it could still be difficult for the agency to restrict common foods containing caffeine when a company can’t control how much of its product a child might consume, says Frankos.

“The only other thing [FDA] could do is possibly say that you cannot add caffeine to children’s cereals, let’s say, because they’re targeted to children and we don’t have enough evidence to determine what is a safe level of caffeine for children,” says Frankos. “That is something they could do, but it would have to be very specific to something that’s used only by children.”

Whether or not FDA actually does act on caffeine this year, keep an eye out for these elements of the caffeine discussion to continue making headlines in 2015 and beyond.

**References**

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Can Milk Casein Formula Alleviate Burnout?

Jacquet A et al. "Burnout: Evaluation of the efficacy and tolerability of TARGET 1 for professional fatigue syndrome (burnout)." Journal of International Medical Research, vol. 43, no. 1 (February 2015): 54-66

Workplace burnout has attracted plenty of attention in recent years. Whether it's stress-induced exhaustion or a general lack of involvement in work, burnout can be a crippling force for workers in any industry.

One potential source of relief may come in the form of a casozepine (milk casein) blend called Target 1, which performed well in a recent clinical trial of 87 participants. The Target 1 formula featured Lactium, a milk casein product from Pharmachem Laboratories (Kearny, NJ), which has been described as having a "benzodiazepine-like profile" by the French Pharmacopoeia, according to a press release.

The double-blind, randomized, placebo-controlled study took place at the University of Bordeaux (France), where 44 participants aged 18-65 suffering from some degree of burnout were given two 640-mg Target 1 tablets to take twice daily for 12 weeks. A comparable group of 41 participants received a placebo. All participants underwent verbal interviews on their life and mental state at the beginning and conclusion of the study. In addition to Lactium, Target 1 includes Extramel, a melon extract rich in antioxidants; taurine, an ingredient believed to have energizing properties; and the adaptogenic herb Eleutherococcus senticosus, which may increase the body's resistance to stress, said researchers.

At the outset of the study, all participants reported feeling at least "present" burnout exposure as evaluated on the Burnout Measure Scale (BMS-10), which is based on the degree to which participants score themselves on 10 parameters, such as feeling tired, disappointed with people, hopeless, trapped, helpless, depressed, physically weak, worthless/like a failure, difficulty sleeping, or feeling of "I've had it." The majority of participants reported "high" burnout, with a few reporting "very high" burnout.

By the end of the 12 weeks, 14 of the placebo participants still had a "high" level of burnout compared with 26 at the beginning of the trial, while only two participants taking Target 1 reported a "high" level of burnout compared with 33 at the trial's outset. The supplement group also presented greater improvement on the Maslach's Burnout Inventory Scale-Human Service Survey for professional fatigue than the placebo group.

The researchers concluded that "the dietary supplement Target 1, when used in association with verbal expression, might represent a primary tool in the care of people affected by burnout in the future."

Whey Protein May Preserve Lean Muscle during Weight Loss


Although consumers may embark on a weight-loss diet with hopes of shedding a few pounds of fat, a common and less-desired outcome can often be the loss of muscle mass.

However, a new study suggests that whey protein may be more effective at preserving lean muscle mass during weight loss than soy protein or carbohydrate supplementation. Taken simultaneously with a reduced-calorie diet, whey protein was found to preserve myofibrillar protein synthesis (MPS) to a significantly greater degree than the other supplements, according to a press release.

Losing hard-earned muscle may be every bodybuilder's nightmare, but it can also have metabolic consequences, according to the study's senior author, Stuart Phillips, PhD, Exercise Metabolism Research Group, McMaster University (Hamilton, ON, Canada).

"The greatest metabolic health benefits resulting from weight loss would be achieved with retention of muscle and a loss of fat," said Phillips, in a press release.

The double-blind, randomized controlled trial included 40 overweight or obese participants aged 35-65. For 14 days, the participants all followed a controlled diet of pre-packaged meals, resulting in a daily intake that was 750 calories less than the subjects previously typically consumed. The participants were randomly assigned to receive twice-daily supplements of isolated whey protein, soy protein, or isoenergetic carbohydrate (maltodextrin). The supplements were figured into each participant's daily energy allowance.

Participants were assessed before and after the weight-loss period with blood samples for plasma amino acid, insulin, glucose, and glycerol concentrations; muscle biopsies before and after meals; and body composition analyses by a DXA scan.

By the end of the 14-day trial period, all participants lost total body mass, fat mass, lean body mass, and trunk fat mass. Although MPS decreased in all groups, postprandial rates of MPS were reduced by just 9% in the whey group compared with 28% and 31% in the soy and carbohydrate groups, respectively. The researchers concluded that the reduced rate of MPS decline in the whey protein group could translate to preserving lean body mass in longer-term weight loss. "Our results indicate whey would be effective at promoting the retention of muscle when people are trying to lose weight," said Phillips.
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INGREDIENT SPOTLIGHT

Turmeric

By Shaheen Majeed, Sabinsa Corp.

