The year's top industry leaders, suppliers/providers, and retail brands

Also: People-to-Watch Directory, p. 37

December 2018
Vol. 21, No. 10
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Nature for Health
In this year’s Best of the Industry awards, we are recognizing individuals, groups, and companies whose initiatives today may help shape, for the better, the state of the dietary supplement and food and beverage industries for years to come.

First, there is CV Sciences, a company doing its best to establish a responsible presence in the midst of the mushrooming CBD market. As more CBD players, delivery forms, and product claims fly about the market—with little guidance, it seems—CV Sciences is staying grounded and, in a historical move, has become the first CBD nutraceutical firm to achieve a Generally Recognized as Safe (GRAS) self-determination for its proprietary, natural, CBD-rich hemp extract. This GRAS self-determination now sets the bar in the CBD market and an example for other CBD firms to follow, and there is no telling how this GRAS self-determination could pave tomorrow’s road to a better regulatory environment for CBD supplements and food.

Ardent Mills is another company laying a path forward for the markets it serves. Its new business unit, The Annex by Ardent Mills, is committed to increasing the supply of ancient and heirloom grains in North America through its grower relationships and taking an end-to-end look at the supply chain, helping formulators by providing innovative new grain formats and guidance. Altogether, the ability to source grains domestically and from more regions of North America will help companies as they face growing demand for these grains in healthy foods and beverages.

We are also recognizing two new initiatives, the Supplement Safety Compliance Initiative (SSCI) and the Global Retailer and Manufacturer Alliance (GRMA), for the work they are doing to, if all goes well, increase the level of industry self-regulation and quality control. While these initiatives are still in their infancy, their achievements so far in bringing together stakeholders throughout industries will help companies and retailers ensure that the quality standards and the benchmarking of those standards at the end of the day secure a safer, higher-quality product market for consumers.

And then there is Senator Orrin Hatch, whose support of dietary supplements has been the industry’s foundation—past, present, and future. The industry owes much of its existence today to Senator Hatch’s contributions. As Senator Hatch retires his congressional seat at the end of year, industry leaders remember his support and his friendship.

Congratulations again to Nutritional Outlook’s 2018 Best of the Industry winners.

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Amarin Pharma Inc. (Dublin, Ireland), maker of high-concentration EPA-only omega-3 drug Vascepa, filed false-advertising lawsuits in October against two omega-3 dietary supplement manufacturers: Coromega Health Inc. and Omax Health Inc. Amarin contends that these companies used the recently released results of Amarin’s REDUCE-IT clinical trial to bolster the marketing of their own products. Amarin is stressing that Vascepa is materially different from dietary supplements in composition, dosage, and regulatory status.

Amarin shared topline results from its large-scale REDUCE-IT trial (Reduction of Cardiovascular Events with EPA Intervention Trial) in September. The results show that subjects taking Vascepa (4 g/day) saw a 25% risk reduction in the first occurrence of major adverse cardiovascular events.

“With REDUCE-IT results in hand, Amarin is fully committed to defending the Vascepa franchise against outlier dietary supplement and any drug companies that seek to mislead the public and cardiovascular patients in need by fraudulently leveraging the landmark REDUCE-IT study results or the REDUCE-IT or Vascepa names for profit,” Amarin general counsel Joseph Kennedy said in a statement to Law360. “Amarin is prepared to file multiple new lawsuits should it become aware of any similar claims.”

In the complaint against Coromega, Amarin quotes statements made in a Coromega press release that Amarin says suggest the results of the REDUCE-IT trial reflect positively on Coromega’s own dietary supplements. “Thanks to results from Amarin’s REDUCE-IT clinical study, we have great news on how omega-3s can positively affect those at risk for heart attack and stroke,” states the press release. This press release is no longer on Coromega’s website.

In its complaint against Omax, Amarin accuses the company of making similar statements in one of its press releases. “Today, Amarin released the long-awaited results of the Vascepa (icosapent ethyl) REDUCE-IT trial, further validating Omax3’s 10-year position, that high-concentrate omega-3 fatty acids have a profound and lasting effect on cardiovascular health,” stated Omax in a press release celebrating the company’s 10-year anniversary.

Amarin is asking for a permanent injunction against the supplement companies, a judgment that the companies violated the Lanham Act and California state law, as well as damages, attorney’s fees, and other relief.

This is not the first action Amarin has taken against omega-3 dietary supplement companies, recently filing a complaint with the International Trade Commission alleging that synthetically produced omega-3s predominantly composed of EPA should not be considered dietary supplements.
Jiaherb recognizes that there is much uncertainty among manufacturers and consumers about the integral quality of the botanical products they purchase. As a testament to our never-ending commitment to customer satisfaction, and to ease customer concerns about the integrity of our products, Jiaherb proudly introduces HerbaLink™.

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The Registry Question

Would an FDA mandatory product registry for dietary supplements really result in better enforcement?

BY JENNIFER GREBOW, EDITOR-IN-CHIEF

Should FDA create a mandatory product-listing database in which dietary supplement companies can list the products they sell at retail, giving FDA a better idea of which dietary supplement products are on the market? It’s a question being discussed now among some members and leaders of the dietary supplements industry. *Nutritional Outlook* has reported on these discussions in recent months. At the Council for Responsible Nutrition’s (CRN; Washington, DC) annual The Conference in California in October, a panel debated the topic.

Two panelists—attorneys Scott Bass, partner at Sidley Austin LLP, and Anthony Young, partner at Kleinfeld, Kaplan & Becker—argued the pros and cons of such a hypothetical mandatory listing database. They also debated the pros and cons of an alternative: the industry-led, self-regulatory product-listing database in the form of the Supplement OWL registry that has been operational since CRN created it last April. As discussed below, both of these options have potential strengths and weaknesses.

**In Favor of a Federal Listing**

First and foremost, a mandatory federal listing would, as mentioned above, give FDA eyes on what’s on the market—theoretically. All dietary supplement products that are on the market would be required to be listed in this FDA database. If the agency found a product that isn’t listed in the database, it would know that a company is out of compliance with the listing requirement.

Such a system makes outliers more visible to the agency, Bass argued, and helps the agency better funnel its enforcement efforts so that it can pursue bad actors accordingly. “The beauty of this mandatory listing...is that it just makes it easy within FDA, taking very few resources, to cite a company for not listing,” Bass said at The Conference. “It gives the opportunity to FDA to investigate much more selectively...and then they can focus their resources. It’s a no-brainer.”

**In Favor of a Voluntary Listing**

Rather than favoring a mandatory listing, Young said that a voluntary listing like the Supplement OWL is preferable—and that it can work as other voluntary programs in other industries have worked.

