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Counterfeiting and Amazon

Online dietary supplement sales are quickly outpacing supplement sales in other retail channels. In February, e-commerce and analytics firm Slice Intelligence reported that online vitamin and dietary supplement sales are growing 12% faster than the average e-commerce category. Unsurprisingly, Amazon.com accounts for a vast percentage of those online sales: up to 77% of all online supplement sales, Slice estimates.

With so much third-party reseller activity over dietary supplements happening on Amazon.com, it’s almost expected that some of that activity will be at the hands of bad actors, such as those selling counterfeit products.

And indeed, counterfeiting is happening. In July, Wired magazine was the first to report that Amazon had warned customers via e-mail that they might have purchased counterfeit products passed off as Procter & Gamble’s Align probiotic supplement. (According to an attorney I spoke to for this piece—CJ Rosenbaum, a founding partner of law firm Rosenbaum Famularo PC, which also runs the website AmazonSellersLawyer.com—Amazon does not often warn customers about counterfeit products.) Another supplement counterfeit case was reported this year when Nutramax Laboratories issued a warning that consumers purchasing its Avmacol supplement from a reseller on Amazon had likely been sold counterfeit product.

But just how often are counterfeit dietary supplements being sold on Amazon?

Surprisingly, not as often as one might think, according to Rosenbaum. Whatever the reason may be, he says, “We don’t see anywhere near as much counterfeiting—or the accusation of counterfeiting—in supplements as we do in other areas.” Compare this, he says, to other hot categories like electronics, or even beauty products. Rosenbaum should know. His company is dedicated to helping companies fight counterfeiting—particularly, counterfeiting on Amazon. “We help third-party sellers all over the world deal with the bumps in the road of doing business on Amazon. We also help a lot of small-to-medium-size brands protect themselves and protect their brands against counterfeit sales,” he says.

It’s good news that supplement counterfeiting isn’t rampant. The bad news? When supplement counterfeiting does happen, there can be dangerous consequences for human health. “If you buy a counterfeit lightning cable…you know, who cares? No one is getting hurt from a counterfeit lightning cable. But if you’re taking a counterfeit Garcinia cambogia supplement, for example, someone could get really sick. So I think the problem [of dietary supplement counterfeiting] is relatively small, but when it craps out, the damages are big,” says Rosenbaum. Those damages, of course, also include the sales lost by a legitimate company to a counterfeit—not to mention degradation of the company’s good name and consumers’ brand loyalty.

In some respects, a behemoth like Amazon will never be able to control the behaviors of all that use its platform. It’s the same problem that another giant platform, Facebook, faces, because bad actors will always be part of the landscape. But these platforms could be doing a better job. Like Facebook, Amazon has used the defense that it is simply providing a marketplace where third parties and customers can do business and that it is not responsible for the behaviors of those parties, including counterfeiting. (For a deeper understanding of Amazon’s history and defense, I encourage you to read the series of articles that the author Louise Matsakis has written for Wired.) It also should be pointed out that Amazon itself also participates in reselling—in fact, this represents a good chunk of Amazon’s business—and can itself fall prey to selling counterfeit products, Rosenbaum says. (He says that in these cases, Amazon often does not issue warnings to consumers. “I tend to trust a third-party seller myself more than Amazon based on what I’ve learned,” he says. “Some I can share with you, some I can’t.”)

What could Amazon be doing better? Plenty, according to Rosenbaum. To start, he says, Amazon could attempt to do a cursory inspection of products to ensure they are authentic before they are passed on to consumers. Wouldn’t the resources to do that be prohibitive, I asked him, considering the sheer volume of product Amazon.com sells? No, he says, because 80% of the counterfeits on the market are very apparent and detectable because those counterfeiters do such a poor job. (Think: misspellings on the label or other obvious callouts.) “The vast majority of counterfeits you see in two seconds,” he says. “So by just having some review system in place, Amazon would protect legitimate sellers who are not sending in counterfeit products, and protect consumers.”

Unfortunately, he says, a review process like this is “nonexistent” at Amazon. “It would cost Amazon some time and some money, and Amazon likes to pass the buck on to everybody else and onto the sellers rather than take responsibility itself, which I guess is good business but it doesn’t really protect the consumers,” he says. (In the past, Amazon has tried to establish initiatives such as Project Zero to enable brands to take action themselves on counterfeit listings, but according to Rosenbaum, those programs “haven’t really taken off.”)

Short of any changes made on Amazon’s end, what can responsible sellers and customers do to protect themselves? Be aware, Rosenbaum says, and inspect the product you are buying more closely. And take some comfort in knowing that, at least when it comes to dietary supplements, the problem with Amazon is—one hopes—not as vast as one might imagine.

Jennifer Grebow
Editor-in-Chief
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In August, SPINS (Chicago, IL) released its first-ever “State of the Natural Industry” report and shared some facts and figures via webinar. One of the most important takeaways was that the natural food and beverage space is outpacing its conventional counterparts in dollar growth. The total food and beverage market, which amounts to $448.2 billion, grew 1.7% year over year in 2018, while the natural food and beverage space, which accounts for $47.2 billion of the total market, grew 5%.

So, even though the natural category represents 10.5% of the sales volume in the total food and beverage market, it accounts for 29.3% of the dollar growth. Even within the conventional multi-outlet retail channel, natural represents 9.1% of the sales volume but made up 27.4% of the dollar growth in the channel.

Product attributes driving growth in the marketplace are organic, plant-based, and paleo. Organic products make up $13.4 billion in cross-channel grocery—3% of the total food and beverage sales volume—but are outpacing the total market’s growth rate by 1%. Products labeled as vegan grew 10.1% in 2018 to a $7.1 billion market, a significant portion of which comes from the conventional multi-outlet channel, which saw $5.5 billion with 10.8% growth. While paleo and grain-free products have been growing for some time, SPINS was impressed by the growth of 45.3% and 76% for paleo and grain-free, respectively, in the conventional multi-outlet channel.

Another fascinating takeaway is the growing significance of the convenience channel. Natural products make up less than 5% of the channel’s food and beverage volume, but natural sales are up 12.6% to $2.7 billion. Some key sub-categories driving this growth are natural performance beverages, enhanced water, puffed snacks, and kombucha. While the convenience channel has a smaller volume, it’s growing three times faster for natural products than natural and specialty gourmet channels, and twice as fast as conventional multi-outlet.

SPINS attributes this to higher distribution changes than the legacy and conventional multi-outlet channels, meaning that more natural products are entering the assortment and replacing mainstream products that aren’t performing well. Convenience also offers a lot of grab-and-go options, which supports the idea that consumers buy natural products when it is convenient for them. Other channels, in turn, should adjust their assortment to include more innovative products.

When it comes to vitamins and supplements by channel, the sale of vitamins and supplements in legacy channels like the natural channel make up 12% of total store sales; conventional multi-outlet makes up 7%; and convenience makes up only 4% of total sales. While share of sales is fairly constant in legacy channels, at 1.7% growth, conventional multi-outlet fell 1.2%, and the convenience channel has grown its share by 23.4% year over year. It’s on a much smaller base, but it’s indicative of the migration of natural products to this channel, says SPINS. The food supplements category—products such as medium-chain triglycerides (MCTs), cannabidiol (CBD), and fish oil—is driving this increase with a year-over-year percent share change increasing by 523%.

Because the natural and specialty channels are a pipeline for innovative products that eventually migrate into the conventional and convenience channels once trends and products mature, brands have to decide whether they want to be innovators or join once a product or trend is proven. Therefore, monitoring progress cross-channel is crucial, says SPINS.
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Innovation and market trends frequently get ahead of regulations, but the blazing speed at which hemp cannabidiol (CBD) products are being marketed in the U.S. ahead of a clear regulatory pathway may be record-setting in this regard.

Hemp Agriculture Rules Not Yet Established

While the December 2018 Agriculture Improvement Act—also referred to as the 2018 Farm Bill—removed hemp from the Drug Enforcement Administration’s (DEA) Controlled Substances list and allows for U.S. hemp cultivation, that allowance only applies to future crops: crops that can be planted, grown, and harvested only after the U.S. Department of Agriculture (USDA) promulgates the enacting regulations and policies for hemp agriculture. At the time this article was written, USDA had not yet promulgated its regulations. Despite the fact that it has been widely published that these regulations are still in the works, there has been no apparent slowdown in the growth of the CBD sector.

A further reality that does not appear to have affected CBD sales is the fact that the 2018 Farm Bill does not legalize interstate commerce of CBD. It simply allows each “state or Indian tribe” to develop programs that will conform to the yet unwritten federal regulations. In January 2019, shipment of hemp grown in Oregon was seized and the truck driver arrested for transportation of an illegal substance in Idaho, a state which has not participated in the federal hemp program. As of this writing, the case is under appeal after a judge ruled that the hemp being transported in January 2019 could not have been produced under the 2018 Farm Bill, whose rules have not yet been written. However, in late May 2019, USDA’s General Counsel, Stephen Vaden, published an opinion asserting that states could not prohibit the transportation of hemp that had been legally produced under the 2014 Farm Bill. However, the authors of this article point out that hemp produced under the 2014 Farm Bill is allowed for research purposes only, not for commercial purposes, so is the hemp grown in Oregon still considered “legally” produced? The United States Court of Appeals for the Ninth Circuit will have to decide this case.

The Cloudy CBD Market

A further complication for CBD sellers is the fact that the regulatory landscape for CBD products is confusing. After passage of the 2018 Farm Bill, many in the food, dietary supplement, and cosmetic industries falsely believed—and still attest—that CBD is now legal. In actuality under the Federal Food, Drug, and Cosmetic Act, CBD is not permitted in foods, beverages, or dietary supplements. According to U.S. Food and...
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Drug Administration (FDA) regulations, foods and beverages containing CBD are adulterated unless permitted at the state level. Furthermore, CBD-containing foods and beverages may not be sold in interstate commerce.

Potential Regulatory Pathways
With respect to regulatory categories that CBD may fall into, there are a few that are relevant to the topic at hand:

New Food Ingredient
A substance that was not in the U.S. food supply before 1958 must either have Generally Recognized as Safe (GRAS) status or be approved as a food additive. Some groups claim to have self-affirmed GRAS status for their CBD ingredients, but the publicly available data that our experienced team has been able to review to date do not appear to sufficiently meet the GRAS requirement of a “reasonable certainty of safety.”

New Dietary Ingredient
CBD is not a grandfathered dietary ingredient (an ingredient sold in the market prior to October 25, 1994, the day the dietary supplement law, the Dietary Supplement Health and Education Act, or DSHEA, passed). Because of this, CBD is not permitted in dietary supplements without the submission of a new dietary ingredient (NDI) notification to FDA.

Companies have unsuccessfully tried to submit NDI notifications to the agency. In 2017, HoneyColony submitted an NDI notification for its Superior Hemp/CBD Oil. In its response, FDA rejected this CBD oil as a new dietary ingredient, citing conflict with the investigational new drug (IND) provision prohibiting CBD’s use as a dietary ingredient if it has first been investigated as a drug. (More on this ahead.)

FDA stated:

Based on available evidence, FDA has concluded that CBD products are excluded from the dietary supplement definition under 21 U.S.C. § 321(ff)(3)(B)(ii) (section 201(ff)(3)(B)(ii) of the Act). This is because CBD has been authorized for investigations as a new drug for which substantial clinical investigations have been instituted and for which the existence of such investigations has been made public. Prior to such authorization it was not marketed as a dietary supplement or as a food.

FDA rejected a 2015 NDI notification for cannabinoids, including CBD, from Pure Evolution Enterprise for similar reasons.

Is FDA’s Regulatory Stance on CBD Evolving?
In June 2018, FDA approved the CBD-based drug Epidiolex® from GW Pharmaceuticals as a treatment for two rare forms of epilepsy. DSHEA, the law governing supplements, prohibits approved drugs or substances for which substantial clinical investigations have been instituted to be marketed as dietary supplements.

On March 28, 2019, during a Senate appropriations subcommittee hearing, then-FDA Commissioner Scott Gottlieb, MD, stated that FDA was using enforcement discretion towards CBD products already on the market but that the agency would take action against companies making drug claims. U.S. Senator Patrick Leahy (D-VT) asked for certainty on this approach for the industry; Gottlieb responded that there was not a “clear route short of new regulations” but that FDA was looking at “options to propose to Congress for legislation on this topic.”

However, it has since been reported that at the May 14, 2019, Dietary Supplement Regulatory Summit—a one-day event organized by leading dietary supplement industry trade associations featuring updates and insights from FDA on regulatory matters—Steven Tave, director of FDA’s Office of Dietary Supplement Programs, stated that the agency hasn’t adopted a formal policy of enforcement discretion.

At FDA’s first public hearing on CBD on May 31, 2019, “Public Hearing on Scientific Data and Information about Products Containing Cannabis or Cannabis-Derived Compounds,” acting FDA commissioner Norman Sharpless, MD, plainly stated that “under current law, CBD and THC (delta-9 tetrahydrocannabinol) cannot lawfully be added to a food or marketed as a dietary supplement.” He further stated that the agency does not have a policy of enforcement discretion with respect to any CBD products.

During that May 31 public hearing, approximately 120 companies, organizations, and private citizens also made public comments regarding CBD. There were consistent calls for FDA to act quickly to set up a regulatory framework to police the mushrooming CBD market. Several speakers pointed to risks of an otherwise underregulated market, noting that CBD products can often be contaminated with pesticides and heavy metals and often do not contain the amount of CBD claimed on their labels. Some showed data indicating that CBD products were often of lower potency than claimed, or, conversely, some many times higher than claimed. Still other products contained significant levels of THC when they should not. Many presenters asked that FDA require good manufacturing procedures and proof of purity and potency for CBD manufacturers.

In June, the U.S. House of Representatives passed an appropriations bill “to include critical funds that would enable FDA

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to undertake the appropriate processes and set a safe level of CBD for consumers to use each day. It has been reported that Senate Majority Leader Mitch McConnell (R-KY) is also interested in seeing FDA move quickly on CBD regulations. The Majority Leader stated, “Congress’s intent was clear with the passage of the Farm Bill that these products should be legal, and our farmers, producers, and manufacturers need clarity as well as a workable pathway forward regarding the agency's enforcement...Like my constituents, I am anxious to know the FDA’s plans to ensure public access to safe CBD products.”

On July 23, 2019, FDA announced that the agency had sent a warning letter to a company called Curaleaf Inc. (Wakefield, MA) for illegally selling unapproved CBD-containing products. In its press release, the agency noted that a high-level working group was exploring potential pathways to lawfully market CBD products. The press release quoted FDA’s Principal Deputy Commissioner Amy Abernethy, MD, PhD, saying that the working group “plan[s] to report our progress by early this fall as we expedite our work to address the many questions about CBD. The step-wise, science-based approach we’re taking protects patients and the public health, fosters innovation for safe and appropriate products, and promotes consumer confidence.”

Dr. Abernethy provided a fuller description of the working group in her July 25, 2019, testimony before the Senate Committee on Agriculture, Nutrition, and Forestry.

Also notably, former FDA Commissioner Scott Gottlieb, MD, published an editorial in The Washington Post on July 30, 2019, that largely echoed Dr. Abernethy’s statement on the need to develop a CBD regulatory pathway but added, “The FDA is being pushed by all sides to act quickly. Meanwhile, responsible food makers waiting for regulators to address the legal and safety considerations before launching CBD products are being eclipsed by unscrupulous purveyors. Obligating the industry to do the front end of this scientific work—and sweeping the market of those who won’t—could advance a safe path and help establish the stable market for hemp-derived CBD envisioned by lawmakers.”

Regulatory Assessment
So, what is the regulatory status of CBD, and are we likely to see updated regulations soon? It seems that foods and beverages containing CBD are likely to remain high-risk, while dietary supplements would appear to be a slightly lower-risk option for manufacturers or distributors of CBD-containing products. We expect that it will be many months before the regulations catch up with the market. FDA would clearly have a hard time removing all CBD-containing products from the market, and yet the agency is charged with ensuring the safety of foods and dietary supplements sold in the U.S.

What should a responsible manufacturer or distributor do to ensure product safety and mitigate their regulatory risk as much as possible? The authors recommend the following steps:

- Follow state regulations on grow and transport operations
- Follow dietary supplement current Good Manufacturing Practices (cGMP) regulations
- Test the product for purity and potency
- Label the product as a dietary supplement without implied or explicit therapeutic claims
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Foods and beverages containing CBD are likely to remain high-risk, while dietary supplements would appear to be a slightly lower-risk option for manufacturers or distributors of CBD-containing products.

- Clearly indicate the level of CBD on the product label
- Partner with industry groups to develop a dossier demonstrating safety for use in a future NDI notification or GRAS notification
- Prepare a plan B in the event of unfavorable changes to the regulatory situation

The key to success in any venture is to understand the various factors that could affect your business. Any products that are ingested are subject to regulation by FDA, making understanding applicable regulations crucial. In an uncertain industry such as the market for CBD-containing products, it is imperative to work with experts who can help you understand the current environment and respond to future changes.

About the Authors

As a team of experts, our companies collaborate together and are currently working with several CBD clients, from seed to finished manufactured product.

Katrina Emmel, PhD, is the founder and president of analytical laboratory KemmelCal Inc. (www.kemmelcal.com). She is experienced in analytical method selection, data review, and establishing product specifications for ingredients used in foods and dietary supplements. Dr. Emmel has over seven years of experience in drafting, reviewing, and serving as an expert panelist for GRAS evaluations.

Evelyn Cadman is the owner and principal consultant for FDA Compliance Simplified (www.FDASimplified.com), offering technology evaluation, product development, and regulatory affairs services to the food, cosmetic, nutritional supplement, and biotech industries. She has worked in regulatory affairs and product development for FDA-regulated products since 1997.

Cheryl Dicks is managing partner of Live Well RACE and CBD Compliance Simplified (www.CBDcompliancesimplified.com). With over 20 years’ experience in the dietary supplement and pharmaceutical arenas, the company offers its clients support in product development, manufacturing, cGMP compliance, clinical trial development, quality management system development, and regulatory agency support and filings.

References

In this series on cannabinoids and full-spectrum hemp, we have touched on the regulatory challenges in this ever-changing landscape (see page 14) as well as the need to set quality controls or standards for the product being produced (see page 46). FDA has one main focus regarding all molecular entities—whether chemical, botanical, or food-derived: to ensure that the safety, identity, purity/quality, and intended use of an ingredient is suitable for human and animal use. A product’s use, depending on the label claim and other regulatory considerations, can be categorized as a cosmetic, drug, food ingredient, or dietary supplement. First, we implement regulatory and quality considerations; then a standard for manufacturing follows.