Turmeric (Curcuma longa) is a plant that grows in tropical South Asia. The history of turmeric dates back to Marco Polo, who described turmeric in his journals when traveling to India in 1280 and introduced it to the Europeans on his return.1 Turmeric has long been used as a spice, a food color, and a natural remedy for various ailments in India’s Ayurvedic medical tradition dating back thousands of years. It has been used historically to treat chronic diseases and inflammation. In addition, turmeric has been used as an anti-aging, antibacterial, wound healing, analgesic, and antidepressant agent.2, 3

Scientific research and clinical studies in the modern era validate turmeric’s traditional use—in particular, the curcuminoids produced by the rhizome, or the underground stem, of Curcuma longa. Turmeric’s principal curcuminoid is curcumin, turmeric’s primary pharmacologically active ingredient. Other curcuminoids are demethoxycurcumin and bisdemethoxycurcumin.

Major, longstanding interest relates to curcumin’s effect on oxidative stress, joint inflammation, and hepatoprotection, but in recent times studies on curcuminoids have explored a wider range of health benefits in areas of anti-aging, hyperlipidemia, obesity, and metabolic syndrome.

Modern Science
* Editor’s note: All clinical studies mentioned ahead were performed on Sabinsa Corp’s (East Windsor, NJ) standardized curcumin extract, a composition containing naturally occurring curcuminoids—curcumin, demethoxycurcumin, and bisdemethoxycurcumin—which has been patented as a bioprotectant4 against biological tissue damage from free radicals.

Glycation
Glycation is part of the aging process in which sugar molecules chemically bond with human DNA, lipids, and proteins, damaging them and leading to completely irreparable compounds called advanced glycation end-products, or AGEs. Glycation has been implicated in many age-related chronic conditions and in the aging process itself. In skin, glycation reactions are responsible for weakening collagen fiber’s regenerative ability, which leads to the characteristics we commonly associate with visible skin aging: wrinkling, sagging, and looseness.

Curcumin has potent anti-glycation properties, suggesting that it may be employed as an adjunctive treatment in preventing glycation.5

Obesity
High blood fats, or hyperlipidemia, is a complication and often a risk factor associated with obesity. Curcumin has been demonstrated to have excellent lipid-lowering properties in obese subjects suffering from dyslipidemia.6

Metabolic Syndrome
Metabolic syndrome, a term little known prior to the last decade, has already reached epidemic-like proportions today, affecting millions. Metabolic syndrome is often associated with an increase in plasma triglycerides and LDL cholesterol, as well as low HDL cholesterol levels. Clinical studies on curcuminoids have shown remarkable effects on reducing lipid levels and thus reducing the risk factors for coronary heart diseases in metabolic syndrome patients.7

Curcumin’s metabolites, on the other hand, have shown the ability to trigger insulin release through free radical quenching and stimulating the body’s own endogenous antioxidant enzymes—SOD, catalase, and glutathione peroxidase. Curcumin metabolites such as tetrahydrocurcuminoids (THC) allowed the release of insulin into the blood more efficiently than curcumin alone in both animals with normal glucose and high glucose levels.8

Neurological Effects
Animal-model studies on curcumin suggest its neuroprotective activity. Initial studies demonstrate that curcumin minimizes brain damage in rodents when they are administered a brain-disrupting chemical, D-galactose, which causes rapid senescence, or senility, in these animals. This accelerated brain damage is a model for poor mental health that also occurs in humans. One study shows that curcumin passes the blood-brain barrier and exerts strong antioxidant effects when it gets there.9

Forced swimming tests in animal models showed that curcumin has a positive effect on mood by shortening the immobility period in animals when they are placed in water and forced to swim. Curcumin worked by increasing serotonin levels in the brain. It also lowered the dose of mood-elevating drugs needed to achieve therapeutic effects.10 The healthy mood effects of curcumin were enhanced when combined with small doses...
of piperine (Sabinsa’s patented BioPerine ingredient).11

Since cognitive decline is often related to age, the safety of any intervention in geriatric subjects cannot be ignored. A recent study on curcuminoids in geriatric subjects suffering from mild to moderate symptoms of Alzheimer’s disease provided support that curcumin can be considered safe when taken for long duration in geriatric subjects.12

Curcumin has also been studied for its benefits in management of major depressive disorders (MDD), a neurological condition. A clinical study conducted on over 100 subjects for six weeks showed improvement in the HADS score (Hospital Anxiety and Depression Scale) in subjects taking curcuminoids, thus improving the quality of life.13

Chemistry of Curcumin

The chemistry of curcumin in the body is quite interesting, and it is extremely important to understand it to gain the greatest benefits from this gift of nature.