“There’s a rich history of self-regulation” in many industries, Young said. He pointed to various industry-led self-regulatory initiatives that have been in operation for decades. One is the Cosmetic Ingredient Review, which was created by the industry trade association the Personal Care Products Council (PCPC) in 1976, but that operates separately from the association and that has the support of FDA. The Cosmetic Ingredient
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Review enables companies to share information on their product ingredients, and allows expert panels to review information on the safety of ingredients used in the cosmetic and personal care market. Another example Young cited is the industry-led National Animal Supplement Council, which helps oversee the safety of dietary supplements for animals, a product category not officially recognized by FDA’s Center for Veterinary Medicine, where animal products are only classified as food or drugs. Both of these self-regulatory initiatives came from industry and are voluntary, Young pointed out, and they have effectively worked to capture majority participation by their respective industries.

Young then pointed to existing listing resources the dietary supplements industry already has at its fingertips. One is the aforementioned industry-led Supplement OWL. The other is the National Institutes of Health’s Dietary Supplement Label Database, which lists a number of dietary ingredients and specific products on the market. The database captures “the labels of about 17,000 dietary supplements,” NIH says. Like the Supplement OWL, the NIH’s Dietary Supplement Label Database is a repository for label information only and does not reflect the legal standing of any products or ingredients therein. Indeed, NIH states, “All information contained in the Dietary Supplement Label Database (DSLD) comes from product labels. Label information has not been verified or checked for conformity with existing U.S. Food and Drug Administration (FDA) regulations.”

Young also mentioned the fear many have that FDA would use the information in a federal listing to police the dietary supplement industry in other ways detrimental to industry. “I just don’t think FDA can put blinders on to the information received,” he said. “They will look at this information. They will use it down the road. There will be a creep. That’s what happens with all of these systems. There’s a creep.”

Where Are the Bad Actors?

Whether voluntary or mandatory, no product listing system will solve all regulatory problems due to a likely reason: non-law-abiding entities will not surface to participate in a listing system of any kind. Even with a federal registry in hand, FDA will still need to search, somehow, to find these bad actors.

During the panel debate, Young was adamant on this. These “bad boys and girls—these are criminals,” he said, who “will not register their products. And so, this system [of a mandatory registry] is not going to create, even by omission, a help to FDA in finding those companies.” (He also said he believes a listing system would “inhibit” small businesses. He added: “I think it will cause companies to think more about the ingredients they put into their supplements because they’re going to have the added concern that they’re sending [the information] to the government.”)

Bass maintains that a mandatory listing would help FDA. “If you have a system like this...[FDA] can merely say, ‘It’s not on the list,’ and therefore we go after the source and expend our enforcement resources accordingly, he said.

The existence of a federal listing system could help quiet some critics who claim that the dietary supplements industry is not operating transparently or regulated effectively. Bass said, “The only way we’re going to combat [the continual onslaught of negative press circulating around the dietary supplements industry for many years] is to say, ‘We’re now...’
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Does a mandatory registry give FDA the means to find—and more importantly, to catch—bad players?

giving FDA the ability to see what’s there, to know what the bad products are, and to go after them...We're giving you everything you need; go get them.' And then the story shifts to the people who aren't getting them.”

Young said he doesn’t believe a mandatory listing would dissuade detractors from criticizing the industry. "I just don't think it's going to stop anything," he added. "We have a situation where our FDA has a limited, very limited, scope in terms of how it can enforce. So if there's a registration system, and we go through all the trouble of registration, I don't have any belief that that's going to help FDA in its law-enforcement mechanism. I also don't believe it will stop The New York Times and other of our detractors..."

But Bass argued that the onslaught of negative press will continue "unless we do something and do something now and people know we're taking charge of our future. In my opinion, there isn't a choice...I think the only way we're going to take ourselves out of the negative spotlight, out of the increasing efforts to put us into a premarket approval system, is to take charge and give the government the means to find the really bad players."

The Enforcement Question

Does a mandatory registry give FDA the means to find—and, more importantly, to catch—bad players? Alone, a federal registry will not be effective in policing the market if FDA does not have the resources to search for and enforce against companies who fail to list their products. FDA itself has noted that it has limited resources. Would there be other ways to get FDA the additional funding it would need to pursue registry offenders?

One option, Bass said, would be for Congress to provide the agency with additional funding. "My view would be that Congress would be more than willing to publicly fund given the pressure that's been brought by not only the press but by a lot of constituencies, like [U.S. Senator Dick Durbin; D-IL], who are constantly pressing for this kind of thing," he said.

Another proposal circulating among industry is the notion of user fees: a fee companies would pay when listing their products in the federal database. Users would pay the fee and, perhaps, receive a number from FDA indicating that their product has been listed.

In a previous interview with Nutritional Outlook, CRN's president and CEO, Steve Mister, likened this kind of system to the system of getting a birth certificate: companies would automatically get a listing number upon adding themselves to the database, with no product scrutiny, judgment, or withholding of a listing number from FDA of any kind.

Other industries pay administrative fees of a similar nature, so it is not unthinkable that it could work in the dietary supplements industry. I spoke to Mister by phone after The Conference. He pointed out that such fees could be "earmarked" to guarantee that they would only be used by the government for enforcement of the dietary supplements industry. "So whatever money that gets raised in fees is used to give FDA additional enforcement. And that would be your revenue stream to ensure that FDA does have people that can go out and enforce the registry requirement," he said.

Mister pointed out some other industries where FDA imposes fees. For instance, he said, when drug companies submit a new drug for review by FDA, they are required to pay a fee. He said that, in return, companies "are guaranteed a timeline in which the drug will be reviewed...[So] there is something in return."

"Those fees come with a guarantee that the money will be used in that industry," he said.

I asked Mister whether he thinks a mandatory listing requirement (which, for the record, CRN has not endorsed or taken a position on to date), backed by the enforcement resources from user fees, could actually work. Could this scheme actually give FDA the power it would need to go after bad actors on a registry basis? He said that he does think it could work.

Waiting for Self-Regulation to Work

Some, like Young, still opt for the voluntary, industry-led option. At The Conference, both Young and Bass complimented the Supplement OWL. (Bass called it "a terrific first step," noting that "it could be a model for how we turn [toward] a mandatory system.")

Young argued for sticking with a voluntary system like the Supplement OWL. "I think our best argument would be the voluntary system, the OWL. It's working, and we can make that voluntary system stronger within the industry." He added: "A voluntary dietary supplement program registration has a strong foundation in the OWL and in the NIH Dietary Supplement Label Database."