So, where do hemp and cannabinoid products fit in the manufacturing standards landscape? This has become the question in the absence of clear FDA guidance and regulations for manufacturing.

In 1994, the law governing dietary supplements, the Dietary Supplement Health and Education Act (DSHEA) was passed, giving FDA authority to establish federal guidelines for current good manufacturing practices (cGMPs) in order to guide industry in the manufacturing of quality finished products for human consumption. Today, the Cannabis industry appears to be following the dietary supplement industry in a similar fashion, with conversations now happening between industry and FDA regarding the agency’s regulatory views.

The 2018 Farm Bill removed hemp-derived products from the Drug Enforcement Administration’s (DEA) Schedule I of the Controlled Substances Act. The removal of hemp (with a limit of < 0.3% tetrahydrocannabinol, or THC) from the definition of “marihuana” redefined hemp as an agricultural product and has led to an explosion in the industry of hemp-derived cannabinoid extracts. The Farm Bill does not, however, exempt “hemp” from the Food, Drug, and Cosmetic Act (FD&C Act), which legally requires compliance with manufacturing standards in order to produce a quality and safe product.

This article is part of a three-part series written by the authors for Nutritional Outlook. See the other articles in this series on pages 14 and 46.
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While the regulatory debate continues around hemp and cannabidiol (CBD), what can the industry do to prepare for the likelihood of cGMP requirements if they are one day mandated for this class of ingredient? Will the cGMP requirements mimic those for pharmaceuticals (under 21 CFR 210/211), food (21 CFR 117), food under the Food Safety Modernization Act (FSMA), or dietary supplements (21 CFR 111)? There are several variances between the cGMP regulations for foods, dietary supplements, and pharmaceuticals. These regulations have long been amended and enforced in order to provide safe and efficacious products for consumption and treatment of diseases in the human condition.

Regardless of the product category (drug, food, or dietary supplement), cGMP regulations are applicable to any facility that manufactures, processes, packs, or holds a product for sale. The goal of cGMPs is to provide the following compliance standards:

- Identity testing of the raw material
- Establishing a quality assurance/quality control unit in house
- Mandatory expiration dating on the finished product
- Control records for master and batch productions
- Establishment of process and production controls to meet product specifications
- Establishment of written standard operating procedures (SOPs) and documentation
- Expanded procedures for storage and distribution of the raw material and final product
- Procedures to handle consumer complaints and product returns
- Requirement for reliable and reproducible data, test methods, and results to specifications
- Safety data of finished product and its beginning and intermediate products

Whether hemp producers should follow the cGMPs for pharmaceuticals, foods, or dietary supplements will be determined by:

- The label claim
- Whether the producer is a grower and/or processor making a raw material to be used as an ingredient for the pharmaceutical or dietary/food market
- Whether the producer is manufacturing a finished dietary supplement product

Let’s take a look at each possible option, depending on the category, with regard to non-psychoactive hemp ingredients (not more than 0.3% THC by dry weight) with the intent to be used as a food or dietary
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Numerous factors determine whether hemp companies should follow cGMPs for pharmaceuticals, foods, or dietary supplements.

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References

supplement ingredient. Which cGMP regulation may then apply?

Hemp Growers Providing Dry, Unprocessed Product to the Market
There are a few considerations here in this category. First, the U.S. Department of Agriculture (USDA) becomes the prime regulatory authority both on federal and state levels, with the requirement under the interim final rule published in 7 CFR 990 to establish a domestic hemp production program. Growers can set quality standards for their product by considering the use of organic certification standards for their crop and keeping good production records, as well as strain/species identification records. Furthermore, developing an analytical profile of the harvested dried crop that identifies the THC level, cannabinoids, terpenes, and phenolic compound levels will support the quality and identity of the processed CBD products downstream. Growers can establish a quality system and good agricultural practices (which can be related to cGMPs).

Hemp as an Ingredient
(Processors/Product Manufacturers)
This category references the production or manufacturing of extracts from the dried harvested hemp. If processors are claiming to produce a food or dietary supplement ingredient, compliance with 21 CFR 117 cGMPs comes into play. It is important to note that proper procedures for the identification of the raw material to be processed (i.e., dry harvested crop product) is critical. This links back to the grower and their quality standards and good agricultural practices.

If one is producing an ingredient for use in a future finished product, the establishment of identity, chemical profile, specifications, and reproducible processes and procedures for manufacturing to establish product specifications is a must. A spin-off to compliance with cGMPs is the establishment of an overall robust quality management system (QMS), another attribute that is expected in the production of a quality ingredient.

Part 117 establishes cGMPs, as well as the requirements for food safety plans, hazard analyses, and risk-based preventive controls, which concern preparing and maintaining records for such areas as:

- Production
- Complaints
- Corrective actions
- Verification/validation of processes and procedures for manufacturing
- Identification of raw materials and finished products
- Specifications
- Receiving and distribution
- Other required cGMP records

Hemp as a Dietary Supplement
For companies manufacturing or contracting the manufacture of a dietary supplement, 21 CFR 111, “Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements,” comes into play. Compliance with these regulations also looks back along the supply chain to the quality of the product provided by both the hemp grower and the ingredient manufacturer. These cGMPs cover such areas as quality systems, personnel and training, conditions of facility and grounds, established and verified production processes and procedures, complaints, corrective actions, recordkeeping, receiving and distribution procedures, and specifications for ingredients and finished products.

Regardless of where in the production/supply chain a company sits, establishing a robust QMS and demonstrating compliance with a set of cGMPs or Good Agricultural Practices will situate a company well for preparation of any future FDA regulatory guidance for cannabinoid products.
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Is It Natural?

Economic adulteration in the natural products industry and the need for carbon-14 testing

By Haley Gershon, Beta Analytic

Throughout the supply chain, producers, manufacturers, and distributors are struggling to meet consumer demand for naturally sourced products. With this increasing pressure to satisfy consumers, there is the consequent potential for ingredient adulteration.

Economic adulteration and ingredient fraud are common risks within the food and flavor industries, especially as companies compete with one another on product prices. Economically motivated adulteration refers to the act of fraudulently and intentionally adding or substituting a substance in a product for the purpose of either adding value to a product or decreasing the cost of production, with the overall goal of economic gain. This is especially common with food ingredients and flavors as unscrupulous manufacturers and distributors produce, buy, and sell adulterated products while competing with one another.

Often, products which are 100% naturally sourced (i.e., sourced from plants, animals, or microbiological materials) tend to be more expensive compared to their synthetic counterparts. For example, naturally derived sandalwood is priced high due to variable crop output and shortages. Thus, some stakeholders may be inclined to fraudulently mislabel less-expensive petrochemical-derived product ingredients as naturally sourced.

Bitter almond oil is another example. Bitter almond oil is in high demand and widely used as a flavoring agent. Bitter almond oil consists of benzaldehyde naturally sourced from almond kernels, peach kernels, and apricot kernels. Due to the high cost and limited supply of naturally sourced bitter almond oil, the oil is highly susceptible to adulteration. In some cases, synthetic benzaldehyde from petrochemical feedstocks is fraudulently used in place of the naturally sourced ingredients.
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This is likewise the case with several other highly priced extracts and essential oils which are popular among consumers, including: adulteration of turmeric with petrochemical-derived synthetic curcumin, sandalwood oil substituted with petrochemical-derived synthetics, and bergamot oil adulterated with synthetic linalool.3,6,7 Economically motivated adulteration is prevalent among some of the most in-demand ingredients. In response, quality-control departments are in need of analytical techniques that can detect ingredient adulteration.

Natural-Source Testing Using Carbon-14 Analysis
As botanical adulteration continues to challenge the food and flavor sectors, natural product testing using carbon-14 analysis is a necessary addition to quality-control procedures.

Carbon-14 is a radioactive isotope which decays at an exponential rate after the death of a living organism. There is a known level of carbon-14 in recently living feedstocks such as plant extract, whereas there is no carbon-14 left in fossil fuel–derived material.8 Thus, to distinguish between naturally sourced and petrochemical-based ingredients, the amount of carbon-14 present in a given sample is counted.

The carbon-14 content is measured according to standardized methods such as ISO 16620-2 and ASTM D6866, which can be used specifically for products such as flavors, fragrances, supplements, food ingredients, and beverages.9,10 Both ISO 16620-2 and ASTM D6866 determine the biobased content of solid, liquid, or gas samples using carbon-14 analysis. An analytical report under ISO 16620-2 or ASTM D6866 will represent the percentage of the sample that is sourced from bio-based material. Materials completely sourced from biomass...
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will be 100% biobased, while, on the other hand, a material only sourced from petrochemical-derived synthetic constituents will be reported as 0% biobased. Furthermore, if a product is a mixture of both plant extracts and fossil fuel content, then the result reported will reflect a percentage between 0% and 100% in proportion to the amount of each component in the product.8

A Necessary Step
Due to economic factors, some stakeholders within the food and flavor sectors are tempted to replace biomass-based ingredients with petrochemical synthetic adulterants. Because of this, there are widespread instances of adulteration, several of which are left undetected. In order to detect cases of adulteration, carbon-14 analysis serves as an effective and accurate technique to distinguish between petrochemical-derived ingredients and naturally sourced ingredients.9

References
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The 2018 Farm Bill removed hemp and hemp-derived cannabidiol (CBD) from the U.S. Drug Enforcement Administration’s Schedule I drug list, but even so, there’s still much uncertainty around how the resulting CBD marketplace will be regulated and to what extent existing rules and best practices will be enforced. In the meantime, responsible parties aren’t waiting for standards to come from above. A growing faction of industry associations, testing labs, suppliers, and finished product manufacturers are exercising due diligence, each in their own way, to self-regulate and promote responsible behavior, claims, and best practices in an immature hemp and CBD market. Here’s a snapshot of their progress.

**Testing Your Own Ingredient**

Because the current CBD market is already full of diverse claims—including claims of superior bioavailability, specialized extraction processes, and various ranges of cannabinoid content—it’s safe to say that not every CBD extract is the same.

“What the CBD industry can’t do is market heavily on the fact that their CBD is unique, better, or different—and at the same time not be willing to gather the requisite data on safety and benefits,” says Duffy MacKay, ND, CV Sciences’ (San Diego, CA) senior vice president of scientific and regulatory affairs.

Though many CBD companies are going to market without rigorous safety data on their own unique products, CV Sciences is doing the hard work. Last year, the company contracted AIBMR Life Sciences (Seattle, WA) to conduct a toxicological assessment of its PlusCBD brand of hemp-derived CBD oil. Following this toxicological assessment, CV Sciences achieved the first Generally Recognized as Safe (GRAS) self-determination for a CBD hemp oil extract.

To this day, the company continues to track safety data on its products by utilizing a third party that collects and analyzes all product complaints and adverse events with the aid of medical doctors on staff and a system called Nutravigilance. CV Sciences says it has already submitted a year’s worth of data, combined with data from other CBD firms, to FDA as part of the public comments that hemp-advocacy group U.S. Hemp Roundtable (Lexington, KY) submitted to FDA this
The need for standardized analytical testing grows greater each day as more products flood the CBD market. The need for analytical labs that know how to properly handle cannabis also grows.

Seeing a need to create integrity through analytical testing, cannabis certification bodies are forming. Perhaps largest in scope is the recently formed International Cannabinoid Analysis Program (ICAP), a joint venture between the contract research organization Nutrasource (Guelph, ON, Canada) and independent botanical testing lab Alkemist Labs (Garden Grove, CA). As an international program rather than a strictly U.S. one, ICAP’s THC threshold is set at 0.2% THC so that it falls under the THC cap for the U.S. but also EU regulations.

In another effort to increase confidence and improve decision making in the hemp products market, independent testing labs are developing methods to, first and foremost, detect the presence of delta-9-tetrahydrocannabinol (THC) in hemp products. THC is the psychoactive compound in cannabis. Under the 2018 Farm Bill, industrial hemp—which would be the hemp used in hemp foods and health products—cannot have a THC concentration higher than 0.3% on a dry weight basis.

The need for standardized analytical testing grows greater each day as more products flood the CBD market. The need for analytical labs that know how to properly handle cannabis also grows. “There are, at this point, a handful of peer-reviewed and validated methods available to all labs,” says Alkemist Labs CEO Elan Sudberg. “They produce slightly different results. That’s confusing and problematic if labs don’t know how to resolve those discrepancies.”

The first ICAP certifications were scheduled to be awarded this September.
Raw-Material Sourcing

Industry associations are taking it upon themselves to create best practices for self-regulation of the hemp and CBD industries in ways that reach all the way from the farms that grow hemp to the manufacturers of branded, finished products.

Seeing an immediate need to embrace the new CBD market, dietary supplement association the Council for Responsible Nutrition (CRN; Washington, DC) began opening up its membership to CBD food and dietary supplement companies in April. Besides requiring that each CBD manufacturer’s products be derived from hemp and contain no more than 0.3% THC (the U.S. limit), the standards CRN demands of its CBD members are largely in line with those normally required of CRN member companies. They must use facilities that adhere to current Good Manufacturing Practices (cGMPs), abide by food safety regulations such as adverse event reporting, not make illegal disease claims on products, and back any lawful claims on products with scientific substantiation. The list goes on, but it’s largely in line with dietary supplement regulations in general.

For standards unique to hemp and CBD extraction, specialized organizations are emerging. The U.S. Hemp Authority (Lexington, KY) is a new certifying body situated in one of the fastest-growing states for U.S. hemp production. Led by experts from across the hemp and natural products industry, it already has more than 20 certified companies—including growers, manufacturers, and brands—that are adopting core principles for all things hemp. Examples of these particular hemp industry standards include best practices for pre- and post-harvest sampling, cannabinoid testing, contaminant testing, and hemp drying and curing. Interested parties are encouraged to check out the full U.S. Hemp Authority Guidance on the certifier’s website for a wealth of beneficial hemp industry guidance soon to be updated in a 2.0 version.

For companies seeking safe and vetted sources of hemp materials and CBD extracts, the Hemp Exchange is a useful new service designed to verify hemp farms, processors, and manufacturers for accurate representation and product traceability. Member
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<tr>
<th>Component</th>
<th>Details</th>
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<tr>
<td>Probiotic powder</td>
<td>300 to 400mg (depending on density)</td>
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<td>Membrane material</td>
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companies are routinely audited for accurate business information, unaltered Certificates of Analysis, and product integrity. The goal of the project is to provide a safe and reliable hemp marketplace free of the issues that currently penetrate the hemp market but that are also part of the global ingredient trade in general.

"First and foremost, there are several brokers in the industry today who are less than honest and often intentionally misrepresent themselves as well as products they have," says Hemp Exchange CEO Chris Fon tes. "Often times, the broker will claim they are the processor or the farmer, or they will claim they are the exclusive broker for said processor or farmer when, in fact, they don’t have any real relationship to the processor or farmer at all. In fact, they often will attempt to sell product they have never seen, touched, and have no access to."

**Vertical Supply Chain**

If you have the capability of taking full control of your own CBD sourcing, here’s some inspiration that it can be done.

Gaia Herbs is a leading herbal supplement brand that grows many of its own ingredients on a 350-acre farm in North Carolina. The company now has two full-spectrum hemp extracts for sale, but they had to outsource the raw-material farming of their hemp because it was illegal to grow hemp in North Carolina—until the passage of the U.S. Farm Bill in 2018. Stacey Gillespie, Gaia Herbs director of product strategy, says, “There were definitely challenges to find a hemp oil supplier that could meet all of our rigorous standards—including their overall growing conditions, facility conditions, a commitment to regenerative agriculture, their environmentally and socially responsible business practices, their harvesting philosophy (harvesting at the peak time of phytochemical activity according to nature versus a set production schedule), and also their community resource protection practices.”

Since the passage of the Farm Bill, Gaia Herbs has received its own license to grow hemp in North Carolina and is now actively exploring the possibility of farming its own hemp. With its farm being certified organic, Gaia Herbs hopes to eventually have its own certified-organic hemp, which would be a rarity in the current hemp supply chain.
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Formulating a functional food or beverage with cannabidiol (CBD) takes a bit of a masochistic streak. Sure, there’s gold—and green—to be mined in the hemp-derived CBD products market, a market that cannabis-industry analysts at the Brightfield Group predict will be worth $22 billion by 2022. And sure, a bumper crop of research is investigating the extent to which benefits ranging from pain relief to clearer skin may be attributable to this cannabinoid—a non-psychoactive cousin of tetrahydrocannabinol (THC) occurring naturally in cannabis plants like hemp and marijuana.

But even setting aside the regulatory uncertainty that still hovers over CBD—hemp cultivation may now be legal, but FDA doesn’t yet know how it will oversee the plant’s constituent cannabinoids—CBD is, quite simply, a tricky substance to work with.

“It’s a very inefficient molecule,” says Mark Coffie, chief business development officer, Ananda Scientific (Greenwood Village, CO), “it’s a very inefficient molecule to extract, and it’s an inefficient molecule to get into the body.”

Same goes for getting it into food and beverage systems. But brands can’t afford to ignore CBD, so it comes as some relief—though little surprise—that CBD processors are developing clever technologies for delivering it to consumers who crave it, in products they’ll crave.

**Optimism, with a Healthy Dose of Caution**

The excitement around CBD is inescapable. But, says Jesse Lopez, president and CEO, Geocann (Fort Collins, CO), “CBD is just one of more than 80 to 100 cannabinoids that deliver a range of health benefits. Clinical trials are underway, with more starting each day, to explore the range of health benefits cannabinoids may deliver, and this goes well beyond a single cannabinoid.”

The heightened interest in CBD owes to evidence of its potential anti-seizure, analgesic, anxiolytic, antidepressant, antipsychotic, antioxidant, and anti-inflammatory properties—just to list the entries in the “A” section.

But prudence remains in order, warns David Chadwick, CEO, Leading Edge Pharm (Henderson, NV), for the same body of research responsible for the hope also hints that “while CBD is generally well tolerated and considered safe, it may cause adverse reactions in some people.” Because CBD can also interact with some medications, he advises consumers to speak with their physicians before including CBD-containing foods, drinks, or supplements in their routines.