Curcumin tends to metabolize quickly in the body, a fact that we understand from observations of its rapid disappearance from the blood. Recent studies have shown that the effect of curcuminoids in the body may partly stem from its active metabolites, one of which is THC. In 2011, Hassaninasab et al. discovered that the curcuminoids in turmeric, including curcumin itself, undergo immediate biotransformation by NADPH curcumin/dihydrocurcumin reductase to form active curcuminoid metabolites such as THC.14 Sabinsa Corp. posits that any low systemic levels of curcumin itself may be related to curcumin’s conversion into its metabolites. Curcumin also forms the conjugates such as curcumin sulphates and glucuronides, which have been studied to be inactive or do not have any therapeutic benefits.

Bioavailability Debate

Despite the fact that knowledge on the metabolism of curcumin is still limited, bioenhanced curcuminoids nevertheless continue to be introduced in the market today promoting more bioavailable forms of curcumin. In our opinion, these bio-enhanced curcuminoids may be only measuring curcumin glucuronides, and their “enhancement” methods are simply raising levels of inactive curcumin metabolites in the blood at the expense of active metabolites from curcuminoids.

We believe that current science on curcumin indicates the need to look more deeply into the metabolites of this ingredient, as these metabolites may hold the key to releasing the true potential of the biological activity of curcumin in the body.15

Shaheen Majeed is the marketing director of Sabinsa (East Windsor, NJ), a leading supplier of quality herbal ingredients of Indian origin supported by clinical studies, patents, and trademarked brands.

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Tea Time

Ready-to-drink teas venture into new territory

BY MICHAEL CRANE, ASSOCIATE EDITOR

It’s a good time to be in the tea business. In March, the American Botanical Council (ABC; Austin, TX) announced that U.S. sales of brew and ready-to-drink (RTD) teas increased by 4.1% in 2014, reaching a total of more than $4.3 billion. Loose, bagged, concentrated, and herbal teas accounted for approximately $1.8 billion of the market with 3.6% growth in 2014, but ready-to-drink (RTD) teas are still the larger force with 4.4% growth in 2014 to reach a total of nearly $2.5 billion. The report was published in ABC’s peer-reviewed journal, HerbalGram.

But even in an industry as established as tea, there’s still room for the new and different. Whether it’s tea enhanced with whey protein or tea made just for kids, plenty of innovation is taking place around one of the world’s oldest drinks.

Protein Tea

With its first U.S. launch last fall, one beverage company is combining the specialized benefits of a functional beverage with the mainstream appeal of a RTD tea. Blu-Dot Beverage Company (Oakville, ON, Canada) now offers five RTD teas that include 12 g of whey protein and 6 g of chicory root fiber in each 473-ml bottle. The flavors range from blueberry acai to cranberry pomegranate, and the teas are sweetened with either organic cane juice or stevia for a lower-calorie option.

“I thought this product would have a much better chance of crossing the chasm from being seen as a sports nutrition drink just because it has protein, into an everyday, supporting-a-healthy-lifestyle beverage,” says Kevin Stratton, CEO, Blu-Dot. He adds that the stevia-sweetened drinks contain only 60 calories and 1 g of sugar per bottle.

There were some challenges that came along with infusing a tea with protein and fiber. Stratton says whey protein has a “naturally astringent quality,” so it required a careful balance to maintain the flavor of the tea while also including the functional elements. The addition of the protein and fiber can start to cloud a beverage, but Blu-Dot worked to keep the teas looking clear. Blu-Dot’s teas also have a more substantial mouthfeel than other mainstream RTDs, says Stratton, but still maintain a flavorful taste.

Since the brand first launched in Canada three years ago, Stratton says he has “absolutely” seen the market for functional teas growing.

“It really has quite a mass appeal to a wide range of people,” says Stratton.

Tea for Kids

Another emerging trend is tea designed specifically for children. Winner of the Best of East Press Award 2014 at last fall’s Natural Products Expo East, Little Me Tea (Lawrenceville, GA) offers a line of RTD children’s teas in single-serve juice box size. Melinda Hicks, founder, promotes the teas as a healthier alternative to juice.

“Many parents have forsaken any juice for their children, giving only milk and water,” says Hicks. “When they find out about Little Me Tea, they’re thrilled because now they have a third beverage choice that’s healthy and nutritious but not loaded with sugar.”

Little Me Teas are made from a blend of white, rooibos, hibiscus, and chamomile teas. There are currently four available flavors, two of which were introduced in September of 2014—Fruit Punch Tea and Berry Tasty Tea. The 6.75-oz single-serve boxes contain 6 g of sugar, 30 calories, and zero caffeine, according to Little Me Tea’s website.

“Tea for kids is actually a burgeoning market,” says Hicks. “It’s becoming more and more mainstream as people try to shift their children away from sugary sodas and juices.”

Although tea may be outpaced on the caffeine market by coffee and energy drinks, products like these suggest that tea’s healthy appeal remains a strong driver of growth.
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