But how long would it take for the majority of industry to get on board and to list their products in a voluntary industry registry? The Supplement OWL was born last April. Already, the number of labels in the OWL is approaching 12,000—but there are still many companies who have not yet joined the OWL. CRN is working hard to increase participation, the latest news being that the association has initiated a pilot program to encourage more companies to participate in the Commercial Data Exchange arm of the Supplement OWL.

In order for a voluntary listing system to convey to FDA and the public that the whole industry is being transparent, everyone, ideally, will need to participate and list their products in the voluntary registry. If not, a listing system will not be able to make the argument that it is giving FDA a substantial look at what is on the market.

"The primary difference that I see between a mandatory registry that’s run by FDA versus what we’re doing with the Supplement
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Debating…and Waiting

Voluntary or mandatory: those are the choices industry is discussing now. As the debate goes on, one question that comes to mind is how long the industry is willing to wait for a voluntary listing process like the Supplement OWL to reach critical mass and to reach a level of industry participation to make the registry truly effective. As the voices of industry critics get louder, should the industry wait for a voluntary, industry-led option to scale up—or should it opt for a mandatory listing instead?

It’s also worth noting that even as the Supplement OWL builds industry participation in real time, a mandatory federal listing is still hypothetical. There’s no telling how long it would take for a mandatory listing to pass through channels—not to mention to be authorized and created. The Supplement OWL is operational now and is setting an example of how a dietary supplement listing process can work. (There are also discussions of how the Supplement OWL could, having figured out how to make an industry listing successful, serve as a model framework for any federal listing system down the road. Mister said: “I’m not saying we will, but we could hand off the Supplement OWL to FDA and say, ‘It’s now yours. We’ve done the hard work. We’ve created it. We’ve figured out what works and what doesn’t, and we will give it to you if you will enforce it and keep it up.’”)

Again, Mister pointed out, CRN does not have an official position on a mandatory registry. He said, however, that the decision on whether or not to embrace a mandatory federal listing should not be based on how long, by comparison, an industry-led initiative like the Supplement OWL to scale up—or should it opt for a mandatory listing instead?

OWL is the ability to compel companies to put their products in,” Mister told me. “As an industry initiative, we don’t have a stick at the end of the day that we can use to force somebody to do this. So we try to create lots of carrots that encourage people and incentivize them to get into the Supplement OWL. But there is nothing hanging over their head if they choose not to. A mandatory registry, run by FDA, would presumably have the ability to compel companies to get in and have some kind of regulatory consequence if [companies] did not [participate].”

He added, “There would have to be some provisions in this that would have some consequences for companies who don’t bother to register. I think there are a lot of options out there that we have to talk about. But there would have to be a consequence for companies that didn’t register; otherwise, it’s no different than the Supplement OWL.”
The votes are in!

Nutritional Outlook’s readers and editors highlight these five winners for their standout achievements.
Senator Orrin Hatch

As Senator Hatch retires his congressional seat this year, industry leaders reflect on how his support paved the road to today’s dietary supplement industry.

BY SEBASTIAN KRAWIEC, ASSOCIATE EDITOR

There are few figures more revered in the dietary supplement industry than Senator Orrin Grant Hatch, the Republican senator who has represented the state of Utah since 1977 and championed dietary supplements throughout his career, most notably with his most seminal contribution: the passage of the Dietary Supplement Health and Education Act of 1994 (DSHEA). Introduced by Senator Hatch in 1993 and co-sponsored by Democratic Senator Tom Harkin of Iowa, DSHEA laid the foundation for what the dietary supplement industry has become today.

“The Dietary Supplement Health and Education Act was the watershed event that created the modern dietary supplement industry by finally creating a regulatory home that included, for the first time, a legal definition for this category of products within foods,” explains Frank Lampe, vice president, communications and industry relations, United Natural Products Alliance. “It established a regulatory structure and good manufacturing practices and also provided the U.S. Food and Drug Administration with abundant power to enforce the new law through a defined safety standard and authorities. The law explicitly allowed certain third-party literature to be provided in conjunction with a sale and for statements of nutritional support, or structure function claims. Additionally, the law also established the Office of Dietary
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DSHEA enabled the growth and prosperity of dietary supplements as an industry as well as a resource consumers rely on to live a healthy lifestyle. “Today, more than 170 million Americans take dietary supplements each year,” says Mike Greene, senior vice president and government relations, the Council for Responsible Nutrition. “The dietary supplement industry provides 750,000 good paying jobs in the United States, and with national sales just under $50 billion, the industry continues to thrive and grow.”

Providing some historical context, Daniel Fabricant, PhD, CEO and president of the Natural Products Association, explains that prior to DSHEA, the U.S. Food and Drug Administration treated dietary supplements as food additives, making ingredients subject to extensive toxicological testing despite most of the ingredients in question having precedent as a food. This was under a new FDA policy bolstered by the passage of the Nutrition Education Labeling Act in 1990, which considered any non-vitamin or mineral dietary supplements to be food additives, not food, as they had been regulated as since the passage of the Federal Food, Drug, and Cosmetic Act in 1938.1

At the same time, there was a self-care movement in which more and more people were taking supplements. Senator Hatch was one of them. Beyond his responsibility to Utah, which has a high concentration of dietary supplement manufacturers, he cared about the products and the people taking them. “He took the products, believed in the products. It was the way he stayed healthy,” says Fabricant. “Senator Hatch was a boxer at a young age. He was athletic, very much interested in health.”

“He clearly understands how [supplements] support the well-being of millions of Americans and how important broad access to the products is for those consumers,” says Lampe. This, too, is one of DSHEA’s most important achievements, beyond helping manufacturers. “Its importance cannot possibly be overstated as it ensured that consumers had broad access to safe and reliable products” by enabling the industry to innovate responsibly, Lampe explains. “Instead of assuming all companies are making unsafe products, the law operates on the assumption that most products are safe, and the burden of proof is on the agency to prove otherwise.”

It’s also important to note, in these currently polarizing political times, that DSHEA was created under bipartisan leadership, showcasing the senator’s gift of reaching across the aisle.

**Beyond DSHEA**

DSHEA is far from the only contribution Senator Hatch has made to the industry. He has consistently demonstrated his commitment to defending the rights of both dietary supplement manufacturers and consumers. His commitment led to the achievement of other supplement-related policies, including the release of Good Manufacturing Practices for dietary supplements (cGMPs), serious adverse event reporting, and the Designer Anabolic Steroid Control Act (DASCA).