**Tally of Challenges**

It certainly can’t hurt; as Lopez points out, “Even with the recent explosion of CBD products hitting the marketplace, we’re still in the infancy of this ingredient and its plant source.”

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**FROM INSOLUBILITY TO LOW BIOAVAILABILITY, CBD IS A CHALLENGING INGREDIENT TO WORK WITH.**

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And that matters not just to consumers and their doctors, but to product developers, too. Lopez emphasizes that "CBD is a relatively new ingredient with a learning curve for formulators, who have to manage both formulation stability and ingredient stability over time relative to oxidation and CBD potency." Squaring that circle is a work in progress.

The first hurdle involves getting your hands on a consistent starting material. "Once you achieve a consistent starting CBD material," Lopez says, "then palatability is a challenge, especially at the higher per-serving doses consumers seek."

Coffee adds that CBD is "truly insoluble in water, lacks absorption when taken orally, is a variably stable and very sensitive molecule, and—the ultimate piece of the puzzle—displays low bioavailability. All those factors hamper development of products containing it."

Beverages, he says, are "the toughest nuts to crack."

Chadwick agrees, noting that the main culprit is solubility. Key is keeping the CBD soluble in the beverage so it doesn’t settle out as sediment, he explains. "Further, the CBD must be completely soluble or opacity will result, making the beverage less attractive to the consumer. And there’s always a concern for CBD to influence the color, taste, and texture of the beverage."

Though formulating CBD into food is more straightforward, it’s hardly trouble-free either: "Solubility may be less an issue in foods than in beverages," Chadwick continues, "but taste and color may still influence the final product."

**Form Forecasts Function**

Wisely, suppliers are creating CBD ingredients that tackle some of these challenges.

One option is CBD isolate, which Chadwick says is pure CBD; meanwhile, full-spectrum and broad-spectrum CBD extracts exhibit "varying degrees of concentration and composition," he says. Full-spectrum extracts are unfiltered and include all cannabinoids and terpenes; in broad-spectrum products, the THC and/or other specific cannabinoids have been removed. "The higher the concentration of CBD in the CBD extract oil, the lighter the color," Chadwick notes. "This is an advantage since it won’t influence the final color of products as much as a darker CBD oil will."

So which to use where? Pure CBD is appealing for its lack of color or taste—and "one knows the exact composition of the ingredient," Chadwick says. But its poor solubility confounds formulation, so many turn to the solubility and stability of CBD oil at about 85% purity for some skincare, food, and drink applications, rather than to 99.9%-pure CBD crystal isolate, he says.

And while dissolving pure CBD in an oil carrier has been a game-changer in improving the compound’s formulation compatibility, "again, that can influence the taste and color of the finished food or beverage," Chadwick concludes. "So it can be a tradeoff depending on the product."

**Of Tradeoffs and Test Results**

Having to trade sensory qualities for solubility or stability—to say nothing of bioactive potency—leaves formulators in a bind. "Simply put," Lopez observes, "if the product doesn’t taste good, consumers won’t buy it a second time. They also want to know it works and that they’re getting the CBD benefits they seek."
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Alas, he believes the category’s development has been stymied by what he calls “poor quality and inconsistent products that fall short of even meeting label claims for potency. Reports of product testing from FDA and others have caused a ‘buyer-beware’ mentality with consumers.”

Indeed, heat treatments as mild as baking can destabilize CBD, compromising its bioavailability and subsequent therapeutic benefits, Chadwick says. “And keeping a food or drink in direct sunlight may cause issues like degradation of potency, color change, taste influences, and more.”

No wonder analyses are coming back spotty, with some off-the-shelf products testing as mislabeled due to diminished active levels. “Never before has FDA been post-testing product in the nutraceutical space as much as they’re doing now in the cannabinoid/CBD space,” Coffie says. “Most CBD molecules today have a six-week to six-month shelf life depending on processing and development, so a beverage could have half the 10 mg that was there on the day it was bottled.”

In other words, we have a lot to learn. But the industry remains bullish. Just ask Lopez. “It’s exciting to consider the possibilities for formulating CBD for improved performance and an even broader range of safe and effective applications that meet consumer preferences,” he says. “It’s clear that cannabinoids will play a role in health consumers’ daily regimens, from morning coffee and personal care to condition-specific formulations.” If those formulations can deliver on all fronts, we’ll all be better off for it.

CBD suppliers are now working to eliminate hurdles to successful food and beverage formulation. Here are just some of the ways.

**Ultrasonication**

Beverage formulation has been a consistent headache for product developers in the CBD space. But Chadwick and the team at Leading Edge Pharms think they’ve cooked up a workaround.

Called ultrasonication, the technology uses high-frequency sound waves to reduce CBD particle size to the nanometer range, improving solubility and stability in beverages. “At 20 nm, the CBD particle becomes pellucid,” Chadwick says. In fact, he believes the technology is the best way to improve stability, maintain batch-to-batch consistency, and not influence taste.

The company has applied ultrasonication to nano-liposomal CBD as well as to a unique strain of *Aloe vera* called Silvidiol in skincare products. “We’ve shown that the Silvidiol is carried to the appropriate depths of the skin for optimal efficacy for relief of inflammation and pain,” Chadwick says.

They’ve also put it to work in Cannavin, a proprietary process for infusing wine with CBD. “Cannavin addresses the issues of precision measurement and CBD molecule stability in a production ethanol environment,” he says.
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A signal drawback of CBD is its limited oral bioavailability—a product of its lipophilicity and extensive first-pass metabolism, which significantly reduces the cannabinoid's concentration before it even reaches systemic circulation. And, Lopez adds, "CBD is known for its high intra- and inter-subject absorption variability in humans."

Making matters foggier, Lopez continues, "There have been very few studies about CBD's pharmacokinetic, or PK, performance, and even fewer peer-reviewed published studies that demonstrate which delivery technologies are fast-acting, achieve much higher blood levels, and can deliver significantly improved bioavailability."

Lopez says his company’s VESIsorb delivery system makes formulation easier and CBD's PK performance in the body better. The system is a self-emulsifying drug-delivery formulation technology, or SEDDS, developed by Vesifact AG (Baar, Switzerland). Lopez says peer-reviewed and published research as well as proof-of-concept pilot tests show that VESIsorb increases oral bioavailability of lipophilic molecules like CBD.

Geocann has used it to incorporate CBD, other cannabinoids, and terpenes into every-thing from softgels, functional drinks, and edibles to sprays, tinctures, and topicals. Lopez says that users appreciate the bioavailability, shelf life, higher active loading, sensory improvement, and stability—both of the CBD itself and of the finished product—the system provides.

Structured-Liquid Vehicle

Yes, food and beverage formulators want to ensure their products deliver a potent, bioavailable dose of CBD with the pharmacokinetic wherewithal to improve consumers’ health. But, says Coffie, they also care about more bread-and-butter formulation issues.

"They look for shelf life, bacteriostatic properties, and a stable, water-soluble ingredient," he says. "And they’re looking for a homogeneous product that’s never going to break out of uniform."

His company’s “structured-liquid vehicle” for CBD checks all those boxes, permitting CBD to remain shelf stable for more than two years at various temperature ranges, he claims. He describes the vehicle as being like a 15-nanometer “breadbasket” that they can load with a number—and variety—of molecular loaves: up to 13 CBD molecules, for example, or even 10 CBD molecules and three curcumin molecules.

Extraction Always Matters

No matter the delivery vehicle or ingredient technology, how CBD is extracted invariably influences how it behaves.

"Extraction and processing are critically important to CBD formulations as they’re essential to producing consistent and reliable starting CBD material," Lopez says. "The goal is to extract the valuable cannabinoids and terpenes, like CBD and BCP”—beta-caryophyllene—"while removing unwanted constituents like waxes and fatty acids from the natural hemp biomass.” Also critical: safely removing pesticides, heavy metals, and other contaminants.

Chadwick considers the use of supercritical fluid CO2 the “most attractive” method for extracting CBD. Why? "It leaves no residual organic solvents and is a ‘greener’ process," he says. "It’s also very efficient in extracting the lipophilic components of the plant.”

Reference

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Standardizing key components and setting rigorous specifications are essential in establishing safety and maintaining the quality of botanically derived food ingredients. This is especially true for hemp-derived ingredients, including cannabidiol (CBD) preparations, which have recently experienced a surge of interest since the 2018 Farm Bill authorized hemp agriculture and removed hemp as a controlled substance.

Manufacturing extracts of natural products can be especially challenging because there is so much inherent natural variation, making it difficult to prepare consistent finished products that meet established specifications. Genetic, environmental, and processing factors all impact the quality and composition of the botanical material and finished products derived from it. There is a vast array of phytochemicals present in Cannabis sativa L., including cannabinoids, terpenes, and phenolic compounds. The concentration of these compounds is known to vary based on tissue type, age, chemotype, growth conditions, harvest, and storage conditions. In order to properly analyze a hemp extract or CBD ingredient, it is essential to understand the compounds at hand as well as best practices when it comes to testing.

Understanding Cannabis
In Cannabis, genetics play a key role in the levels of the cannabinoids CBD and THC (delta-9 tetrahydrocannabinol), the two active compounds in the plant that have historically garnered the most interest. The term cannabis is typically used to refer to the chemotype optimized for THC levels, whereas the terms hemp or industrial hemp are generally used to refer to Cannabis varieties in which the THC content is not more than 0.3% on a dry weight basis. Furthermore, hemp seed is known to contain only trace amounts of CBD and THC, and preparations of hemp seed oil (GRAS Reference Number/GRN 778), hemp seed protein (GRN 771), and dehulled hemp seed (GRN 765) have achieved Generally Recognized as Safe (GRAS) status with subsequent “no questions” letters from FDA.

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odors and are the primary components of essential oils derived from plants and flowers. In Cannabis, these terpenes include D-limonene, beta-myrcene, alpha- and beta-pinene, linalool, terpinolene, and beta-caryophyllene. Phenolic compounds, including phenolic acids, flavonoids, stilbenes, and lignans, are also present in hemp. A review by Andre et al. (2016) provides an excellent overview of the compounds that have been identified in Cannabis as well as the current biotechnology surrounding Cannabis sativa production.

**Best Practices for Hemp-Extract and Hemp-CBD Analysis**

**Documentation**

It is essential to maintain an established and thorough “paper trail” when it comes to sourcing, manufacturing, and analyzing food ingredients, including those derived from hemp. The trade certification group U.S. Hemp Authority recommends that electronic or hard copy records should be maintained for at least five years, and should include the provenance of the hemp seed, the variety, planting and harvest records, processing records, and analytical results. Furthermore, manufacturers should always follow current good manufacturing practices (cGMPs), as discussed further in the following section.

**Characterization**

Evaluating the typical levels of phytochemicals present in the hemp plants used to prepare CBD extracts is an important part of the quality-control process, given the phytochemical complexity of Cannabis. Proximate testing can provide important information about the moisture, protein, fat, fiber, and ash content of the source material, which can be applicable to selecting an appropriate CBD-extraction method.

Identification testing should be utilized to ensure the correct variety of Cannabis sativa is used and to verify that the raw material is free from botanical adulterants such as Acer palmatum (Japanese maple), Datisca cannabina (false hemp), Dizygotheca elegantissima (false aralia), Hibiscus cannabinus (kenaf), Potentilla recta (sulphur cinquefoil), and Urtica cannabina (nettles). Thin-layer chromatography (TLC) is typically used to identify Cannabis and can also be used to determine chemotype (i.e., cannabis vs. hemp) as well as indicate any of the potential botanical adulterants for which macroscopic and microscopic visual inspection methods are insufficient.

**Standardization**

Given the natural variation of Cannabis, it is necessary to standardize extracts derived from hemp. Manufacturers should specify the nature and quantity of reference substances in the extracts to ensure batch-to-batch consistency for consumers, as well as create a uniform product for which to establish safety. Standardization can be achieved by blending multiple batches, introducing refining steps to the manufacturing process, or optimizing harvest conditions so that the constituents are present in the established range. For products such as CBD oil, reference substances should include cannabidiol and an array of the predominant terpenoids. Monoterpenoids and sesquiterpenoids (such as alpha- and beta-pinene, limonene, terpinolene, linalol, caryophyllene, and humulene) comprise approximately 50%-90% and 7%-48% of the essential oil extracted from fresh material, respectively.

Both gas chromatography (GC) and high-performance liquid chromatography (HPLC) techniques can be used to quantitate cannabinoids and other components present in CBD extracts. While there is currently no “gold standard” method of analysis, the American Herbal Pharmacopoeia (AHP) outlines methods of analysis in its 2014 Cannabis Inflorescence monograph², and AOAC International published “Standard Method Performance Requirements for Quantitation of Cannabinoids in Dried Plant Materials” in 2017.

**Specifications**

Establishing complete and thorough specifications is an integral step towards ensuring product safety, suitability, and quality of hemp-derived ingredients. Furthermore, having a well-characterized material is essential with regard to demonstrating safety-in-use, as the composition of the hemp extract has a direct bearing on the results of toxicology and metabolism studies. Given the dearth of publicly available information on genotoxicity, cytotoxicity, mutagenicity, acute and sub-acute toxicity, and other safety studies performed on hemp-derived extracts, it is likely that many manufacturers will need to undertake these studies on their ingredients, in which case well-defined specifications will be required.

It’s also essential to establish minimum specifications for all raw materials (i.e., solvents, flow agents, blending oils, antioxidants, etc.) and processing aids (i.e., resins, filters, etc.) used in the manufacturing process. Food-grade materials that comply with the appropriate 21 Code of Federal Regulations (CFR) and/or Food Chemicals Codex (FCC) requirements should be used at all times.

**Physical**

A physical description of the product should be included on the product specification sheet. The appearance, odor, and taste of the material are all relevant parameters that should be assessed through visual and organoleptic methods. In addition, particle size, tap density, or viscosity may also provide insight into the preparation.
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Chemical
This section of the product specification sheet should include the acceptable ranges of the reference substances (i.e., CBD, terpenes) in the material.

Impurities/Contaminants

THC
Since hemp-derived CBD extracts are manufactured from low-THC Cannabis varieties (< 0.3% THC on a dry weight basis), there is an expectation that the level of THC will also be low in the finished product. FDA responded with “no questions” to GRAS Reference Number 778 for a hemp seed oil with a tolerance specification for THC ≤10 μg/g.

Pesticides
Since CBD extracts are derived from botanical material that could be exposed to pesticides, it is important to test either the raw material or finished product for pesticide residues. The Pesticide Analytical Manual (PAM), available on FDA’s website, provides guidance on establishing pesticide limits. While the pesticide limit is zero (0) for crops for which no specific limit has been set, the limits are generally observed as the lowest analytically detectable levels, which are often reported as < 0.01 ppm.

Microbial & Fungal Contaminants
Tolerance limits for microbes and fungi should be established for food and dietary supplement ingredients and should be set as low as reasonably possible to ensure consumer safety.
Depending on the extraction method, the tolerance limits may require adjustment, but a good starting point for processed botanical materials, including CBD oil preparations, is as follows:
- < 10,000 CFU/g Total aerobic plate count
- < 10,000 CFU/g Total yeast and mold
- < 1,000 CFU/g Total coliforms
- < 1,000 CFU/g Bile-tolerant gram-negative bacteria
- Not detected in 1 g E. coli
- Not detected in 1 g Salmonella spp.

It should be noted that for CBD oils prepared using carbon dioxide or solvent-based extracts, the microbial limits can likely be reduced 10-fold.

Aflatoxins and ochratoxins are fungal metabolites that have been associated with hemp and hemp-derived ingredients and therefore should be tested for in any CBD extract preparations. Aflatoxins B₁, B₂, G₁, and G₂ are produced by some strains of Aspergillus molds, and their ingestion can result in liver damage. Ochratoxin A is produced by certain strains of Aspergillus and Penicillium molds, and their ingestion can result in kidney damage. These mycotoxins are known potential contaminants of many food commodities, and methods have been developed to test for their presence by immunoaffinity assays. Fungal contamination can occur at multiple steps during the growth, harvesting, and storage process, so ideally, both the raw materials and finished products derived from hemp should be tested.

Heavy Metals
Tolerance limits for heavy metals should also be established for food and dietary supplement ingredients, and should be set as low as reasonably possible to ensure consumer safety. Plants grown outdoors in fields are likely to have more natural exposure to heavy metals than those grown in more controlled greenhouse environments.
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For hemp-derived products, heavy metal testing should include arsenic, cadmium, lead, and mercury. A good starting point for ingredients such as CBD oil is as follows:

- Arsenic ≤ 1 ppm
- Cadmium ≤ 1 ppm
- Lead ≤ 3 ppm
- Mercury ≤ 0.1 ppm

**Residual Solvents**

For any CBD extracts prepared using a solvent-extraction process, it will also be essential to establish tolerance limits for residual solvents such as ethanol, propane, butane, and hexane. Residual solvent tolerance levels should be kept as low as reasonably possible to ensure consumer safety.

The International Conference on Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH) established limits on solvents used in the manufacture of botanically derived products. The use of Class 1 solvents, including benzene and carbon tetrachloride, should be strictly avoided since they are known hazards. Class 2 solvents have individually determined permissible daily exposures (PDE), such as 2.9 mg/day for hexane. For Class 3 or other solvents, the residual solvent levels are not to exceed 0.5% by weight or 5,000 ppm per 10 g of product.

**Prop 65**

Hemp contains a number of compounds that have been added to the list of “Chemicals Known to the State to Cause Cancer or Reproductive Toxicity” (California’s Prop 65), including beta-myrcene, acetaldehyde, and pulegone. Since beta-myrcene is likely to be present in CBD oil, it should be quantitated and, if necessary, the appropriate warning should be added to the label of any products destined for sale in California.

Additionally, the current Prop 65 list includes heavy metals, pesticides, aflatoxins, and ochratoxin A, which were discussed above. Manufacturers should monitor finished products for the presence of these components and label products for sale in California accordingly.

**Stability**

A full battery of shelf-stability studies should be conducted on at least one representative lot of material. These studies should include both accelerated and real-time conditions, and analysis of reference substances and microbiological testing should occur at pre-determined intervals to ensure the product meets specifications until the reported expiry date.

**Establishing Safety**

As with any botanically derived food ingredient, developing robust specifications and quality-control procedures will ensure product consistency and support consumer confidence. The manufacture of consistent and well-characterized CBD extracts will also help researchers investigate the safety of these products and provide a basis for establishing the safety of this newly emerging ingredient.

The following sources are recommended for additional reading:


**About the Authors**

As a team of experts, our companies collaborate together and are currently working with several CBD clients, from seed to finished manufactured product.

Katrina Emmel, PhD, is the founder and president of analytical laboratory KemmelCal Inc. (www.kemmelcal.com). She is experienced in analytical method selection, data review, and establishing product specifications for ingredients used in foods and dietary supplements. Dr. Emmel has over seven years of experience in drafting, reviewing, and serving as an expert panelist for GRAS evaluations.

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**References**

1. It should be noted that in West Virginia Code, Chapter 19, Article 12E, Industrial Hemp Development Act, industrial hemp is defined as containing no greater than 1% THC. See: [http://wvlegislature.gov/wvcode/code.cfm?chap=19&art=12E](http://wvlegislature.gov/wvcode/code.cfm?chap=19&art=12E)
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The popularity of cannabidiol (CBD) continues to explode, with estimates from BDS Analytics, a cannabis research firm, suggesting that the U.S. market could reach $20 billion by 2024. A trip to any convenience store, grocery store, or natural foods store today is likely to yield a plethora of CBD products in almost any form imaginable.

CBD is a phytocannabinoid most often extracted from plants in the Cannabis genus, including hemp and marijuana. Unlike another phytocannabinoid from Cannabis, tetrahydrocannabinol (THC), CBD has a complete lack of psychoactivity. Phytocannabinoids generally exert their effects by binding to cannabinoid receptors that are a part of the human endocannabinoid system; however, CBD itself shows negligible affinity for binding to the CB₁ and CB₂ receptors, indicating that it exerts its effects through other mechanisms. Preliminary research on CBD is promising, showing that the compound has anti-inflammatory, anti-anxiety, anti-depressive, and neuroprotective properties.

Recent studies demonstrating the beneficial effects of CBD in laboratory and animal models are detailed here. Initial clinical trials have also been conducted, showing therapeutic potential in several health conditions; however, it should be noted that the majority of these use pharmacological (drug) preparations of CBD, meaning it can’t be assumed their results translate to comparable benefits in dietary supplement, food, beverage, or other non-drug delivery forms.

Even with the proliferation of products containing CBD, a lack of clarity regarding the promise of CBD

Here’s what we know about CBD’s potential health benefits so far.

BY IRFAN QURESHI, ND

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the regulatory status of CBD is a significant hurdle to more robust clinical research. As FDA works on developing a legal path to market for this compound, it is likely that better-quality research will be performed to determine what levels of CBD are safe and efficacious.

Concerns about the safety of CBD have also been raised recently, and this remains an open question. An animal study conducted at the University of Arkansas for Medical Sciences (Little Rock, AR) found liver toxicity concerns at certain dose levels,4 highlighting the necessity of establishing safe intake levels for humans. Given that CBD-containing products with many compositions and dosages are already freely available in the marketplace, this issue will need resolution and clarity. So, while CBD offers a new paradigm of treatment for various health conditions, significant questions remain to be answered.

**Neuroprotection in Alzheimer’s Disease Model**

In several laboratory and animal studies, CBD was found to confer beneficial effects on the neurological system. Blathnai Hughes and Caroline Herron from University College Dublin (Dublin, Ireland) aimed to evaluate the potential neuroprotective effect of CBD in a lab model of Alzheimer’s disease.5

Hippocampal slices from mice were exposed to soluble beta-amyloid peptide associated with Alzheimer’s disease. Application of beta-amyloid led to a decrease in long-term potentiation, a measure of the efficacy of synaptic (or nerve) transmission. CBD from STI Pharmaceuticals (Essex, United Kingdom) was then applied to the slices; however, no improvement in long-term potentiation was noted. The researchers then pretreated mouse hippocampal slices with CBD prior to adding beta-amyloid protein. In this scenario, CBD showed a neuroprotective effect, inhibiting the beta-amyloid–induced deficit in long-term potentiation.

In evaluating the mechanism of action, investigators discovered that CBD may interact with PPAR-gamma, a nuclear receptor that is normally present in the central nervous system at low levels; however, its expression is increased under inflammatory conditions. CBD likely activates the expression of PPAR-gamma, leading to the inhibition of pro-inflammatory gene expression by blocking NF-κB, a transcription factor involved in the inflammatory pathway. Thus, an important aspect of CBD’s neuroprotective effect may be related to a reduction in inflammation.

**Antidepressant Effect**

Current treatment options for depression can be problematic as there is often a time lag associated with their effect. CBD may hold potential as a promising alternative in this area. Amanda Sales and colleagues from the University of São Paulo (São Paulo, Brazil) looked at the anti-depressant effects of CBD in mice and rats in order to investigate whether CBD has a fast-acting onset.6

In the animal study, CBD from THC Pharma (Germany) was administered as a single dose in an amount of 7, 10, or 30 mg/kg body weight. Mice then underwent a forced swim test at 30 minutes or 7 days following treatment. Results showed that CBD induced an anti-depressant effect in a dose-dependent manner. Repeating this test with rat species yielded similar results. These acute antidepressant effects (evaluated in the swim task 30 minutes after CBD administration) were found to be related to CBD’s ability to increase brain-derived neurotrophic factor (BDNF) levels in the hippocampus and prefrontal cortex of the animals. BDNF is an important growth factor for neurons. Markers of synaptic plasticity (necessary for brain remodeling) were also increased in the prefrontal cortex.

The longer-term antidepressant effects of CBD (evaluated in the forced swimming task seven days after CBD administration) were found to be associated with an enhancement of synaptic function in the prefrontal cortex. These results support the notion that CBD is a fast-acting antidepressant and possesses sustained effects, leading to longer-term antidepressant activity. While further studies are needed, this initial data suggests that CBD could be a promising therapy for mood disorders, including depression.

**Chronic Pain and Neurological Dysfunction**

Traumatic brain injury leads to persistent neurological dysfunction and is often associated with chronic pain, anxiety, and depression. Many of the symptoms experienced may be related to inflammation and cellular death. Currently, no adequate treatment options exist for these symptoms.

Carmela Belardo and colleagues from University of Campania Luigi Vanvitelli (Naples, Italy) looked at the potential role of CBD in a mouse model of traumatic brain injury. In the study, 10% CBD oil from the Enecta Group (Bologna, Italy) was administered to mice with and without mild traumatic brain injury orally by gavage on days 1 to 14 and days 50 to 60 of the study. Thereafter, the effect on sensory and neuropsychiatric dysfunction was evaluated.7 The timepoints of administration were chosen based on previous work in mice showing that symptoms of traumatic brain injury such as aggressiveness, recklessness, and sensory changes occur in the acute phase, while depression-like behavior occurs in the late phase.

CBD oil was found to exert a beneficial effect on behavioral dysfunctions associated with traumatic brain injury, while no abnormal behavioral changes were seen in non-injured animals given CBD. Moreover, treatment with CBD in mice with TBI significantly reduced pain behaviors. Many of these changes were associated with alterations in cortical biochemical release. CBD was found to partially normalize the biochemical changes, showing that it may exert...
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Nonalcoholic fatty liver disease (NAFLD) impacts 25%-45% of the population, with obesity, type 2 diabetes mellitus, hyperlipidemia, and metabolic syndrome considered major risk factors. Nonalcoholic steatohepatitis is an intermediate stage within the NAFLD spectrum and in the U.S. is the third main cause of liver transplants. Research has suggested that CBD may be protective against hepatic fat accumulation.

Yuanling Huang and colleagues from Sun Yat-sen University (Guangzhou, Guangdong, China) decided to investigate the effects of CBD administration on liver inflammation in mice fed a high-fat diet. Mice were divided into three groups: control, high-fat diet, and high-fat diet plus CBD—5 mg/kg body weight per day from Tocris Bioscience (Ellisville, MO)—for eight weeks. The high-fat diet was used to induce hepatic steatosis.

After the end of the study, tissue analysis revealed that CBD attenuated high-fat, diet-induced liver injury and inflammation, including normalization of serum lipids and liver enzymes (ALT). Additional work led to an investigation of the mechanism of action and revealed that CBD deactivated NF-κB in mouse liver cells, leading to a reduction of inflammation. As NF-κB is a transcription factor associated with hepatic steatosis and injury, this effect of CBD was significant. As a potent anti-inflammatory in the liver, CBD may be a novel treatment protecting against the progression of NAFLD.

It should be noted that the majority of studies use drug preparations of CBD, meaning it can’t be assumed their results translate to dietary supplements, food, or beverages.

Irfan Qureshi, ND, is vice president, product development and quality assurance, for Healthy Directions.

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Cannabidiol (CBD) is arguably the most talked about ingredient in the health products marketplace right now. Since the 2018 Farm Bill legalized hemp in the United States, products containing hemp's prized compound CBD have been flooding the market. And regardless of whether you call it CBD or “hemp extract,” the end goal is to deliver CBD and other cannabinoids direct to the consumer in a satisfactory fashion.

Much of the activity in CBD products is occurring in the beverage space. Infused waters, seltzers, sodas, and shots are just a few drinkable formats for hemp-derived CBD, and brands are varied in how they’re presenting CBD education to consumers. With the exclusion of hemp products containing tetrahydrocannabinol (THC)—the psychoactive cannabinoid for which marijuana is grown, but not hemp—we’ve compiled a short list of eye-catching CBD drink releases in the last 12 months.

**Kill Cliff**
Launching a Hemp-Infused Recovery Drink in August, Kill Cliff says it became the first national sports drink brand to bring a CBD drink to market. While most CBD beverages are aimed at the general adult consumer market, Kill Cliff says its new product was formatted particularly for athletes and veterans—many of whom are already using CBD. Each 12-oz can contains 25 mg of CBD alongside vitamins, electrolytes, minerals, caffeine from green tea, and other plant extracts.

In an FAQ section on the company’s online product page, CBD is said to be associated with use for anxiety, pain, inflammation, and muscle soreness. A 12-pack of Kill Cliff’s retails for $69.00 and is available in “Orange Kush” flavor.

**Honeydrop**
To get skin in the hemp game, Honeydrop, a cold-pressed-lemonade specialist, partnered with Colorado-based Evo Hemp to create

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**A TOAST to CBD**

CBD drinks make a splash in the marketplace.

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a line of hemp-infused lemonades. Like its other cold-pressed and ready-to-drink lemonades, Honeydrop’s hemp-infused lemonades are made with raw honey. The absence of pasteurization may help preserve active compounds in the hemp lemonades. Flavors include matcha, lemon, and turmeric. A portion of proceeds will go to research on Colony Collapse Disorder, a threat to the health of bees around the world.

Sunday Scaries
A CBD energy shot from Sunday Scaries packs 50 mg of CBD extract into a single 2-oz. bottle. Dubbed the YOLO Shot, it’s an energy formula combining CBD with caffeine from green coffee beans, B vitamins, ginseng, taurine, and 5-HTP. Sunday Scaries introduced its product this July in a vegan-friendly format available in three flavors: Coconut Lime, Sour Fruit Punch, and Tropical Pineapple. The company claims that CBD’s benefits and effects include providing energy and alertness, improving mood, and decreasing anxiety. One 12-pack of YOLO shots sells for $69.00.

SOL
It’s not a reach to think that SOL, a brand devoted to CBD-infused cosmetic products, would at some point expand into the beverage space. This June, the company premiered a line of CBD-infused waters that the company says can be used for hydration, skin and beauty health, and boosting immunity, among other potential benefits.

Good Day
Options are varied with Good Day, a CBD drink brand providing not three flavors of shelf-stable CBD drinks, but three types. Introduced in July, the Good Day brand lineup includes a cold-brew coffee (available for purchase), a citrus sparkling water (available for preorder), and a chamomile herbal tea (available for preorder) in minimally designed cans containing 15 mg of CBD in 7-packs for $42.00 each. Where the cold brew is intended for “a boost of easygoing energy,” the sparkling water is for “mental and physical refreshment” and the tea is for “enhanced relaxation.”
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Good Day refrains from using artificial sweeteners and additives while also adopting practices such as sourcing fair trade beans and using reverse osmosis and UV-filtered water. Its active ingredient is a ‘nano-emulsified (water-soluble) broad-spectrum hemp extract sourced from Farm Bill–certified hemp farms in the beautiful state of Colorado.’

**Bimble**

Unique recognition goes to Bimble, a carbonated CBD beverage brand that is putting transparency first by publishing its Certificate of Analysis for public eyes to see on its website. It’s a rare practice that seems to be in good faith for a hemp extract category that’s just starting to gain widespread legal acceptance.

First launched in January, Bimble drinks are available in Grapefruit Basil Mint and Blueberry Lemon Ginger flavors with a hefty 25-mg dose of CBD in each 12-oz bottle. The brand founder, a...
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lifelong beekeeper, sweetens all Bimble drinks with raw honey.

Bimble is currently available online and at select physical retailers in New York City. Sold with one or both flavors, a 6-pack of Bimble retails for $39.99.

**Drink 420**
The CBD drink craze isn’t just U.S.-centric. Here’s a UK launch from January. Drink 420 brings Colorado-grown hemp to Europe in a sparkling water format, and each 250-ml can contains 15 mg of CBD. Two flavor options, Elderberry Lime and Wild Berries, are crafted with fruit juices for sweetening and zero added sugar.

Consumers are encouraged to use Drink 420 to unwind, target stress, and rebalance. As is the custom in this category, the company has an FAQ page for CBD featured prominently on its website. A 12-pack of Drink 420 currently retails for $27.99.

**ChrgD+**
An honorable mention goes to ChargD+ from Cultivating Wellness. It isn’t a CBD drink, but a water-soluble and beverage-friendly powder.

Cultivating Wellness launched its product in June to give consumers more convenience and flexibility in how and when they consume CBD. ChargD+ is unflavored, unsweetened, odor-free, and suitable for hot and cold beverages. It was formulated using a proprietary technology called DehydraTech that allows CBD to stay suspended in an aqueous solution.

A box of six easy-tear pouches, each containing 20 mg of CBD, retails for $17.99.

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Within the digestive health category, probiotics are so popular that they have transcended from dietary supplements to ingredients in food and drinks. Probiotics, however, are only one piece of the digestive health puzzle. Slowly but surely, prebiotics are being recognized as a necessary component of digestive health. Driving this growth is an overall interest in fiber consumption.

“Innova Market Insights called out fiber as a key trend for 2019, noting that 44% of U.S. consumers were increasing their fiber consumption,” says Taylor Halstead, product manager for specialty carbohydrates, Cargill (Minneapolis, MN). “Those numbers track with consumer research from the International Food Information Council’s (IFIC) 2019 Food & Health Survey, which noted that more than 85% of consumers view fiber as healthy.”

Consumer understanding of prebiotics is less pronounced but growing as more products hit the market and get media coverage. While there is surely a lot of room for prebiotic sales to grow, and for consumers to learn about prebiotics’ function, the market is seeing some traction—albeit, from a still-smaller sales base.

“In the first half of 2019, media coverage on prebiotics was 12% greater than the prior year for the same period. Social media is driving this increase,” explains Samantha Ford, business development director at AIDP (City of Industry, CA), citing data from Meltwater market research. “Many consumers are unaware of the role prebiotics play in digestive health; however, media coverage is helping to drive consumer interest.” Ford says that according to a recent Nutrition Business Journal report, in 2018 probiotic sales grew about 8% while prebiotic sales grew over 130%.

“Clearly, there is growing consumer interest in prebiotics,” Ford says. And let’s not forget: “Most consumer diets do not contain enough fiber.” For prebiotic firms, the challenge is educating consumers on how supplemental prebiotics can complement the diet, “without the effects of large amounts of fiber,” she says.

**Prebiotic: An Increasingly Targeted Approach**

The general nature of prebiotics is that they feed gut bacteria to promote healthy-bacteria growth. As the digestive category evolves and becomes more sophisticated, the notion—and exploration—of prebiotic supplementation is becoming much more selective in terms of targeting specific bacteria, both as a standalone supplement and in a symbiotic formulation that combines prebiotics and probiotics.

This targeted approach to prebiotics has the potential to profoundly change the digestive health space and shake up the probiotic category. “We are already seeing these concepts disrupt the market,” says Ford. “For example, ‘probiotic-free’ digestive health formulas are becoming more and more popular.”

Over time, should this targeted approach to prebiotics become more accepted, probiotic consumers may find themselves moving...
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Prebiotics

Prebiotics have a long history of helping to maintain the human microbiome, with mother’s milk being rich in over 200 types of oligosaccharides, one of the main prebiotic types. Our ancestors consumed a great deal of oligosaccharides by eating roots, tubers, and foraging for fruits and nuts, explains Kiran Krishnan, chief scientific officer of digestive-product brand Microbiome Labs (St. Augustine, FL). Eventually, it became thought that the type of prebiotic is an important factor in just how successfully these ingredients maintain the gut microbiome, Krishnan says.

For instance: A frequent complaint of prebiotics is intolerability, with some suffering from discomfort related to gas and bloating after consuming prebiotics. “The problem is that when you start using prebiotics that aren’t specific to certain groups of bacteria, you end up with food for bacteria that can be consumed and metabolized by lots of different groups of bacteria in the gut,” says Krishnan. That means that if one’s microbiome is already out of balance, some prebiotics may actually feed undesirable bacteria.

According to Krishnan, the ideal characteristic of a prebiotic is for it to have a high degree of polymerization (DP), which determines how far into the bowel the prebiotic will survive.

“A prebiotic with a high DP means it’s a very complex carbohydrate, and because of that complexity there is a very narrow range of bacteria that have the right enzymes to be able to break down and metabolize that carbohydrate,” he explains. “Most of those bacteria that tend to have very sophisticated enzymatic capability to break down complex carbs exist in the large bowel.” Akkermansia and Bifidobacteria are two bacterial strains that exist in the large intestine that are capable of breaking down complex carbohydrates. A high-DP prebiotic is less likely to get broken down by bacteria before it can do its job.

In contrast, prebiotics with low DP tend to be broken down by a wider range of bacteria and sooner in the bowel, causing overgrowth in the small intestine, which is particularly bad if someone is already suffering from small-intestine bacterial overgrowth.