“Ten years after DSHEA became law, many in the industry were concerned that FDA was not implementing or enforcing the law,” explains Greene. “GMPs for dietary supplements had yet to be finalized or promulgated, and in the wake of FDA banning ephedra, there were growing concerns about the safety of dietary supplements. Senator Hatch called on FDA to release GMP [regulations], and passed legislation, supported by many stakeholders, including the industry, that would require serious adverse event reporting for dietary supplement (and non-prescription drug) manufacturers.”

Ironically, the adverse event reporting law saw some resistance from industry companies, says Fabricant. “There were a number of companies at that time in 2006 that thought it was a terrible idea, and a lot of those companies were in Utah,” he explains. “They thought this was going to be hung around their necks like an albatross, and that wasn’t the case at all.”

Once again, Senator Hatch brought people together to compromise. “Senator Hatch really worked with people on both sides of the aisle—people like Dick Durbin, who has been a critic of the industry, and Joe Biden, who at the time was a critic of the industry,” says Fabricant. “He brought them over to the table, brought the OTC folks to the table, and brought the dietary supplement industry people who were opposed, and got it done.”

As bad actors began selling falsely marketed dietary supplements spiked with anabolic steroids, Senator Hatch took additional action to protect consumers and the reputation of the dietary supplement industry by introducing the Designer Anabolic Steroid Control Act alongside Democratic Senator Sheldon Whitehouse of Rhode Island. This legislation provided the Drug Enforcement Agency the authority to remove designer anabolic steroids from the market and stop them from being added to sports nutrition products.

**Legacy**

A similar sentiment shared by many involved in the dietary supplement industry is that no one can replace a champion such as Senator Hatch. His support was singular. “It will be impossible to replace the experience, knowledge, and love that Senator Hatch has for the dietary supplement industry,” says Greene. “But we can continue to make new friends and build alliances.”

Indeed, there do remain friends to the industry within Congress, as is demonstrated by the nearly 50-member bipartisan Dietary Supplement Caucus. So, while no one can replace him, one can hope that there will be those who follow his example.

**References**

CV Sciences

The company is leading the CBD industry with a monumental GRAS self-determination.

BY JENNIFER GREBOW, EDITOR-IN-CHIEF

These days in the dietary supplement industry, no one, it seems, can get away from the topic of CBD. Hemp-derived cannabidiol (CBD) has taken the industry by storm, with more products and players popping up in the market every day and multitudes of questions raised at industry events: Is it legal? Are firms selling CBD taking a risk? And what about that Investigational New Drug (IND) application belonging to CBD drug firm GW Pharmaceuticals, which many cite as the primary reason FDA still says products containing CBD are not an authorized dietary supplement ingredient?

All are worthy questions, but one of the most salient questions is whether or not CBD is actually safe for human consumption. One hemp-derived-CBD company, CV Sciences (San Diego, CA), has taken a leadership role in demonstrating the safety of its ingredient and trying to chart a responsible path to market. In September, CV Sciences announced a monumental achievement: it now has a Generally Recognized as Safe (GRAS) self-determination for its proprietary hemp extract used to make the products in the company’s bestselling PlusCBD Oil Gold Formula consumer product line. This GRAS self-determination stems from a battery of toxicology studies commissioned by the company on its ingredient. These studies, conducted by scientific and regulatory consultant AIBMR Life Sciences (Seattle, WA), are said to be the first published toxicology studies since 1981 on a hemp extract that contains naturally occurring CBD. CV Sciences’ ingredient is a hemp extract containing a full spectrum of naturally occurring phytocannabinoids, including CBD, as well as fatty acids, terpenes, plant sterols, and vitamin E in all of its isomers. It is produced via supercritical CO2 extraction of the aerial parts of the hemp plant (Cannabis sativa) and contains approximately 25% CBD overall.

At this point, it should be mentioned that in March of this year, leading hemp foods brand Manitoba Harvest announced an industry-first GRAS self-determination for the company’s hemp seeds, hemp oil, and hemp protein powder products for foods, with the company submitting its GRAS notification to FDA. There is a marked difference, however, between Manitoba Harvest’s products—seeds, oil, and protein powder—and what CV Sciences has obtained a GRAS determination for: a CBD-rich, full-spectrum hemp extract. In short, CV Sciences’ GRAS self-determination represents the first GRAS assessment of its kind to be performed on a hemp extract containing naturally occurring CBD. In fact, the toxicology studies done on CV Sciences’ Gold Formula CBD are “not only the first peer-reviewed toxicology work published on a hemp extract since 1981 but the first toxicology work published on a natural CBD-containing extract ever,” says Stuart Tomc, vice president of human nutrition for PlusCBD Oil.

John Endres, chief scientific officer for AIBMR Life Sciences, the company that placed, monitored, and published the OECD- (Organisation for Economic Co-operation and Development) and FDA-compliant toxicology studies as well as the GRAS self-determination for CV Sciences, explains the five tests included in the toxicology study, which is now published in the Journal of Toxicology (June 2018):

1) an AMES bacterial reverse mutation test (testing for mutagenicity),
2) an in vitro mammalian chromosomal aberration test (testing for clastogenicity, or chromosomal damage),
3) an in vivo mouse micronucleus test (testing for genotoxicity),
4) a 14-day repeated-dose oral toxicity study in rats (a range-finding study to narrow the dosage range, with researchers testing extreme dosages of 1000, 2000, and 4000 mg/kg body weight per day), and finally, and most critically, 5) a pivotal 90-day repeated-dose oral toxicity study in rats. These are standard tests for determining the safety of consumption of a food ingredient, says Endres, who was the studies’ monitoring scientist.

CV Sciences’ hemp extract was determined to be non-mutagenic, non-clastogenic, and non-genotoxic. In the 90-day repeated-dose test, the researchers determined a No-Observed Adverse-Effect Level (NOAEL) to be 100 mg/kg body weight per day for male rats and 360 mg/kg body weight per day for female rats. Abiding by the more conservative of the two doses, the NOAEL coming out of these rat studies was therefore concluded as 100 mg/kg body weight per day. After dividing that number by a 100-fold uncertainty factor (to account for the differences between rats and humans), the NOAEL for humans is 1 mg/kg body weight per day of the PlusCBD Oil Gold Formula. And when translating that number to an Acceptable Daily Intake (ADI) — “the threshold above which safe use cannot be predicted based upon the current studies,” Endres explains—the ADI works out to 70 mg per day, based on the average 70-kg human. That 70 mg per day sets the ceiling specifically for PlusCBD Oil Gold Formula (the subject of the toxicological investigation) as to the uppermost intake level considered to be safe for humans at this time.