Microbiome Labs, for example, has a prebiotic formula that combines four oligosaccharides that have high DP and have been shown in clinical trials to specifically feed good bacteria and keystone strains such as Akkermansia muciniphila, Faecalibacterium prausnitzii, and Bifidobacteria. Called MegaPreBiotic, the product is composed of galacto-oligosaccharides in the form of Bimuno (an ingredient manufactured by Clasado BioSciences; Jersey, UK), fructo-oligosaccharides in the form of Livaux and Actazin (ingredients distributed by AIDP Inc.), and xylo-oligosaccharides in the form of PreticX (also distributed by AIDP). Xylo-oligosaccharides, like PreticX, boost the levels of Bifidobacteria.

One of the major benefits of such products is the low effective dose required to feed beneficial bacteria, says AIDP’s Ford. “The PreticX clinical research
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studies have also found a significant increase in the *Bacteroides fragilis* strain (a member of the *Bacteroides* family) with 2 grams per day,” says Ford. “The team also concluded that PreticX supplementation did not increase *Lactobacillus* (a member of the *Firmicutes* family). These findings suggest that PreticX supplementation may result in a beneficial *Bacteroides:Firmicutes* ratio that could lead to a better metabolic response and benefits to weight management.”

For example, it has been observed that obese individuals have elevated *Firmicutes* and a reduced population of *Bacteroides*, while the reduction of *Firmicutes* and elevation of *Bacteroides* has been associated with weight loss.1

Livaux, made from the Zespri SunGold brand of kiwifruit, is associated with an increase of *Faecalibacterium prausnitzii* bacteria. *F. prausnitzii* is the most abundant anaerobic bacteria in the colon, making up about 5% of the bacteria in feces, according to a meta-analysis2 conducted by Metagenomics of the Human Intestinal Tract, a project financed by the European Commission to establish associations between the genes of the human intestinal microbiota and human health and disease. It has also been observed that people with inflammatory bowel disorder (IBD) have significantly less *F. prausnitzii* bacteria than healthy individuals.3 Because the bacteria is anaerobic and cannot survive in oxygen, *F. prausnitzii* cannot be taken as a probiotic and therefore must be fortified through the use of prebiotics.

The reason *F. prausnitzii* may be beneficial for people with IBD is because one of the end products created when glucose is fermented by the bacteria *F. prausnitzii* is a substantial amount of butyrate. Butyrate plays a major role in gut physiology, protection against pathogens, and modulation of the immune system. Increasing levels of butyrate by increasing levels of *F. prausnitzii* by using a related prebiotic can therefore aid butyrate’s benefits4. Butyrate is also the primary energy source of intestinal epithelial cells, a fundamental element for maintaining the integrity of the intestinal barrier. Researchers also note that butyrate contributes to anti-inflammatory effects.

Actazin, made from Zespri-brand green kiwifruit, says AIDP, is rich in naturally occurring soluble and insoluble fiber, polyphenols, and the enzyme actinidin. The ingredient supports regular bowel movements with no change in the Bristol Stool Scale, and has a low dose of 600 mg per day. In one study, supplementation with Actazin (2400 mg per day) resulted in a significant increase in mean daily bowel movements5. In a subgroup of participants that experienced an increase of at least one bowel movement per week, supplementation with 600 mg of Actazin per day was shown to be associated with significant increases in daily bowel movements.

**Still Synbiotics**

While there are a great deal of benefits of using prebiotics as standalone products, consumers still value probiotics, and therefore manufacturers are seeking to pair prebiotic fibers with probiotic bacteria to create symbiotic formulas. Cargill, for example, recently announced a new grade of its brand-ed Oliggo-Fiber chicory root fiber called Oliggo-Fiber XL Ultra, which is designed to have low water activity, enabling its use as a blending excipient with probiotics, which are sensitive to moisture. “As a result, our XL Ultra offers enhanced stability of the probiotic culture compared to standard inulins or other fibers,” says Halstead.

“As a prebiotic, [chicory root fiber] enhances the growth of *Lactobacillus* and *Bifidobacterium* species,” he adds. “Consuming 5 grams of chicory root fiber per day stimulates the microflora in the digestive tract, helping to maintain a neutral balance.”

Another unique source of prebiotic fiber ideal for pairing with probiotics is cranberry seed powder, such as that manufactured by Fruit d’Or Nutraceuticals (Villeroy, QC, Canada). Like most prebiotic fibers, the cranberry seed powder acts as a food source for probiotic bacteria, but it contains other important nutritional components, too. “It feeds certain probiotic strains, such as *Bacillus coagulans*,” explains Stephan Lukawski, director of sales and business development for Fruit d’Or Nutraceuticals. “Cranberry seed powder contains protein fiber and all the essential amino acids, as well as omega-3, -6, and -9, along with [proanthocyanidins] and other
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Prebiotics

polyphenols. Cranberry seed powder is about polyphenols, not just fiber. In addition to feeding beneficial probiotic bacteria, studies have shown that cranberry seed powder inhibited the growth of negative bacteria such as E. coli. Cranberry seed powder's ability to feed beneficial bacteria and inhibit the growth of negative bacteria has been demonstrated in clinical research of an ingredient that combines the cranberry seed powder with the patented probiotic strain Bacillus coagulans MTCC 5856 (LactoSpore by Sabinsa; East Windsor, NJ). This trademarked combination ingredient is called LactoCran. The polyphenol aspect is important to keep in mind because polyphenols have a great deal of potential in the digestive health space as well. Lukawski points out that polyphenols also play an important role in the gut-brain-immune axis. “Moving forward, the winners in the probiotic space are those significant role with probiotics. Gut health and brain health will be connected with blueberry. Gut health and immune health will be connected with elderberry, and gut health and the prevention of urinary tract infections are connected with cranberry.”

Krishnan shares a similar sentiment: “The next big thing is, as prebiotics start to get more awareness and people start becoming more aware of it and it sees its day in the spotlight, the next thing is the importance of polyphenols in the microbiome,” says Microbiome Labs’ Kiran Krishnan.

“The next big thing is, as prebiotics start to get more awareness and people start becoming more aware of it and it sees its day in the spotlight, the next thing is the importance of polyphenols in the microbiome,” says Microbiome Labs’ Kiran Krishnan.
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Will prebiotics one day get the widespread attention that probiotics enjoy among consumers and practitioners?

their own. Polyphenols also provide the base building blocks for a lot of important compounds that the microbiome produces for the host.”

Microbiome Labs has even begun incorporating polyphenols in its product called MegaMucosa, which is a mucosal-rebuilding product. “We use a citrus polyphenol mix that has been shown in clinical studies to significantly reduce intestinal permeability, increase [bacterial] diversity, and reduce inflammation in the mucosa, just from the use of the polyphenol alone,” says Krishnan.

New Take on Prebiotic

Another way to selectively fortify gut bacteria is through supplementation with bacteriophages. Bacteriophages are often described as viruses that target negative bacteria. This represents yet another, different approach to prebiotics.

“Phages are minuscule bundles of DNA or RNA enrobed in a protein shell,” explains John Deaton, PhD, vice president of science and technology, Deerland Probiotics and Enzymes (Kennesaw, GA). “Phages are diverse and abundant, found in seawater, soil, humans, and fermented foods—and there are 10-fold more phages than bacteria populations in the human body. Unlike probiotic bacteria, a bacteriophage (‘phage’) is not a living entity. However, phages are active.” Deerland’s novel PreforPro bacteriophage reproduce themselves by targeting and utilizing specific unwanted or pathogenic living bacterial cells as their host. When a phage takes control of its host, it takes command of the undesirable bacterial cell’s metabolic processes, rapidly producing bacteriophage progeny which destabilize the cell wall to escape and seek out more bacteria host cells.

“This effectively reduces the population of the host bacteria, providing more room for good bacteria (probiotics) to proliferate, thus improving host health,” says Deaton.

In a study published in *Nutrients*, researchers found that a 15-mg-per-day dose of the bacteriophage PreforPro for 28 days reduced the presence of *E. coli* and increased specific bacteria populations in the process. More specifically, the phage increased *Bifidobacterium bifidum, Lactobacillus delbrueckii*, and the butyrate-producing *Eubacterium*. Additionally, there was a significant decrease in the pro-inflammatory cytokine interleukin 4.

There is also the potential of using bacteriophage in combination with probiotic bacteria, with over 20 studies showing the ingredient’s ability to promote the growth of beneficial bacterial strains.

“Both *in vitro* and *in vivo* tests have demonstrated the growth-promoting effect of Prefor-Pro on beneficial bacterial strains of *Lactococcus, Lactobacillus, Bifidobacterium*, and *Bacillus subtilis* when competing with undesirable bacterial strains,” says Deaton. “In several *in vitro* tests under physiological conditions, PreforPro has been shown to accelerate the growth of numerous wide-ranging probiotic species, including *B. bifidum, B. breve, B. animalis, B. longum, L. acidophilus, L. paracasei, L. casei, L. rhamnosus, Lactococcus lactis*, and *B. subtilis*.”

**References**

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As ubiquitous as it seems now, the gummy-as-dietary-supplement signaled a turning point for our industry. It made supplementation literally more palatable for everyone from preschoolers to pensioners, and it brought a shot of fun and flavor to a sector that needed a more compelling call to action than “Take your vitamins.”

But despite being ubiquitous as candies before crossing into supplement territory, gummies by no means enjoyed a seamless migration. Dietary supplements, it turns out, are hard to deliver via gummies, which demand very specific formulations and ratios of key ingredients, and often preclude high dose loads or actives that might compromise the finished product’s taste.

Yet manufacturers’ hard work—and formulation and processing savvy—cracked the gummy code. They promise to do the same for emerging supplement delivery forms that already have brands hoping to score another industry turning point.

Those brands will need patience—and a solid relationship with their contract manufacturers—to make it happen. As Eugene Ung, CEO, Best Formulations (City of Industry, CA), says, “New technologies don’t come about overnight, and they typically don’t come for free. But with the right expectations and strategic planning, brands can leverage new technologies to help differentiate themselves.”

“With the right expectations and strategic planning, brands can leverage new technologies,” says Best Formulations’ Eugene Ung.

Inside the Lines
The first step in using that leverage involves determining whether or not a new technology even falls within FDA’s definition of a dietary supplement.

That definition describes products containing a dietary ingredient that are taken by mouth and intended for ingestion. “There are two points to this definition,” Ung notes: “that the delivery form be taken orally and meant to be ingested, and that the product contain dietary ingredients.”

Traditional formats like tablets, capsules, and powders get a pass. FDA even recognizes gummies as a valid dietary supplement dosage form. But the lines blur when it comes to melts, sublinguals, sprays, and even tinctures, which arguably aren’t ingested, and whose regulatory status FDA hasn’t entirely clarified.

That hasn’t stopped some brands from commercializing them. But, says Shaheen Majeed, president worldwide, Sabinsa (East Windsor, NJ), “You’ll see that most of the time—or at least for brands following regulatory guidelines—the directions for delivery
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You can’t blame brands for pushing the envelope, given increased interest in innovative supplement forms.

Demands like clean label, vegan, non-GMO, and organic on top of requests for fewer and cleaner excipients and binders have made manufacturing trickier these days.

You almost can’t blame brands for pushing the envelope, given increased interest in innovative supplement forms. Comparing 2013 to 2018, Nutrition Business Journal estimates that alternative and novel delivery options, including powders, effervescent products, and gummies, are all up 12%.

Notes Vincent Tricarico, vice president, contract manufacturing, NutraScience Labs (Farmingdale, NY), “While the majority of our clients opt for either capsules or powders, we’ve absolutely seen more inquiries for vegetarian capsules and clean powders.”

Similarly, Brad Buchholz, vice president of sales, Robinson Pharma (Santa Ana, CA), observes that clean label, vegetarian, non-GMO, and organic have all been popular marketing terms with upstart supplement brands for years—but that the restrictions the terms impose have made it difficult for supplement manufacturers across the board to bring such products to market.

Soft Spot
For example, time was when the softgel category had nothing to offer consumers with religious or dietary restrictions prohibiting consumption of the gelatin used in softgel encapsulation. But with the advent of vegetarian softgels, such consumers “can meet their nutritional requirements without violating their principles,” Buchholz says.

Ung and colleagues have been making non-animal softgels for 14 years, and despite the form’s being “exceptionally challenging to produce,” he says, “we’re learning and innovating every day—from using different ingredients for the shell to improving machine and production efficiency.”

He still fields taxing requests, like those for tapioca-based non-animal softgels. “The technical characteristics of the starch itself, as well as the scaled softgel manufacturing process, have made meeting those requests harder,” Ung says. “New technologies aren’t often fully vetted when launched, and there’s a learning curve for all parties involved.”

In fact, whether vegetarian or not, softgels in general inherently test manufacturers’ capabilities. As Steve Holtby, president and CEO, Soft Gel Technologies Inc. (SGTI; Commerce, CA), says, “Softgel production is a very unique and complicated process.” And given his company’s softgel focus, he should know: “Not every manufacturer can do it.”

Among the challenges is the high level of training and skill operators need to run encapsulation equipment smoothly and efficiently. For example, “During the rotary process,” Holtby explains, “the gelatin temperature, ribbon thickness, seam width, and fill quantity all need monitoring and control. This involves high precision and requires constant oversight. Inaccuracies make production costlier.”
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Clearing Hurdles
Yet the quest for newer delivery forms continues.

The difference, Ung says, is that he sees experienced brands taking “a much deeper dive” into their target formats’ requirements, better to grasp—and clear—the three main hurdles to launch: equipment, ingredient compatibility, and stability.

Consider equipment. “With novel dosage forms, there isn’t a lot of equipment or expertise on how to run it,” Ung says. “Oftentimes, novel delivery forms are manufactured using customized or modified equipment. Then there’s a whole other discussion regarding equipment validation, maintenance, parts changes, and more, which all factor into novel format production.”

Buchholz knows this firsthand. “Our management realized that we wouldn’t be able to use existing equipment to make the highest-quality product, so we looked globally for technology, equipment, and production leaders and began vegetarian softgel production from the ground up,” he says. “Many of the machines we use today are customized to our facilities and unique requirements.”

Can’t We All Just Get Along?
As for ingredient compatibility, it may be the most tenacious sticking point to bringing new delivery forms online.

“One of the biggest challenges we encounter is when a brand owner wants a dose form for a product that’s simply not compatible,” says NutraScience Labs’ Vincent Tricarico.

“One of the biggest challenges we encounter is when a brand owner wants a dose form for a product that’s simply not compatible,” Tricarico says. “A perfect example is a tablet that contains an oil-based ingredient, such as vitamin E or fish oils. The oil makes it incredibly difficult to compress the tablet, and thus an alternative dose form needs to be selected.”

Given that oil-based actives are often as incompatible with capsule, gummy, and water-based formats as they are with tablets, Holtby says, “they often need to be converted into water-dispersible or dried forms” prior to incorporation. “While this allows for their inclusion in such formats, it also typically reduces the nutrient’s potency significantly.”
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Outsourcing

One advantage of contracting with manufacturers is that they can shoulder the prep work—from dotting FDA’s “i”s to scheduling pilot runs and testing shelf life.

Other compatibility challenges involve incorporation of oxygen-sensitive components into tablets or two-piece capsules that see exposure to air. (Holtby’s suggestion: Don’t do it; opt for softgel encapsulation instead.)

Majeed points to his company’s Bi-Layer INC integrated nutritional composites as a tablet technology that lets brands keep two ingredients separate while delivering them in a single tablet. He says the format is great for physically or chemically incompatible ingredients—think acids and bases, or enzymes and substrates—and for situations when seeing the two separate layers helps educate consumers as to each one’s unique role in the formulation. Even better, Majeed adds, “The resulting bilayer tablets are almost the same size as regular tablets.”

Hold Steady
Close kin to the hurdle of ingredient compatibility is finished-product stability. And though FDA requires no expiration date on dietary supplements, “brands have an expectation of printing an expiration date anyway, and the date needs to be substantiated by stability studies,” Ung says.

Several years ago, Buchholz’s team accepted the challenge of making a shelf-stable softgel-encapsulated probiotic. “Probiotics have been among the most popular categories within the past few years, but production proved challenging because most strains are sensitive to heat, moisture, and oxygen—and softgel production requires heat and moisture,” he says. In response, his team developed a platform that delivers viable probiotics and maintains viability for two years. Says Buchholz, “It’s now astounding that there once was no way of producing a shelf-stable encapsulated softgel probiotic.”

His stability advice for brands: “Run pilot tests when possible. That can be expensive, but in the long run it may end up saving time, stress, and money by taking care of the prep work at the start.”

Let’s Talk
One advantage of contracting with manufacturers is that they can shoulder this prep work—from dotting FDA’s “i”s to scheduling pilot runs and testing shelf life. But brands only benefit from this expertise if they know how to access it. And that involves clear communication.

Or, as Ung says, “Communicate, communicate, communicate.”

Tricarico agrees. “If your account or order manager isn’t updating you regularly during the manufacturing process or answering your calls and emails, those should be red flags that you’re working with the wrong contract manufacturer,” he says. “You also don’t want a contract manufacturer who’s a ‘yes man.’ A good contract manufacturer will push back to an extent and offer either constructive feedback or an alternative solution.”

Adds Holtby, “Clearly articulated requests are important to a successful partnership. It’s imperative for a customer to establish clear priorities that meet the company’s needs.” That means not only tending to matters of product integrity—using clinically substantiated ingredients, say—but minding factors like price, timelines, and batch sizes. His company spends considerable time advising customers on what is and isn’t realistic. “One advantage of having a skilled and experienced sales team like ours is that it promotes clarity and understanding of the customer’s expectations.”

Oh, expectations. “Today’s market is driven by consumers doing research, and sadly, some of that research isn’t always correct,” Buchholz says. “Our team has had numerous conversations that began with, ‘I saw this product online so I know it’s possible,’ while in reality some of those products may not be or do all they claim.”

Ung sums it up simply. “There’s a well-known scenario of being able to pick only two out of these three: good, fast, and cheap,” he says. “You can realistically expect only two when it comes to new product dosage formats.”

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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Like the little black dress, omega-3 fatty acids never really fall out of fashion. Their hemlines, so to speak, may rise and fall with the times, and they may get nudged to the back of the closet when a buzzier nutrient hits the racks with the fanfare of a flouncy new romper.

But as industry watchers and category insiders know, consumers always return to these fatty-acid classics. Why? Because the science is on omega-3s’ side.

“More than 4,000 studies have demonstrated that EPA and DHA play crucial roles in the healthy functioning of our hearts, eyes, and brains across all life stages,” says Chris Gearheart, director, member communications and engagement, Global Organization for EPA and DHA Omega-3s (GOED; Salt Lake City, UT). “They also support the health of expecting and nursing mothers and the development of their babies.”