Tomc says CV Sciences wanted to have this GRAS self-determination in hand before the company launched its new hemp CBD...
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gummy product this September, a product the company calls “the first hemp-derived CBD gummy in the natural products space.”

“We timed our gummy launch with the publication of our formal safety studies to give consumers even more confidence in our brand,” he says. With this successful GRAS self-determination now in hand, “Consumers can now feel confident that our proprietary hemp extract is presumably safe for its intended use,” he says. “Many companies have elected to watch from the sidelines and have been waiting to have a green light to participate in the hemp market.”

That market, the U.S. hemp CBD market, could be worth $646 million by 2022, according to recent predictions by Hemp Business Journal. The journal noted that U.S. CBD product sales have grown almost 440% since January 2014, with sales of $264 million in 2018 alone. As the CBD market becomes more sophisticated, and as more players enter the space, companies that demonstrate responsible practices are the companies that other parties (retailers, large corporations, etc.) will want to work with.

CV Sciences has elevated its position. When asked why the company decided to pursue a GRAS assessment in the first place, Tomc answers: “We followed the directions set forth by FDA with regard to getting regulatory status as an ingredient to be added to foods and have introduced our proprietary hemp extract into the U.S. food supply via the existing regulatory framework. Not only that, Tomc says, the GRAS self-determination “provides a regulatory exemption” in terms of FDA’s new dietary ingredient (NDI) requirements for dietary ingredients. He adds, “We are building a monumental safety dossier, including extensive after-market surveillance, to support our branded hemp extract.”

Whether or not CV Sciences’ GRAS determination opens other doors, regulatory and otherwise, remains to be seen. For now, Tomc claims, this designation at the least allows the company to bring other types of foods and beverages containing its hemp extract to market: “This gives us a tremendous amount of flexibility, as we are selling the only GRAS-self-determined hemp extract in the world. The opportunities are endless.”

It also strengthens the company’s standing in the hemp CBD food and beverage market—a market that’s only just begun. The promise is there. Tomc notes that while functional foods and beverages containing CBD are “just starting to hit the market, the market is maturing at a fast pace, and we expect a significant wave of hemp-based food and beverage products.”

CV Sciences deserves recognition for taking steps that no other CBD dietary supplement company has taken. As Tomc says, “Our historic GRAS work demonstrates the safety of our ingredient and represents incremental progress in the regulatory evolution of hemp in America.”

AIBMR’s Endres says, “We were really impressed by what they did because they were going out on a limb, for many reasons.” One of those reasons is that CV Sciences did not know for certain whether the study results would result in a NOAEL and thus a conclusion of general recognition of safety, yet the company invested significant resources to fund this study. “They definitely put their money where their mouths are,” Endres says. “CV Sciences is the only one that went out on a limb with money, investment, and time to properly establish safety and to obtain regulatory status, and as far as I know, they’re the only company in the United States that has proper GRAS regulatory status for their hemp oil extract containing CBD.”
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In a September CV Sciences press release announcing the company’s milestone GRAS achievement, the company stated: “CV Sciences is the only hemp CBD nutraceutical company to invest in the scientific evidence necessary to achieve this sought-after designation, recognizing an ingredient as presumably safe among experts under the conditions of its use.” In that same press release, company CEO Joseph Dowling said, “This milestone significantly advances our leadership in this space and provides us with opportunities to broaden consumer access to our products, while removing any doubts [about] the safety and benefits of our products.” He called the GRAS self-affirmation “a milestone for CV Sciences as well as the entire hemp CBD industry.”

Michael McGuffin, president of the American Herbal Products Association (AHPA; Silver Spring, MD), says, “CV Sciences has made a significant investment to conduct a self-affirmed GRAS determination. The U.S. Food and Drug Administration (FDA) sets stringent safety guidelines for the self-affirmed Generally Recognized as Safe (GRAS) status, and CV Sciences has reported that it has identified and provided the scientific evidence required to establish that this ingredient is presumed to be safe among experts when used as intended.”

McGuffin adds “As an early member of AHPA’s Cannabis Committee, CV Sciences’ business practices and contributions to the industry demonstrate the company’s commitment to using scientific evidence to build consumer trust in the safety and quality of its CBD products. CV Sciences is also dedicated to providing complete traceability and transparency to ensure quality and safety, from seed to shelf. These practices have helped the company become one of the leaders in this emerging market.”

CV Sciences is leading by example, but it also hopes more CBD companies will step up to the plate and perform safety studies on their own unique ingredients. AIBMR’s Endres says more CBD companies are already “contacting [AIBMR Life Sciences] because they seem to want to follow suit.” He says, “I applaud that effort to try to do things the right way. Also, unless a company can prove its ingredient is bioequivalent to CV Sciences’ PlusCBD Oil Gold Formula—“which would be difficult,” Endres says—companies can’t piggyback off of CV Sciences’ GRAS assessment; they would most likely need to conduct toxicology studies and a GRAS self-determination on their own article of commerce.

If more CBD firms can build hard scientific evidence demonstrating their CBD ingredients are safe, everyone benefits, Tomc says. More evidence and substantiation will grow CBD’s credibility among consumers, regulators, retailers—the public at large.

“We don’t want to all participate in demonstrating the safety of CBD, because the market demand will be greater than what any of us can meet alone,” Tomc says. “If everybody did this, that would be the way in which we could help secure the safety argument in the marketplace.”

“We would like to see other hemp companies make the investment in time and money to publish formal toxicology work,” he says. “Borrowed safety data will be of no help to other manufacturers. Everyone needs to roll up their sleeves and do the hard work.”

References


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Ancient grains are a small percentage of the overall grains market, but there is no denying their growing popularity. “What’s old is new again” is the saying often used when discussing trending grains like quinoa, amaranth, millet, sorghum, teff, spelt, einkorn, and more. These specialty grains are increasingly favored by consumers who enjoy not only the eating experience but also the healthy halo often ascribed to ancient and heirloom grains.

The numbers reflect growing consumption. In January 2018, for instance, market researcher The NPD Group reported double-digit year-over-year growth in case shipments of ancient grains to U.S. foodservice outlets specifically.1 The company reported: “Case shipments of quinoa, which is the most widely used ancient grain, increased by 18.5% in the year ending October 2017 compared to the same period a year ago. Two ancient grains not as commonly known—spelt, a distinct type of whole-grain wheat, and farro, a whole grain similar to barley, quinoa, and wheat berries—also realized double-digit growth in case shipments. Shipments of amaranth, a staple food of the Aztecs and comparable to rice or maize, increased by 19.4% in the period.” In February 2018, market researcher Euromonitor named ancient grains one of the “8 Food Trends for 2018” alongside fermented foods and healthy fats.2

Consumers can’t get enough of ancient grains these days—and, therefore, neither can food manufacturers, foodservice firms, and artisan bakers. But it may surprise some to learn that while commodity grains are grown aplenty in the United States, many of the ancient grains popular in the North American market are actually not grown in North America. Grains like quinoa, amaranth, and teff are, in large part, still imported. Quinoa, for example, is heavily sourced from South America. (Other ancient and heirloom grains, such as sorghum, millet, spelt, emmer, and White Sonora, are gaining popularity and are being grown on more farms in North America.)

One company is helping to grow the ancient grains supply in North America with an initiative started earlier this year. At the March 2018 Natural Products Expo West trade show, leading North American flour and grain innovator Ardent Mills (Denver, CO) launched a new business unit called The Annex by Ardent Mills (“The Annex”). The Annex’s sole purpose is to grow the company’s specialty business, which includes ancient and heirloom grains, organic grains, sprouted grains, pulses, and more. The Annex not only works closely with farmers and crop breeders to increase acreage of ancient grains in North America, it offers formulating and innovation services downstream to help manufacturers learn how to incorporate these grains in their finished products—truly providing support from the ground up.

“We look at grains in our portfolio and at how we can grow these grains in the U.S. We want to help the family farms we work with diversify and add these grains into their rotation,” says Shrene White, general manager of The Annex.

First, the company offers farmers the expertise of the public and private crop breeders it works with. Through its network, The Annex helps farmers who would like to diversify their crops by including more ancient grains and heirloom grains and pulses answer such questions...
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as: “Is this a spring crop? Is this a winter crop? How does it fit into my rotation? Do I live in an area that is conducive to growing something like a quinoa or a teff? All of those things need to be taken into consideration when farmers are looking to add a grain like that into their rotation,” says White. “We can work with the farmers on planting the best varieties that will work best in climates that we have here across the United States.”

Diversifying their crop portfolio gives farmers added security as well as the chance to participate in new, emerging markets. “It allows the family farms we work with to participate in new, growing markets that they maybe wouldn’t have been able to participate in before,” White says.

It’s no wonder that farmers are interested in what The Annex offers. “We get calls weekly from these farmers who are looking to do something different, who are looking to diversify what they’re doing on the farm,” White says. Some farmers also see sustainability benefits, “where rotating with a sorghum or a quinoa will help save water, or rotating with some type of chickpea or a legume might be a nitrogen fixer for an organic farmer,” she explains.

Working with more farmers mitigates The Annex’s own risk, too. “It helps us diversify our growing regions so we’re not so dependent on one area,” White says. “If you get a hailstorm or you get rained on during harvest, you haven’t ruined your whole supply chain.”

The payoff is a consistent product supply. “We can offer our customers long-term contracts because we know that we’ve got farmers in all areas of the country that are growing grains for us,” White says. The Annex allows the company to be more nimble and proactive at meeting its customers’ needs by putting supply local and readily at hand. And it allows the company to engage in more markets. “Products and formats provided by The Annex are opening doors for Ardent Mills to participate in new areas within foodservice, the snack market, the pet food market, and the distilling market. It’s really opening up new channels for us that we just wouldn’t have been able to supply [to] had we just stayed with our core commodity flour business,” White says.

The Annex aims to keep increasing the number of farmers it works with. Through relationships built at Ardent Mills, the firm says it is contract growing with family farms in just about every state west of the Mississippi today.

White adds, “As we’ve gone out and talked more about The Annex and we’ve participated on different panels across the United States, we always seem to have farmers who make contact with us and want to come in and be part of the program. I think some of that is just knowing that we have a good reputation of supporting farmers.”

The Annex supports farmers by guaranteeing the company will buy the farmers’ crops at a set price and set quantity. “If we ask them to plant something, we’re going to stand behind it, and we’re going to buy that grain and find a way to use it,” White says. “Farmers know that if they’re growing something in our program, they’re going to get the support they need. They’re going to get paid for it, they’re going to be able to deliver the grain, and we’re going to find a home for it.”

That’s where The Annex shines: helping participants up and down the supply chain work with ancient and heirloom grains. The Annex offers the support of R&D and other staff to help end-product manufacturers find new and
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innovative ways of formulating with ancient grains and other specialty ingredients—for instance, “understanding the baking characteristics of a particular grain,” White says, or developing new ancient grain formats such as crisps, flakes, and individual quick frozen formats. Breeders can also help “to get traits into grains that are going to help our customers and the end consumer,” White adds.

White describes The Annex as a team of “15 really specialized people.” The team includes food/R&D scientists, sales and marketing specialists, regulatory/operations advisors, and even a culinary chef and a bakery. “These are people who can work with an R&D person, work with a marketing person, with the company, to really help develop a product from the ground up,” she says. “We’re not just going in and selling something; we want to be able to work with our customers all the way from innovation, R&D, to that final product. We can go from breeding, growing, innovation, supply chain, all the way to a finished flour or a loaf of bread.”

The Annex also has the full support of Ardent Mills behind it. “We fully understand that the core business is what’s allowing us to do all the cool, funky stuff we’re doing in The Annex,” White says. “That’s what keeps the lights on for us.”

By helping manufacturers create new ancient grain products consumers will love, and by reducing manufacturers’ concerns about stable supply—thereby making them less anxious about formulating with ancient grains—The Annex is helping make ancient and heirloom grains more accessible, which will only increase demand for ancient grains in the first place. “Making the right connections, both with the farmers and the customer, and understanding what is driving these trends is really helping us connect that whole supply chain,” says White.

It really comes full circle, White says. And it’s making a difference. “Take White Sonora as an example,” she says. “We started a few years ago with just a few acres of White Sonora, and we’ve been able to work with farmers up in the Pacific Northwest to expand acres and do seed grow-outs. This is allowing our customers to add White Sonora to their products and know they’re going to have a consistent supply.” She says, “I think North American quinoa is another really good example where we’re working all the way from breeding work with new varieties that are more adaptable to North America and helping farmers understand how to grow quinoa and get it adapted into their rotation.”


She continues: “Do I ever think ancient grains are going to be as big as the commodity market? No. But I think we’re going to continue to find new ways to innovate and new, unique formats and ways to get these grains into the diet.”

References
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In recent years, self-regulation has become a key dietary supplement industry priority. While many manufacturers have incredible reputations because of their long history of ensuring quality and safety, it has become clear that the most effective way to earn respect as an industry is to come together as one. That is why Nutritional Outlook is recognizing two self-regulatory initiatives: The Supplement Safety Compliance Initiative (SSCI) and the Global Retailer and Manufacturer Alliance (GRMA).