So even in the face of an equivocal study or two—or concerns over sourcing, regulatory setbacks, and the occasional pharma-driven lawsuit—omega-3s retain a sterling reputation that other supplements can only envy. And they retain such a hold on our attention that it’s never too soon to revisit how they’re doing and where they’re headed next.

Going Places
From Kate Pastor’s vantage, omega-3s are headed toward good things. “Currently, the omega-3 market is stable,” says the senior vice president of Superba North America, Aker BioMarine Antarctic US LLC (Oslo, Norway). “but there’s great potential for growth.”

According to Grand View Research, omega-3s enjoyed an estimated market value of $2.29 billion globally in 2018, with a 7.4% CAGR forecast for 2019 to 2025. And while Grand View wagers that the active pharmaceutical ingredients market drives most of this growth, supplements and functional foods remain North America’s dominant application category.

Gearheart attributes omega-3 supplements’ modest global growth particularly to consumers in the emerging economies of Southeast Asia, China, and India whose spending power is on the upswing. “This is in contrast to flat to slightly contracted omega-3 supplement demand in more established markets like the U.S. and Europe,” he says.

Taken to Heart
Nevertheless, Gearheart has faith that the flow of supportive science will keep omega-3s’ overall curve moving up and to the right.

The science linking the fatty acids with cardiovascular health still attracts the lion’s share of interest, and Gearheart notes that three major human trials studying EPA, DHA, and cardiovascular outcomes published in the second half of 2018 “effectively
double the number of subjects who've been studied.

Results of the ASCEND (A Study of Cardiovascular Events in Diabetes) study published in August 2018—though neutral on balance—demonstrated an 18% statistically significant reduction in vascular death risk among diabetic subjects supplementing with 1 g of omega-3s versus those taking an olive-oil placebo, Gearheart says.2

And while the VITAL (Vitamin D and Omega-3 Trial) study—which Gearheart calls "the first primary prevention trial in healthy subjects"—failed to attain its primary endpoint of reducing major cardiovascular disease risk, it did find a statistically significant 17% reduction in coronary heart disease risk and a 28% reduction in risk for myocardial infarction among subjects receiving the omega-3 drug Omacor plus vitamin D.3

The REDUCE-IT (Reduction of Cardiovascular Events with EPA Intervention Trial) study also looked at the effects of an omega-3 pharmaceutical—Amarin Pharma’s EPA-only Vascepa—on long-term cardiovascular events; recently published findings show that the drug, which delivers 4 g of EPA, reduced the risk of several negative cardiovascular outcomes by a statistically significant 25% or more, depending on the endpoint.4

Great Starts

"Because these three studies strengthen the body of evidence linking omega-3s to positive heart-health outcomes, GOED is working on a paper looking at omega-3 dose response, which we hope to publish this year,” Gearheart says.

That's not all they're looking at. The benefits of omega-3s for pregnant women and their babies are also on the organization's radar, with results of a Cochrane review published in November 2018 proving especially heartening.

The study found that a daily dose of 500-1,000 mg of EPA and DHA for pregnant women decreased the risk of early preterm birth by 42%, preterm birth by 11%, and low birth weight by 10%. "The evidence was so strong that the authors stated 'no further research is needed' to be sure of the benefit,” Gearheart notes.5

Spreading the Word

The authors of the Cochrane study also published a set of best practices for doctors based on their results, which GOED translated into a consumer-facing infographic and a social-media-friendly video highlighting the importance of omega-3s during pregnancy.

In fact, GOED has spent several years developing educational materials for consumers and healthcare professionals, Gearheart says. AlwaysOmega3s.com offers consumers information on omega-3s’ heart, brain, eye, prenatal, and maternal benefits, while FatsofLife.com communicates those same benefits in greater scientific detail and with corroborating research to practitioners.

"As part of our consumer outreach, we've developed a library of infographics and videos we share on social media and with our members and industry to share with their audiences,” Gearheart adds. "In the health-
care-practitioner space, we’re running media campaigns or continuing education programs for nurse practitioners, physicians’ assistants, pharmacists, and registered dietitians, and we’ve sponsored education sessions at several practitioner events.”

As the scientific publications mount, GOED’s even shouldered the mantle of building a searchable clinical-study database “to quantify and clarify the research around omega-3s,” he says.

More evidence-based good news came in the form of FDA’s recent announcement of a qualified health claim for EPA and DHA. “Omega-3 companies can now link seafood, fortified food, and beverages and dietary supplements containing at least 800 mg of both EPA and DHA to a reduction in blood pressure, using very specific language,” Gearheart notes.6 FDA also updated its allowable upper limit for EPA and DHA in supplements from 3 g/day to 5 g/day for brands making the qualified health claim, he added.7

**Krilling Me Softly**

So the science and labeling fronts bring cause for contentment. Even better, the sourcing horizon is also looking up—and increasingly diverse.

“The omega-3 industry is unique in the wide array of EPA and DHA sources available,” Gearheart says. “Algal EPA and DHA are becoming more widely available, as are diverse sources like oil from hoki fish, calanus”—a marine copepod—and herring roe. Each offers a marketing story to appeal to different consumer audiences.”

Pastor is happy to share krill oil’s story, noting that the market for the omega-3-rich oil “is heading into new territories like never before, especially in regards to science.” Exhibit A: A clinical trial examining krill oil’s effects on lupus patients began last year, bringing together the Lupus Research Alliance and Aker BioMarine. Chronic inflammation is a hallmark lupus symptom, and patients frequently exhibit low levels of omega-3 fatty acids—thus, researchers suspect omega-3s might help manage the disease’s attendant inflammatory effects. Trial results are expected in 2020.

Krill oil also evades some of the sustainability and traceability issues that dog other omega-3 sources. Within the past year, Aker BioMarine was “instrumental” in convincing most Antarctic-based krill-harvesting companies to voluntarily stop fishing in areas around the breeding colonies of penguins. Notes Pastor, “Companies in the omega-3 space continually need to invest in initiatives that help ensure the health of the biomass.”

And in terms of traceability, she continues, Aker owns and controls its entire supply chain, “which means we can ensure secure supply volume, product quality, and seamless service.”

**Algae’s Alright**

Meanwhile, algae’s potential as a renewable, non-animal omega-3 source keeps generating excitement within the industry.

Miguel Calatayud, CEO, Qualitas Health (Houston), calls algae-based omega-3 EPA and DHA “the perfect alternative to fish and krill oils: vegan, non-GMO, and fully traceable and sustainable.” No wonder his company, a leading algae cultivator, collaborated with ADM (Chicago) to launch a line of Onavita Algal DHA and Almega EPA blends for use in cognitive-, heart-, immune-, and eye-health support formulations.

ADM’s earlier algal-oil offerings comprised solely DHA, Calatayud notes, so Qualitas Health’s partnership introduces an EPA option to ADM’s catalogue. What’s more, “Partnering with ADM is a significant step toward our goal of bringing sustainable ingredients into the global supply chain,” he says.

As more algal EPA and DHA enter the market, brands must contend with the inherent difficulty of formulating and producing stable plant-based omega-3 products. As Barri Sigverson, senior marketing manager, consumer health and nutrition, Lonza (Basel, Switzerland), says, “To create an omega-3 supplement that delivers a plant-based positioning, it’s essential to consider both the ingredient and the delivery system.”

Their vegetarian Plantcaps capsules are “ideally suited” to delivering plant-based algal
omega-3s, Sigvertsen says. Made from pullulan, a product of natural tapioca fermentation, they’re vegan, non-GMO, and vegetarian certified. They also provide a superior oxygen barrier to prevent the oxidation that makes omega-3 supplements both less palatable and less biologically effective.

Oxidation the Enemy

Steve Holtby, president and CEO, Soft Gel Technologies Inc. (SGTI; Commerce, CA), also understands the perils of oxidation. “It’s important to protect fish oils as much as possible through all handling steps,” he states. “Containing the fresh oil in an environment with minimal oxygen exposure, along with low-temperature manufacturing, maintains freshness.”

His company has developed a system for encapsulating omega-3 fish oils, pulling a vacuum and/or nitrogen-blanketing the ingredients during blending. They also molecularly distill the fish oils themselves to remove oxidized components and manmade pollutants, and they include the natural antioxidant d-alpha tocopherol in the formulation to forestall rancidity.

Outstanding in Their Field

Such innovations have gone a long way toward making omega-3 supplements reliable, effective, and increasingly commonplace.

But, says Karin Hermoni, PhD, head of science and nutrition, Lycored (Orange, NJ), “While we see many omega-3 products on shelves, the question arises: How can brands differentiate themselves and create innovative, powerful products? Cracking the code for how to elevate the power of omega-3s is a powerful asset for any brand looking to launch an omega-3 product.”

Her company’s contributions take their inspiration from the Mediterranean diet and capitalize on synergies between omega-3s and carotenoids like tomato lycopene and polyphenols such as carnosic acid. The tag-team formulations received patent protection in March for their “synergistic ability to balance inflammatory processes and reduce the secretion of cellular mediators from immune cells,” Hermoni says, citing research from 2017 showing that the omega-3/antioxidant combinations exert beneficial effects on microglia, neuron-supporting cells known to participate in cognitive processes, brain inflammation, and overall brain health.

“The brain-health market is on the rise in all demographics concerned with aspects like focus, attention, concentration, and memory,” notes Elyse Lovett, senior marketing manager, Kyowa Hakko USA (New York City). So given that her company’s branded Cognizin citicoline supplies nutrients that support brain function and protect it from free radicals, and that DHA “is known to fight free radicals, which is important for brain development,” Lovett says, “it made sense to combine the two ingredients to show how the ‘fighting power and protective power’ of the two could work together.”

A study of cognitively impaired mice showed synergistic activity that improved learning and memory, she continues. “From
a marketing standpoint, we felt it’s important to deliver science to customers that shows the effects not only of Cognizin alone, but in combination with other potent brain-health nutrients.”

Finally, Sigvertsen notes, her company’s DuoCap capsule-in-capsule system lets brands deliver omega-3s plus trending ingredients like black seed oil and prenatal or multivitamins all in one dosage form. “This significantly broadens the spectrum of supplement combinations possible and offers supplement producers new opportunities to drive innovation and ensure that products stand out from the crowd,” she says.

For a little black dress like omega-3s, you couldn’t ask for more.

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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Osteoporosis impacts 200 million women worldwide and affects an estimated 75 million people—men and women—just in Europe, the United States, and Japan, according to recent International Osteoporosis Foundation estimates. Worldwide, osteoporosis is responsible for nearly nine million fractures every year. Nearly 25% of annual hip fractures occur in men. Hip fractures are a significant cause of mortality: in men, the overall mortality rate in the first 12 months following a hip fracture is approximately 20%. These sobering statistics highlight the need for men and women to consider interventions to support bone health throughout life.

While eating a healthy diet, getting enough weight-bearing exercise, and ensuring calcium and vitamin D adequacy are good first steps in a nutritional and lifestyle plan to stop or slow down bone loss, research suggests this may not be enough. Several other nutritional compounds are known to play a major role in supporting bone health, and combining these with traditional strategies may be necessary to optimize the building blocks the body needs for healthy bones. These emerging contenders include magnesium, collagen, and vitamin K₂. Current research show all three hold significant promise as adjunct therapies to the mainstays of bone health nutrition. Because of the fundamental roles they play in maintaining and growing healthy bone, leaving them out may not be a wise option.

Magnesium is an essential mineral that acts as a critical cofactor for hundreds of biochemical reactions in the body. With respect to bone health specifically, its importance can’t be overstated. As the fourth most abundant mineral in the human body, nearly half of total body magnesium stores lie in bone tissue. Animal studies reliably show that a low-magnesium diet adversely affects bone strength, while human population-based studies repeatedly have found that dietary levels of magnesium are positively associated with bone mineral density.²

Magnesium may work in several ways to promote healthy bones. Laboratory studies have found that low extracellular levels of magnesium promote the production of osteoclasts in bone tissue, cells responsible for bone breakdown. At the same time, low magnesium levels interfere with the proliferation of osteoblasts, cells that build bone. Overall, this favors a decrease in bone strength. Laboratory and human studies further demonstrate that magnesium has a suppressive effect on parathyroid hormone (PTH) secretion in situations where serum calcium levels are marginally low, leading to a protective

**Here come magnesium, collagen, and vitamin K₂!**

**BY IRFAN QURESHI, ND**
Evidence indicates that magnesium plays a crucial role in the activation and function of vitamin D. A recent review suggests that nearly all of the enzymes that metabolize vitamin D require magnesium as a cofactor. The relationship between magnesium and vitamin D is codependent. Vitamin D improves intestinal magnesium absorption, while magnesium is necessary as a cofactor for the vitamin D–binding protein. In addition, metabolism of vitamin D in the liver and kidneys into its active form requires magnesium. Thus, vitamin D is unable to effectively play its role in influencing the growth of bone tissue by regulating calcium and phosphate balance without the presence of magnesium.

In a recent two-year follow-up cohort study including 113,683 individuals in Japan undergoing hemodialysis, Yusuke Sakaguchi from Osaka University Graduate School of Medicine (Suita, Japan) and colleagues found that those with lower serum magnesium levels had a significantly higher risk of hip fractures than those with higher serum magnesium levels. Each 1 mg/dl increase in magnesium level was associated with a 14.3% decrease in the risk of fracture. The researchers also found that magnesium levels mildly above the normal range (mild hypermagnesemia) were more beneficial in reducing fracture risk in this cohort, indicating additive benefits of higher magnesium levels. Previous research by the same group linked mild hypermagnesemia to improved survival in hemodialysis patients; it is possible that the reduction in hip fractures associated with elevated magnesium is a contributing factor to the enhanced survival rates.

Further evidence in support of the beneficial effects of magnesium comes from a cohort study including 156,575 men and women aged 39 to 72. Led by Alisa Welch from the University of East Anglia (Norwich, UK), investigators assessed measurements of muscle and bone health indicators from individuals that were a part of the UK Biobank cohort. These measurements were compared to dietary intake levels of magnesium. Clinically significant differences were found in grip strength, fat free mass, and bone mineral density in both men and women when assessed across quintiles of dietary magnesium intake. Specific to bone mineral density, higher magnesium intake led to greater bone mineral density measurements in men and women. While these benefits were more pronounced in men, the bone mineral density differences were also significantly higher in women with greater dietary magnesium intake, reinforcing the importance of magnesium for bone health.

Collagen is a vital structural protein for bone that forms the backbone of bone’s mechanical strength. It is made up of three polypeptide strands forming a unique triple helix where the amino acid glycine is in every third position. The other two amino acids most commonly represented in collagen are proline and hydroxyproline. As the most abundant protein in mammals, collagen represents 30% of total protein in the body, while in bone and other connective tissue it represents 80%. In bone, collagen is intertwined with minerals, including calciumapatite crystals. The minerals are responsible for the stiffness and rigidity of bone, and collagen provides skeletal toughness and defines its shape. Nearly 95% of collagen in bone is type I, while type II collagen is also present. Research suggests that type I collagen synthesis promotes osteoblast growth and enhances bone mineral density.

The ability of bone to resist mechanical forces and fractures is dependent on both the quantity of bone tissue (i.e. the amount of mineralization) as well as the quality (i.e. the structural organization of the collagen backbone). Age-related changes can have a significant impact on the collagen framework, leading to reduced bone strength and elasticity, making bone more prone to fractures (such as in osteoporosis). One factor affecting collagen is estrogen deficiency, which decreases collagen maturation rate. Aging also increases the overall metabolism of collagen, leading to a fragile bone matrix. Research further suggests that the formation of advanced glycation end products (AGEs) in bone tissue occurs with aging, weakening
the integrity of the collagen backbone.\textsuperscript{5} Interestingly, laboratory studies in pre-osteoblasts from mice show that collagen peptides from a bovine source were able to enhance the growth and proliferation of osteoblasts and encourage the formation of mineralized bone matrix, highlighting its bone-protective effects.\textsuperscript{7} These factors attest to the importance of replenishing collagen in addition to the key bone-supportive vitamins and minerals in order to maintain healthy bones.

Most supplemental collagen is in the hydrolyzed form. The terms \textit{hydrolyzed collagen}, \textit{collagen hydrolysate}, \textit{hydrolyzed gelatin}, and \textit{collagen peptides} are essentially synonymous. Hydrolyzed collagen taken orally is digested in the gut and crosses the intestinal barrier. Being relatively well-absorbed, it enters circulation and has been found in various research models to reach target tissues.\textsuperscript{5}

While the number of human studies evaluating the use of collagen for bone health is small, the results of early studies are promising. A published systematic review conducted by Brazilian researchers including five human trials and three animal studies published between 1994 and 2014 concluded that supplementation with hydrolyzed collagen had a positive therapeutic role in conditions such as osteoporosis and osteoarthritis, with a dose of 8 grams daily shown to increase plasma glycine and proline concentrations, while 12 grams daily supported significant symptomatic improvement of osteoporosis and osteoarthritis.\textsuperscript{6}

More recently, a clinical trial led by Daniel König from the University of Freiburg (Freiburg, Germany) assessed the effect of collagen supplementation on bone-health markers in postmenopausal women.\textsuperscript{8} In the 12-month, double-blind, placebo-controlled study, 131 women with an average age of 64 were randomized to supplement with 5 grams of specific collagen peptides—the Fortibone brand from Gelita AG (Eberbach, Germany)—or a maltodextrin placebo daily. The primary endpoint was a change in bone mineral density at the femoral neck and spine after 12 months. Plasma levels of the bone turnover markers amino-terminal propeptide of type I collagen (PINP) and C-telopeptide of type I collagen (CTX-I) were also assessed. The women were also encouraged to consume 500-800 mg of calcium supplements and 400-800 IU of vitamin D daily, although the intake of these supplements was not controlled.

At the end of the study, bone mineral density at the femoral neck and spine increased significantly versus placebo in the collagen group. PINP also increased significantly in the collagen group whereas CTX-I rose in the placebo group. This indicates that supplementation with specific collagen peptides by postmenopausal women for 12 months led to a favorable shift in bone mineral density and in bone-health markers, leading to increased bone formation and reduced degradation.