A sentiment shared by parties involved in both of these initiatives is that quality and safety are not competitive advantages for companies to leverage against others, but an ethical responsibility shared by all. That is the remarkable thing about SSCI and GRMA, that they each brought together stakeholders from across the industry—competitors, in most cases—to collaborate and develop high standards they can all agree on. Each offers a distinct self-regulatory pathway—SSCI, through benchmarking, and GRMA, through an entirely new standard—but they are not in conflict with one another; rather, they each have a valuable place in how the industry will regulate itself and collectively pursue a higher quality standard moving forward.
Supplement Safety Compliance Initiative

Driven by retailers, SSCI is harmonizing industry standards through benchmarking to ensure product quality, transparency, and traceability.

Retailers are at the front lines of the dietary supplement industry interacting with customers. This also makes them vulnerable to recalls and enforcement actions because they are the gatekeepers of finished products to consumers. After the actions taken by then—New York Attorney General Eric Schneiderman in 2015 against four national retailers that saw retailers pull herbal supplement products off their shelves and led to investigations by state attorneys general throughout the nation, the industry learned that it needed to demonstrate that consumer safety is priority one and to take substantive measures to demonstrate its commitment to safety. This has led to the creation of the retailer-driven Supplement Safety Compliance Initiative (SSCI), spearheaded by major retailers like GNC and Walmart, in partnership with the Natural Products Association (NPA).

SSCI was kicked off by Dadrion Gaston, R.Ph, CCEP, CHC, senior director, corporate compliance for Walmart, and Guru Ramanathan, chief innovation officer at GNC. “[They realized] we need to set up a Global Food Safety Initiative (GFSI)-type system by the industry for the industry... We need to set up a system where we know we are covering the industry,” explains Daniel Fabricant, PhD, president and CEO of NPA. FDA does not have the resources to inspect every facility, so it is up to the industry to instill trust by creating a more consistent and streamlined system. “FDA on its own side may get to 5% of food manufacturing facilities out there, but you never hear that the grocery industry is unregulated, because so much is done through GFSI and self-regulation in that regard,” Fabricant says. “So, what we really wanted to get to was a system that says we understand that FDA can’t solve all our problems, we’re not looking for FDA to solve our problems, we’re going to show that they can have confidence in the industry, and here’s how.”

Among the key concerns expressed by the New York Attorney General at the time were that sufficient quality-control measures did not exist to ensure product authenticity and purity at manufacturers and retailers; that standard chemical testing approaches did not provide adequate assurances of authenticity, and that there was no federal requirement for contaminant testing to ensure the safety of products. Upon investigating these matters themselves, industry leadership found that there were gaps in guidelines available to the industry, specifically regarding raw materials such as botanicals and synthetics, that have led to a lack of harmonized standards, impacting quality, authenticity, traceability, and transparency of the supply chain. They also found that there was not much consistency in audit criteria for finished-product facilities, creating variability in ratings and certifications between different auditors.

Ultimately, there was no comprehensive system to provide end-to-end transparency in the supply chain. Modeled after GFSI, SSCI provides a voluntary pathway to supplement safety certification of the entire supply chain through a harmonized benchmarking process. Driven by retailers, SSCI also brings manufacturers, auditing bodies, and trade associations into the fold. “It’s a coalition of the willing,” says Fabricant.

Benchmarking

A benchmark is the minimum standard of equivalence that another standard is held to. Dietary supplements are required by the U.S. Food and Drug Administration to comply with current good manufacturing practices (21 CFR Part 111), and a variety of third-party certifiers will audit facilities to verify they comply with said standards. Retailers may also request audits of manufacturing facilities to make sure they comply and reduce their liability. Unfortunately, this has led manufacturers to receive multiple, redundant audits that are costly. Not only that, but because of the lack of consistency, each audit can render different results.

Ramanathan remarked at November’s SupplySide West show that GNC’s manufacturing facility was recently subject to 28 audits in one year, and despite the audits being conducted a few months apart by the same audit body, because it was a different person conducting the audit, the facility would receive a different score each time. Therefore, through benchmarking, SSCI seeks to recognize multiple certifiers who meet its standards so that participating retailers and brand owners can be confident about the quality, transparency, and traceability of products, and because it is recognized by multiple parties, reduce the frequency of audits as well as inconsistencies between audits.

The benchmarking process essentially allows SSCI to act as a third-party certifier of third-party certifiers. “A certification body would submit a certification scheme that they want to benchmark to get evaluated by the benchmark committee,” explains Fabricant. “The benchmark committee is effectively a team of industry experts—different folks from different companies that look at the scheme and everything that underlies that scheme with respect to auditor training, qualification, all the way through to conducting the audit and then re-evaluation: is this a program that has continuous improvement?”

The need to learn and improve is key. SSCI has this built into its benchmark, using data from its recognized certifiers to determine shortcomings and address them. “The benchmarking doesn’t just happen once; you’ve got to do it every year,” explains Fabricant. “That’s the advantage, too, after a year, that the benchmarking committee has data about how that certification scheme performed.”

It’s significant to note that SSCI covers the entire supply chain with a number of scopes that cover not only the manufacturing of finished products but also raw materials, including GMPs for synthetic raw materials, Good Agricultural & Cultivation Practices (GACPs), and GMPs for botanical raw materials, as well as the identification and testing of probiotics, to name a few. In the future, SSCI will expand to cover scopes such as wild crafted herbs and the processing of finished supplement products, the processing of plant and animal perishable products, and delivery formats.

In order to develop benchmarks for these various scopes, SSCI relied on a number of resources, developing them with the collaboration...
of a number of industry stakeholders. At its core, the benchmark relied on the law, specifically 21 CFR 111 for finished products and 21 CFR 117 for raw materials, because that is the legal standard all facilities must comply with. Beyond this, SSCI utilized the expertise of auditors, quality assurance and quality control experts, as well as former FDA inspectors in its committees and working groups tasked with developing the benchmark standards and audit guidance.

Besides U.S. law and standards, the benchmarks also utilized global resources. For example, when developing the botanical GACPs and GMPs, SSCI’s global resources included guidance from the Therapeutics Goods Administration in Australia, Health Canada, the U.S. FDA, the World Health Organization, the European Commission, and the American Herbal Products Association. Botanical material processors, botanical supply chain experts, and botanical identity experts were among the experts who were involved in drafting the standard.