Vitamin K is one of the fat-soluble vitamins most well-known for its role as a cofactor in the blood coagulation process. Vitamin K occurs in two main forms. The form that has traditionally been a component of multivitamins is known as K\textsubscript{1}, or phylloquinone. This is the form commonly found in many foods, vegetables, and oils. However, a second form known as K\textsubscript{2}, or menaquinone, also exists and is mainly synthesized by bacteria; certain menaquinones are found in specific foods, including fish, liver, milk, and eggs.\textsuperscript{9}

The different menaquinones (MK) are designated by the number of isoprenoid units occurring on their side chains and occur in configurations between MK-2 and MK-13, with longer-chain forms having a greater half-life and bioactivity. As research into the effects of menaquinones progresses, this form of vitamin K is gaining importance. Specifically, menaquinones play a central role in bone and cardiovascular health because of their influence on calcium balance in the body. MK-4 to MK-10 have superior absorption in the human body and show greater activity than vitamin K\textsubscript{1}. Furthermore, K\textsubscript{1} is mainly stored in the liver and plays a bigger part in coagulation while K\textsubscript{2} is distributed throughout the body and has a greater systemic effect.\textsuperscript{9}

Vitamin K\textsubscript{2}’s role in bone health stems from its function in activating several vitamin K\textsubscript{2}–dependent proteins through a process known as gamma-carboxylation, the most important of which are osteocalcin and matrix Gla protein (MGP).\textsuperscript{9} Osteocalcin is a calcium-binding protein produced by osteoblasts in bone tissue. When activated by K\textsubscript{1} osteocalcin binds to calcium ions and hydroxyapatite crystals. This results in favorable effects on the organization of the extracellular bone matrix...
and an influence on the size and shape of hydroxyapatite crystals, promoting bone mineralization. MGP, on the other hand, exerts its effects in smooth muscle of blood vessels and in cartilage. As another calcium-binding protein, MGP inhibits the calcification of arteries and cartilage, delivering calcium from these areas to the bone, facilitating healthy bone formation. Adequate levels of K$_2$ by playing a major role in activating these proteins, facilitate bone health.

Human clinical trials using the most common supplement form of vitamin K$_2$, known as MK-7, have recently shown promising results for promoting a protective effect on healthy bone. An earlier study led by Marjo Knapen from Maastricht University (Maastricht, The Netherlands) assessed the effect of supplementation with MK-7—the MenaQ7 brand from NattoPharma (Oslo, Norway)—over a three-year period in healthy postmenopausal women. In the placebo-controlled trial, 244 women received placebo or 180 mcg MK-7 daily. Dual-energy X-ray absorptiometry (DXA) assessments for bone mineral content and density of the femoral neck, hip, and lumbar spine were conducted at baseline and after one, two, and three years of supplementation. Serum levels of uncarboxylated and carboxylated osteocalcin were assessed to determine vitamin K$_2$ status. At the end of the study period, MK-7 supplementation led to improved vitamin K$_2$ status and decreased age-related declines in bone mineral content and density at the lumbar spine and femoral neck, but not at the hip, compared to placebo. Measures of bone strength were also improved by supplementation with MK-7 daily.

An additional study conducted by Sofie Rønn and colleagues from Aarhus University Hospital (Aarhus C, Denmark) investigated the role of MK-7 supplementation in preventing age-related degradation of trabecular bone at the tibia. In the randomized, double-blind study, 148 postmenopausal women with osteopenia supplemented with 375 mcg of MK-7 or a placebo daily for 12 months. High-resolution computed tomography was used to assess bone microarchitecture, while DXA scans were conducted to evaluate bone mineral density. Unconventional osteocalcin levels were also measured.

The results of the study showed that MK-7 supplementation maintained trabecular number in the tibia, while this decreased in the placebo group. Furthermore, trabecular spacing and thickness were unchanged with MK-7 supplements, while both significantly increased with placebo. Unconventional osteocalcin levels also decreased with MK-7 significantly more than placebo. While bone
mineral density showed no improvement, there was a pronounced protective effect against deterioration of bone microarchitecture with MK-7.

The Bone Health Toolbox
Given the number of people impacted by bone health issues such as osteoporosis, a paradigm shift in the thought process for nutritional intervention is needed. As fundamental as diet, exercise, calcium, and vitamin D are to prevent bone deterioration, a more holistic approach including other key nutritional cofactors for bone structure is likely to yield greater benefit across the lifespan. Adding critical cofactors, including magnesium, collagen, and vitamin K₂, to current nutritional recommendations for bone health could go a long way towards helping to reduce the occurrence of osteoporosis and related disorders.

Irfan Qureshi, ND, is vice president, product development and quality assurance, for Healthy Directions.

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Run-of-the-mill supplements and stereotypes will not resonate in today’s highly personalized market.

BY MELISSA KVIDAHL

If there’s one trend disrupting nearly every market, it’s personalization. We want ingredients for tonight’s dinner curated to our personal dietary preferences and delivered to our doors. We don’t want to channel surf; we want our television streaming service to tell us what we might want to watch next, based on our unique viewing preferences. And, if the bespoke supplement packs dotting Instagram feeds are any indication, the nutraceuticals market is about to get a personalization makeover.

In the meantime, short of drilling down to each individual, brands and manufacturers can provide specialized formulations in the form of condition- and gender-specific supplements to the consumers who want it most. This includes women.

“Women are taking control of their health like never before,” says Michael Chernyak, president of CK Nutraceuticals (Oakville, ON, Canada). “They are increasingly zoning in on their specific needs and wants, as opposed to choosing broad-based supplements meant to promote general health.”

As a result, brands are seeing increased interest in condition-specific natural health products for women. In short? The women’s supplement market is about so much more than a women’s daily multivitamin or prenatal vitamin.

“The modern consumer has become accustomed to nearly immediate, to-the-door delivery that gets them their product as soon as they need it,” says Amy Upchurch, founder and CEO of supplements brand Pink Stork, noting that the market is shifting as a result. “When it comes to supplements, there is a demand for convenient, on-the-go packaging and products that support the different lifestyles of busy women.”

Evolving Ingredients

Not only do women live longer than men, on average, but their life expectancy is ever on the rise. In 1984, a woman’s life expectancy was 78; today, women are living to age 81. “Consequently, women are living more years in the post-menopause phase of life,” says Sally Aaron, senior vice president of health ingredients and marketing at Evolva (Reinach, Switzerland). This is opening up the market for not just increased interest in supplements addressing menopause-related issues, but also those addressing general health issues women encounter as they age.

“We believe the menopause-relief category continues to offer opportunities for growth in natural solutions,” says Chernyak. CK Nutraceuticals’ EstroG-100 ingredient, a patented combination of herbal extracts, is marketed for a broad range of menopause symptoms.

Yet another tried-and-true area for women’s health supplements is urogenital discomfort, which still posts high prevalence and recurrence, says Elodie Aragon, product manager at Lallemand Health Solutions (Montreal, QC, Canada), marketers of Probiocap probiotics. According to the U.S. Department of Health & Human Services, urinary tract infections occur mainly in women, affecting half of all women at some point in their lives. When it comes to vaginal health, bacterial vaginosis (a condition occurring
when there’s too much of a certain kind of bacteria in the vagina) is the most common vaginal infection in women ages 15 through 44, with about 30% of women in this age group having reported occurrence. Together, these issues are due to "an imbalance of the urogenital microbiota," says Aragon, "and this is increasingly well understood by consumers, hence the demand for natural, holistic supplement approaches to help maintain balanced microbiota." So while probiotics have been generally associated with gut health, demand is increasing in the women’s health category.

But what’s most exciting about the women’s health category is that supplement brands and ingredient suppliers alike are going beyond traditional issues like menopause and vaginal health to offer products for all stages of a woman’s life and appealing to all kinds of health goals.

One of the areas on the rise as women outlive men is cognitive health, Aaron says. "In the U.S., health problems related to cognitive decline, specifically Alzheimer’s disease, are the sixth leading cause of death," she says. "Medical interventions for cognitive decline remain elusive, so women are looking for alternatives across the diet, exercise, and lifestyle spectrum for solutions that will work for them." At Evolva, the ingredient addressing this demand is resveratrol, which the company says can support improved memory, focus, and concentration by enhancing cellular energy uptake, scavenging reactive oxygen species, increasing anti-inflammation capacity, and more.

But that’s not all. "Sports nutrition research historically focused on male athletes, overlooking the nutritional needs of females in regards to supporting proper metabolism," says Bergstrom Nutrition’s (Vancouver, WA) vice president of sales and marketing, Tim Hammond. In response, the company is pursuing female-specific research on its OptiMSM ingredient. Initial findings suggest the ingredient may increase collagen cross-linking in engineered human ligaments treated with high estrogen. "This demonstrates that MSM might completely reverse the negative effects of estrogen on ligament mechanics," Hammond says. "Our follow-up clinical study will focus on determining the impact of OptiMSM on knee laxity changes throughout the menstrual cycle in active young women."

Beauty-from-within is another area impacting the women’s health supplement market, says Karin Hermoni, head of science and nutrition at Lycored (Secaucus, NJ), as women of all ages want to age beautifully. In response, Lycored offers carotenoids like natural tomato extract to support skin health.

Marketing and Delivery

For years, the women’s health market has been plagued by “shrink and pink,” a method of marketing meant to attract female buyers. That just won’t fly with today’s female consumers who want something more than a pinkwashed version of products marketed to men.

Specifically, women want creative delivery formats. According to Staness Jonekos, founder and CEO of the brand Eat Like a Woman Inc., functional foods are becoming increasingly popular in the women’s supplement market. In response, the company...
Women’s Health

PACKAGING DO’S AND DON’TS


Do: Utilize a clean aesthetic. “Product function should be clearly stated,” he says, with any organic claims conspicuously conveyed.

Don’t: Be vague when it comes to packaging design, product function, or claims. “Women are busier now than they have ever been and don’t have time to decipher your product message,” Earl says.

Do: Utilize soft metallics and a mix of matte and foil finishes, which are on-trend and draw the eye. “These printing techniques provide a high-end look many women are drawn to,” he says, “as well as a pop, so products stand out both on store shelves and online.”

Melissa Kvidahl is a freelance journalist and copywriter specializing in the health and wellness industry.

Today’s female shopper is looking for supplements customized for increasingly specific health goals.

offers Life Stage Shakes—plant-based protein powders fortified with probiotics—for reproductive health, pregnancy, lactation, menopause, and other health goals.

“Women are looking for innovative products to take on the go and alternatives to pills and capsules due to pill fatigue,” agrees Aaron. “For example, we know women are interested in powder sachet drink mixes and emerging film strips that are gaining popularity in Europe.” To that end, Evolva offers cold-water-dispersible Veri-Sperse resveratrol for beverage formulations.

Lallemand is meeting demands for convenience by offering ComboCap ’Biotics, which is a delivery format capable of combining probiotics and oils, two incompatible ingredients, into orodispersible sticks (which can be taken at any time of day without water), chewing tablets, and more.

Beyond delivery formats that make taking supplements convenient for on-the-go female consumers, marketing must appeal to them where they are—social media. “The level for social media influencers has never been higher,” says Jacob Fishback, sales supervisor and client product specialist at Lief Labs. “Instagram, Facebook, and YouTube have given women a massive platform to reach consumers on a daily basis,” which means that women have access to a community of peers and experts providing educational and informative content that can help inform their health choices.

“I think this idea of empowering yourself and taking your health and overall wellness into your own hands is something that more women are doing,” agrees Meg Ligot, product development manager at Lief Labs. “Being fit and healthy is the new black, and more and more women are becoming active and taking products to help them live that lifestyle.”

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UT Why?

More urologists are recommending cranberry PACs for reducing UTIs. Here’s why.

BY SOPHIE A. FLETCHER, MD

Worldwide, health regulation agencies are responding to widespread antibiotic-resistant bacterial infections. This global health epidemic has been attributed in part to the overuse of antibiotics for the management of recurrent urinary tract infections (UTIs), as reflected in the rapidly rising antibiotic resistance rates in \textit{E. coli} bacteria. UTIs alone account for up to 60\% of all antibiotic prescriptions. Meanwhile, 30\% of antibiotics prescribed for UTIs in the outpatient setting have been reported as unnecessary.\textsuperscript{1}
An effective, non-antibiotic approach to UTI prevention requires reducing antibiotic use by both patients and the global medical community. The search continues for non-antibiotic treatment alternatives for UTIs. The bioactive compounds in cranberry, called proanthocyanidins (PACs), fit the bill.

In 2019, the American Urological Association (AUA) released its new guidelines for recurrent UTIs, titled “Recurrent Uncomplicated Urinary Tract Infections in Women: AUA/CUA/SUFU Guideline.” The guidelines emphasize the need for non-antibiotic alternatives for reducing UTIs. They also highlight cranberry as an effective means of prevention, citing the newest evidence supporting the benefits of the fruit’s PACs. The AUA guidelines recommend further research into the mechanism of action of PACs and clarification of the ideal dosage and formulation for best clinical effect.

**Benchmark Established**

Researchers have identified soluble A-type linkages in cranberry PACs as an important inhibitor of the adhesion of P-fimbriated uropathogenic bacterium (primarily E. coli) to uroepithelial cells, establishing bacterial anti-adhesion activity as the evidence-based mechanism of action. A dose-dependent, randomized, double-blind study determined that a minimum of 36 mg of the soluble A-type PAC is required to promote bacterial anti-adhesion activity and contribute to UTI prevention. A Cochrane review concluded that one 36-mg bioactive cranberry PAC supplement was as effective as a low-dose antibiotic for UTI prevention. Furthermore, a university-based study found this 36-mg bioactive PAC formula helped to prevent and reduce catheter-associated UTIs, without the side effects and resistance associated with antibiotics.

**Proof Is in the PAC**

Traditional over-the-counter cranberry products typically found in grocery stores and pharmacies vary widely in their quality and ingredients. Therefore, they are substantially unreliable for UTI prevention. Laboratory studies of supplement content show that most contain less than 5 mg of PACs, rendering them ineffective for preventing bacterial adhesion to the bladder. For those supplements that claim to contain 36 mg of PACs, it is important to note that variability exists in the bioavailability of PACs present. Some supplements, for example, are made from whole berry or presscake—the dried skins, stems, and seeds of the fruit—and contain mostly insoluble PACs that bind to cell wall components of the cranberry, such as cellulose. It is an essential distinction that this insoluble PAC does not...
not prevent bacterial adhesion to the bladder.\textsuperscript{10}

Soluble PACs, at high levels necessary for maximum anti-adhesion activity and clinical efficacy, can only be extracted for maximum anti-adhesion activity and comparison among formulations.\textsuperscript{11,12} Microplate method—therefore allowing for recognized standard—i.e., the DMAC/A2 microparticle method—therefore allowing for comparison among formulations.\textsuperscript{11,12} Manufacturers should cite data on their 36-mg PAC content, as well as evidence of maximum anti-adhesion activity. Armed with this knowledge, clinicians and patients alike can take a proactive approach to preventing recurrent UTIs and potentially reducing antibiotic resistance.\textsuperscript{N}

**Prevention in Practice**

The new AUA guidelines caution that products used in scientific studies are often formulated specifically for research purposes, limiting their availability for use. Current commercial products may differ in their effectiveness for preventing UTIs in susceptible populations.\textsuperscript{8} In addition, there are no government regulations that closely monitor standardization or efficacy of products made from cranberry. Therefore, healthcare providers and consumers must evaluate ingredients in current commercial cranberry products against the proven benchmark of 36-mg bioactive PACs to ensure clinical efficacy for UTI prevention.

A reliable product must have rigorous manufacturing standards, transparency of ingredients, and proof of efficacy. PACs can be tested via an internationally recognized standard—i.e., the DMAC/A2 microparticle method—therefore allowing for comparison among formulations.\textsuperscript{11,12}Manufacturers should cite data on their 36-mg PAC content, as well as evidence of maximum anti-adhesion activity. Armed with this knowledge, clinicians and patients alike can take a proactive approach to preventing recurrent UTIs and potentially reducing antibiotic resistance.\textsuperscript{N}

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America may be a diverse place, but there’s one thing we all share: stress. And not the healthy kind, which in small doses can help you tackle a to-do list or reach long-term goals. According to the American Psychological Association’s 2018 Stress in America survey, nearly three-quarters of adults say they have experienced at least one symptom of stress in the past month, and almost half say they lay awake at night due to stress.

APA’s survey also found that one in five adults don’t feel they’re doing enough to manage their stress. So while they may look to friends (48%), significant others (44%), or family members (31%) to help manage their woes, it may not be enough. “When stress becomes too much—common signs include the inability to concentrate or complete tasks, body aches, more frequent illnesses, and trouble falling asleep—it may be time to look at remedy alternatives,” says Chase Shryoc, vice president of sales and business development at Gencor (Irvine, CA). And it seems consumers are doing just that. In fact, data from market researcher SPINS show that U.S. dollar sales for mood-support supplements posted double-digit growth over the past year at 18%, to reach $114.5 million.

“There is certainly a demand for natural ingredients that can help address the challenges around stress management and relaxation,” agrees Josh Beaty, marketing director at NuLiv Science (Brea, CA). “The anxiety phenomenon is taking an increasing toll on the general population due to the ever-growing demands of the workplace, personal commitments, financial stress, and overall health. When consumers are experiencing overload, they want to alleviate the symptoms.”

Alleviating Ingredients

Today’s stress-management ingredients boast body-wide benefits.

Herbs still have a dominant role to play in the relaxation and stress-relief category. At NuLiv Science, ingredients to watch include ashwagandha (Withania somnifera) and rhodiola (Rhodiola rosea). Currently, the company is working on branding a new ingredient to debut in the fall called Zylaria (Xylaria nigripes), which will support GABA production, mood, anxiety, and relaxation. “In other words, it’s really focusing around supporting stress management in an herbal format from a traditional Chinese medicine perspective,” Beaty says.
Other ingredient suppliers are offering solutions that go beyond addressing the stress itself to addressing the effects of stress, from poor sleep and inability to relax to poor focus and lack of energy. “For many consumers, top concerns like relaxation, sleep, mood, and cognitive function are all wrapped up together and directly impacted by stress,” says Brian Appell, marketing manager at OmniActive Health Technologies (Morristown, NJ). “So, formulas that target multiple benefits are more attractive to consumers.”

Appell suggests that brands educate consumers about stress as a symptomatic phenomenon, and that prolonged stress can result in a cluster of health conditions that may seem unrelated at first. In short, he believes “it’s not enough to launch a formula that just targets stress support,” but rather to expand on stress supplements by offering related benefits. And, he says, this is a unique opportunity for growth: to develop and market products that are capable of cross-merchandising across stress but also immune function, cognitive health, sexual performance, sleep, and other health areas.

At OmniActive Health Technologies, the company’s lutein-and-zeaxanthin ingredient Lutemax 2020 shows promise for multiple issues related to stress, including better sleep, better emotional health, and healthier cognition. “Consumers are looking for a variety of natural solutions,” agrees David Daguet, chief innovation officer at Vidya Europe (Villebon-Sur-Yvette, France). “Some are looking for natural solutions just to improve the manifestations of stress like lower back pain, difficulty concentrating, and digestive troubles. Others are conscious of their stressed state and are looking for natural ways to cope with it.” In response, Vidya recently developed an ingredient called Viwithan, an ashwagandha extract that may help with stress management as well as improve the manifestation of stress in cognition, physical capabilities, and the digestive tract.

At Gencor, internal research found a link between hunger and anxiety, specifically that “hungry people tended to be anxious,” says Shryoc. The company offers Slimaluma, a Caralluma fimbriata extract Shryoc says was traditionally used in India as an appetite suppressant. “Gencor conducted animal studies which showed positive improvement in nootropic activities and a significant reduction in anxiety and stress,” he says. “From there, Gencor completed the first human clinical trial on the ingredient’s stress-relief positive effect. The results demonstrated a significant decrease in anxiety and stress at both week four and week eight when compared to the placebo groups.”
The gut/mind connection is also front and center at Lallemand Health Solutions (Canada), where clinical work and mechanistic studies have demonstrated the benefits of a specific probiotic combination: *Lactobacillus helveticus* Rosell-52 and *Bifidobacterium longum* Rosell-175. Together, they “promote a healthy mood balance and support a healthy response to everyday occasional stress,” says marketing director Bérengère Feuz. “With now five clinical trials and nine mechanistic studies, we believe that this psychobiotic formula is the most documented in the brain-gut axis.”

As it turns out, Appell believes the stress-management category can actually follow a similar trajectory as the probiotics market, which started with a focus on one thing (gut health) and then expanded to address body-wide issues. “I think if this industry continues to educate consumers about the specifics of the impact of stress on health and how supplements protect against its effects—not broadly but as specific benefits—then consumers will recognize the importance of managing their stress levels through supplementation,” he says.

Beaty says that consumer education doesn’t just fall on the shoulders of brands and retailers, especially when it comes to a nuanced category like stress management. “Ingredient developers should invest resources into creating a content marketing program that supports ingredient awareness and education for the general public,” he says. “There will be people who look up the origin of a branded ingredient, and the consumer wants to know if the ingredient is legitimate and that there is scientific backing for its inclusion in the supplement being sold.”

Melissa Kvidahl is a freelance journalist and copywriter specializing in the health and wellness industry.

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Almost a century has passed since pioneering Scottish scientist Alexander Fleming realized that a fungal contaminant on a laboratory petri dish was churning out a substance rife with antibacterial properties—a substance we now call penicillin.

Even then, he was but one in a long line of inquiring minds—scientific, civilian, and otherwise—to recognize the health-promoting potential of fungi. That potential is under a whole new spotlight as a stream of studies corroborates medicinal mushrooms’ mind-body benefits, and as consumers tune in to the apparent magic of functional fungi.

From Asia with Love

According to Paul Schulick, founder and CEO, For The Biome (Dummerston, VT), there’s nothing magic about it. “Rather,” he says, “5,000 years of honing their innate survival skills has garnered medicinal mushrooms a position of high honor among natural medicines. Mushrooms are poised to become the new probiotics. We’re on the verge of a medicinal mushroom renaissance.”

That’s an ambitious prediction, but mushrooms’ hallowed reputation in traditional Chinese medicine (TCM) suggests it may be warranted.

“In Asia through the millennia,” Schulick explains, “medicinal mushrooms have represented a primary health resource—and today, a multibillion-dollar market. To say that healing mushrooms have always been the go-to choice for health and wellness throughout Asia is no exaggeration; what’s different now is that the U.S. market is waking up to mushroom wisdom, creating a competitive, burgeoning category that’s growing by leaps and bounds.”

Josh Beaty, marketing director for NuLiv Science USA Inc. (Brea, CA), whose company offers a full portfolio of mushroom ingredients under the brand name Prime, agrees: “Our industry has known for quite some time about the benefits of mushrooms. The evidence is strong enough that a number of countries officially use (from their ministry of health) certain mushroom extracts for immunotherapy. We are seeing increased awareness among consumers. One only needs to look at search volumes on Google and Amazon. For instance, searches for cordyceps have doubled on Amazon within the last 12 months. Some of this upward trend is ‘hip’; some of it is niche and medicinal in nature.”

No Longer Niche

Consider that Technavio’s Global Medicinal Mushroom Market 2018 to 2022 report forecasts growth for the sector as high as...
$13.88 billion, with 39% of that occurring solely in the Americas.¹

Michelle Gillespie, NTP, natural insights analyst, SPINS (Chicago), says SPINS sales data for the 52 weeks ending May 19, 2019, show solid growth in all U.S. channels for products featuring functional mushrooms. While natural-channel sales grew most at 29.7%—hitting $22 million—“mushrooms picked up speed quickly as they made their way into the conventional multi-outlet channel with triple-digit growth of 174.3% to $3.1 million,” she says.

In other words, “Mushrooms are on their way to becoming a major trend,” concludes Sandra Carter, founder, Om Mushrooms (Carlsbad, CA). “Although they’ve been on the fringe in the past, we’re seeing our products appearing in both natural and conventional channels with very impressive, consistent turns.”

Brien Quirk’s witnessed similar interest. “We see customer inquiries for mushroom extracts in formulations and functional foods increasing even more this year, with year-over-year increases for the last four or five,” says the director of R&D at Draco Natural Products (San Jose, CA). While he doubts mushrooms will reach probiotics’ heights, “They do have permanence and show numerous applications and benefits,” he says.

The Right Remedy at the Right Time

Among those benefits is stress mitigation, “which in ancient times was literally tied to basic survival,” Schulick points out. Though contemporary stressors—device fatigue, environmental assaults, sedentary lifestyles—are less acute, their chronic toll means that “current culture still needs those adaptogens,” Schulick continues. That makes functional mushrooms the right remedy at the right time.

“A combination of some very compelling research, growing awareness of mushrooms as effective superfood boosts, and broader availability of trusted products make it easy for consumers to add mushrooms to their daily routines,” Carter adds. “I also feel that with the rise of plant-based eating, consumers have a heightened curiosity about looking to nature for health and nutrition.”

And genetically speaking, mushrooms may be more like us than we thought. “Our internal structures and the ways in which we process oxygen are very similar,” Schulick says. “We see evidence of this biocompatibility in the harmonious way our bodies respond when mushrooms are applied topically.”

Carter agrees. “Because mammal DNA is more closely related to mushroom DNA than to that of plants, it makes sense that...
many of the disease-fighting and wellness-promoting powers that mushrooms evolved for themselves would turn out to be beneficial for us, too.”

**To Your Health**

Nutritionally, functional mushrooms all boast prebiotic fiber—great for the microbiome—and antioxidants to combat free radicals. But individual species have unique functional properties that, says Carter, “work with our bodies to support immunity, energy, sports performance, recovery, cognitive health, and overall health and wellness.”

For instance, immune support often drives consumers to mushrooms like shiitake (*Lentinula edodes*), chaga (*Inonotus obliquus*), and reishi (*Ganoderma lucidum*)—the last of which saw sales grow 47.2% to $9.9 million over the 52 weeks ending May 19, 2019, per SPINS. Other trending benefits include cognitive and brain support—frequently attributed to lion’s mane (*Hericium erinaceus*)—and the purported metabolic benefits of oyster mushroom (*Pleurotus* genus).

**Skin Deeper**

Schulick is excited about mushrooms’ “cutting-edge applications for the ‘third brain’”—that is, the skin. The body’s largest organ, the skin “is an extension of the human microbiome,” he says, “and an underused therapeutic gateway for whole-body wellness, as well as for beautification and antiaging.”

A review article in the journal *Cosmetics* titled “Mushroom cosmetics: The present and future” highlights a who’s-who of popular mushroom beauty products with antioxidant, anti-inflammation, anti-wrinkle, skin-whitening, moisturizing, and collagen- and elastin-supporting benefits, he notes, adding that “with baby boomers seeking ways to stay younger in mind and body, they’ll readily embrace skin-based delivery methods for enhancing youth and beauty, health, and wellness.”

In fact, For the Biome recently collaborated with Om Mushrooms to develop a line of fungi-based skincare products that leverage chaga, reishi, lion’s mane, maitake (*Grifola frondosa*), and king trumpet (*Pleurotus eryngii*) mushrooms to “deliver benefits through dermal application that consumers haven’t been getting from other medicinal mushroom products in the past,” Schulick says.

**Tackling the Big C**

Aiming even higher, Quirk points to scientific findings that hint at a role for functional mushrooms in tackling cancer.

As Quirk notes, studies show that “mushrooms have very powerful effects by triggering the immune system to attack cancer cells.” Credit goes largely to mushroom polysaccharides—especially beta-glucans, large and complex molecules that mimic the polysaccharides found on bacterial cell walls and thus trigger an immune response similar to what the body would mount were it subject to outside attack. Reishi, turkey tail (*Trametes versicolor*), Agaricus *blazei murrill*, and shiitake are all generating particular interest here, Quirk says.

**Coming Attractions**

Quirk adds that functional mushrooms are appearing in applications across platforms—and especially in drinkable options like smoothies, beverages, and beverage mixes.

Gillespie is bullish on beverages, too. While SPINS still tracks herbal supplement formulas as the top mushroom-containing segment, “beverages are catching up quickly,” she says. “Medicinal mushrooms are a natural fit in both ready-to-drink and powdered teas, coffee substitutes, and hot cocoa mixes, adding functional benefits and an earthy flavor.”

Other applications won’t be far behind. As Quirk says, “I think the growth of mushrooms use in products will continue at its current fast pace. There are literally thousands of studies that have been done—and hundreds more every year—that will help improve our understanding of their benefits.”

Ahead, a look at what that science says about marquee mushroom varieties.

**Poria (Poria cocos)**

Poria mushroom—which goes by a litany of aliases including bai fu ling, fu ling, China-root, Indian bread, hongos poria, matsuhodo, and more—is a high-profile mushroom in TCM. Quirk notes its moderating effects on anxiety and sleeplessness, as well as its “very strong effects as a diuretic and for digestive problems.”
Curiously, poria is not a fruiting body—as are most familiar mushrooms—but rather a “large, solid underground white mass almost like a tuber” called a sclerotium, Quirk says.

**Reishi (Ganoderma lucidum)**

Practitioners of TCM know reishi as lingzhi and use it as “a Shen, or spirit, tonic for tranquilizing the mind,” Quirk says.

The variety has a vast body of science supporting it, including noteworthy research on its beta-glucans, which Carter notes may strengthen weak immune function on one hand, while moderating an overactive immune response on the other.

“Reishi is also known for its cardio-protective properties,” Carter says, “including regulation of blood pressure and cholesterol. And its adaptogenic properties have made this mushroom popular with people who find it helps them manage stress.”

**Chaga (Inonotus obliquus)**

Folk healers not just in China but in Russia and Eastern Europe, as well, turn to chaga mushroom to address cardiovascular disease, diabetes, and even gastrointestinal cancer. Its actives exhibit antioxidant, antiviral, and anti-tumoral capacities, Quirk says, with those in the last group able to arrest cancer cells in the G0/G1 phase and then induce cell apoptosis or differentiation.

On a lighter note, “The cellular-protective, antiaging research on chaga makes it particularly appealing for beauty-related products,” Carter says.

**Wood Ear (Auricularia auricula-judae)**

You may be familiar with wood ear—also known as black fungus—as a favorite ingredient in Asian cuisines, but as Quirk says, this edible mushroom is “tasty, nutritious, and medicinal.”

Evidence hints at its ability to reduce blood pressure and cholesterol levels, which...
explains why it’s often prescribed to patients diagnosed with atherosclerosis, coronary heart disease, and thrombosis.

“It improves blood fluidity and treats bruises and hemorrhoids,” Quirk adds. And as a rich source of hydrophilic polysaccharides, it eases dryness of the throat and mouth—perfect for that nagging cough—and may also "moisten the blood and promote circulation, counteracting the effects of dryness on various health symptoms."

**Lion’s mane (Hericium erinaceus)**

“Lion’s mane is a mushroom that’s gained wide appeal across a large age demographic—from Millennials to boomers,” Carter says. “Known for its ability to help with cognitive and nerve function, it has research related to supporting memory, focus, and mood.”

Quirk agrees, adding that studies back up its memory-enhancing and antidepressant effects, identifying bioactives known as hericenones that stimulate nerve growth factor in the brain to regenerate neurons.

Known as hou tou gu in TCM and yamabushitake in Japanese, lion’s mane is also edible.

**Turkey tail (Trametes versicolor)**

Carter says there’s “tremendous research” on turkey tail—and again, signs point to its polysaccharides as the responsible parties.

“Their polysaccharides are related to immune support and function in both humans and animals with significant illness such as cancer,” Carter says. With attention increasingly turning to the cancer-fighting potential of our own immune systems, “mushrooms such as turkey tail can play a role as adjunct therapies to strengthen this and be a tool for prevention and recovery,” she believes.

**Oyster mushroom (Pleurotus genus)**

Sure, they’re great in stir-fries and soups, but oyster mushrooms also demonstrate “potent cholesterol- and triglyceride-lowering effects, anti-diabetic and blood sugar-regulating effects, liver health benefits, and anti-inflammatory effects,” Quirk says.

Bioactives called monacolins—also found in red yeast rice—lipids, sterols, vitamins, oligo- and polysaccharides, amino acids, peptides, and even some enzymes all apparently contribute to oyster mushrooms’ efficacy.

Studies have shown that 100 mg of oyster mushroom beta-glucan helps preserve natural killer cells in a population of athletes following strenuous exercise over two months, and reduced upper respiratory tract infections in 50 athletes undergoing heavy physical training. Quirk says, “And for liver support, oyster mushroom extract protects against liver toxicity from carbon tetrachloride and maintains liver enzymes to near normal.”

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

**References**


81% GROWTH OVER THE PAST 10 YEARS.

Any Questions?

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THE FLAVOR Masking Puzzle

Flavor modification today requires expertise, strategy—and cutting-edge tools.

BY SEBASTIAN KRAWIEC, ASSOCIATE EDITOR

Flavor is always a challenging piece of the formulation puzzle due to the unpleasant notes that active ingredients can impart in functional food and beverages. "Health and wellness foods and beverages contain a range of natural functional ingredients that may impart off-flavors and texture such as acidity, aftertaste, astringency, bitterness, chalkiness, and metallic notes," explains Philip Caputo, marketing and consumer insights manager for Virginia Dare (Brooklyn, NY).

Finding a solution for off-flavors is additionally challenging because taste is subjective. "Bitter taste, for example, is a positive attribute to some consumers regardless of the product, while others find it appealing only in specific items like coffee or dark chocolate," says Caputo. "Some find any bitterness completely unappealing."

Because of this, there is no one-size-fits-all solution. But one of the best places to start is at the very bottom. "One of the main challenges we face is understanding what exactly we've been tasked to mask," explains Will McCormack PhD, business development manager, Nutrition, at Synergy Flavors (Wauconda, IL). "Analyzing the base and the actives that are contributing to the off-notes is fundamental to developing an effective solution, as masking and bitterness-blocking are specific to the active(s)."

Only then can flavor chemists and applications scientists build a flavor solution that both accentuates the positive attributes of the base and conceals the negative attributes through a combination of masking and blocking techniques, keeping in mind that "the toolbox for natural masking and bitter-blocking compounds is more limited and, in general, less potent than synthetic compounds," adds McCormack.

That is why early collaboration between flavor houses and manufacturers is important. "Our taste-improvement systems are application-specific," says Caputo. "A single formulation does not fit all and likely includes a combination of off-flavor masking, flavor profile enhancement, and sweetness enhancement. We identify each of our customers' unique taste objectives or challenges, collaborate to develop a comprehensive solution, and tailor our natural taste-improvement ingredients to deliver preferred taste."

While flavor modification is most effective on a case-by-case basis, there are processes in place to determine how best to pursue flavor modification.

Synergy, for example, has a five-step process. First, a trained panel will perform a sensory analysis to identify the sensory characteristics of the ingredient, such as a pea protein. The pea protein then goes through gas chromatography–mass spectrometry (GC-MS), which analyzes the sample, separating and identifying different flavor compounds and volatiles. Synergy describes this as a blueprint for a flavor. At the same time, gas chromatography–olfactometry (GC-O) identifies which of the volatiles contribute aroma, via expert assessment. So, when GC-MS detects a high concentration of aroma volatiles, human assessors identify what the aroma is (i.e., fatty) and then use the data to identify what compound is contributing to the aroma.

After this is flavor pairing in which the base (i.e., pea protein) is paired with a flavor that will most effectively complement it, enhancing desirable notes and masking unpleasant ones. Chocolate, for example, shares five common characteristics of flavor and aroma with pea protein—namely: floral, nutty, carmellic, fatty, and dairy. Using this data, flavor chemists can then create a custom flavor. Once the flavors are tailored, they are applied to the desired application such as powder, ready-to-eat, or ready-to-drink formats. Then they are evaluated by a team of sensory scientists in a blind taste test to determine how they measure up against existing products on the market.

There are a number of different ingredients that require attention regarding flavor modification, and more often than not, these ingredients are present in combination with one another. This makes the whole process trickier. "Typically, it's a blend of functional ingredients, such as those contained in a product like a pre-workout formula," says McCormick. "For example, individual amino acids such as L-citrulline, L-theanine, and L-arginine are combined with actives such as caffeine, theacrine, and/or a combination of botanical extracts, the number of which seems to be ever expanding!"

"We're also seeing trending health and wellness ingredients that often require masking grow in popularity, such as turmeric, apple cider vinegar, ginger, ginseng, mushrooms, matcha, algae, and oats," adds Caputo.

As more functional food and beverage products hit the market, flavor modification will only get better. This is clear from the huge strides that have already been made in the space, making functional ingredients, like protein, more accessible to everyday consumers.
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