“It was a great collaboration between the different certifiers, between UL, between USP, between Eurofins, and other groups, people who have been doing this a long time,” says Fabricant. “[They] threw all that experience in the middle of the table and then it got shaken up a bit. How it got shaken is the best part: the pilot audits. Draft templates and draft tools were developed to find out what the audit needs to be, [regard]less of [emphasis] whether it’s an audit done by someone with a few years’ experience or 25 years’ experience.”

These pilot audits were crucial in determining how discrepancies occurred between different audits, even when all other factors remain the same. “In the same day, you had three auditors auditing the same facility using the same audit tool and we figured out that there were a lot of discrepancies, not only in the audit findings, but also in how each auditor was auditing or rating the facility, so we were able to identify these gaps and what needed to be done. So the benchmarking committee that is focused on this particular area is focusing not only on standardization of the audits, but also on what minimum training needs to be,” explained Ramanathan at SupplySide West.

Among these discrepancies, explains Fabricant, is background. “One of the things we found was that if someone had some training in microbiology versus if somebody had more of a chemistry background. The chemistry folks tended to spend more of their time on high-performance liquid chromatography, and the micro people tended to spend more time on the microbiology aspects,” he said. “So that made us be very specific with instruction in the guidance to the inspector to say there needs to be a balance.”

In tackling the audit of raw materials and farms, a similar tool was developed, and the pilot audits garnered similar results. “This is very powerful for us, and we are now looking to figure out what is the appropriate tool for an audit body to conduct and audit at a farm and at a raw material manufacturing facility,” said Ramanathan. “A lot of great work has just been started. The teams that are involved in this process are providing deep knowledge and expertise in making sure that we are able to make quick progress.”

Paving the way for SSCI, Ramanathan has also stated that GNC, because it is in the unique position of acting both as a retailer and manufacturer, will become the first SSCI certified facility. GNC will also require finished-product manufacturers who wish to retail their products at GNC to manufacture them in SSCI-benchmarked facilities.

Global Retailer and Manufacturer Alliance

GRMA is a member-based organization harmonizing standards across multiple product categories to a single audit scheme.

The Global Retailer and Manufacturer Alliance (GRMA) is a member-based organization that has brought together stakeholders from across numerous industries, including retailers, manufacturers, trade associations, certification bodies, as well as regulatory agencies and academic institutions, in order to develop a set of standards everyone can get behind. This is a process that has taken over four years, and the amount of time and effort that has been contributed by stakeholders cannot be overstated.

“Here, you have a group of retailers that are all fierce competitors, a group of manufacturers that are fierce competitors, and you have a group of certifying bodies that are fierce competitors,” Randy Slikkers, CEO of GRMA, tells Nutritional Outlook. “Industries don’t always break through that competitive nature to say, ‘Hey, it’s better for all of us if we do this.’

Joint Committees

Standard development was led by NSF International and accredited through the American National Standards Institute (ANSI). “ANSI requires a balanced group of stakeholders in an open and transparent consensus-building process to build the standards,” explains Slikkers.

“So GRMA made a decision early on that instead of the standards being made by an entity like NSF and leave it at that, we wanted it to be done through the ANSI process, to add that additional layer to appeal to consumers, stakeholders, and retailers looking to ensure the quality chain remains at a high quality.”

NSF’s role is to serve as the facilitator of the standard development process, ensuring that the ANSI-accredited process is followed. This means coordinating meetings, sharing information, and including impacted stakeholders.

GRMA covers four product scopes: dietary supplements, cosmetics, over-the-counter drugs, and medical devices. Using each market’s regulatory requirements as the base, standards were developed for each of the four scopes by four joint committees dedicated to each standard, comprising shareholders that included manufacturers, retailers, certifying bodies, and others. A super joint committee then harmonized standards from across the different scopes to accommodate a single audit scheme, which then went back to the original joint committee to be voted on. This process is a constant back and forth.

“Once it got to the point they thought it was time to vote, it was put out for a vote,” explains Slikkers. “So, for instance, if you had a standard that had 50 subtexts and 45 of them passed, but there were negative comments on the other five, then those have to go back to the drawing board, address what the feedback was, reach a consensus again, and then voting is reopened.”
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After everything is voted on and agreed to by joint committees, a 45-day public comment period is opened. These comments then go back to the joint committees to determine how to address them. “That process continues over and over and is part of why this process has taken almost five years because that’s just what needs to occur when you go through this process in a deliberative way,” says Slikkers. Nor is the process ever truly finished. This is an ongoing process in which the joint committees continue to exist and meet regularly to revise and improve the standards.

“That’s a huge part of the whole audit integrity program because as we complete our pilot audits and open up to do the real audits, we are ready to get feedback on a continual basis. That helps to address any issues that arise through the audit process, and if it’s an issue that is standards specific, it has to go back through the continual improvement process,” Slikkers explains.

The process certainly is not easy, but it is rewarding, says Christine Summers, assistant general manager over product safety and quality and environmental compliance for Costco, the membership-only wholesale club retailer. “I think at times it was frustrating,” Summers tells *Nutritional Outlook*. “It’s always frustrating when you’ve got a [large] group—I think there were 16 that were just joint committee members but there were many more participants than that. Sometimes you get bogged down on the semantics of something, but in general I found it to be a really good process. It was educational… it was very open. We could all say what we wanted to say because it’s non-competitive, so I learned a lot about some of the things manufacturers come against, [and] I think now the manufacturers have a better understanding of what retailers come against when dealing with customers.”

“These standards did take a ton of time, and that’s the benefit of using the ANSI standard, because with this consensus of the different interest groups, it’s not an industry-driven policy or procedure,” explains Mike Finamore, CEO of Gemini Pharmaceuticals (Commack, NY) and chairman of GRMA’s Governance Board, to *Nutritional Outlook*. “When you have an objective standard such as ANSI, it presupposes that it’s going to be the highest standard, and every interest group is represented in the process.”

**The Audit**
Audits are an important part of quality control because they determine whether a manufacturer meets cGMP standards as required by the U.S. Food and Drug Administration under 21 CFR Part 111. Retailers will often request to audit a manufacturer to make sure their products are qualified to be sold in their stores. When a manufacturer works with different retailers, this can lead to many audits, which becomes resource and time intensive. For example, Slikkers recalled that one manufacturer had over 80 audits in the span of a year. So, the goal of GRMA was to enhance consumer safety while streamlining the process for manufacturers.

“As a midsized manufacturer, we recognize that the cost of managing all of these different audits—all of which are best intended—will sometimes have diminishing returns due to both the interruption in manufacturing cycles and the distinctions between different auditors and their training. Sometimes this would lead to conflicting or contradictory findings during the audit, which ultimately didn’t deliver to the customer the value they were anticipating from having the audit,” explains Finamore. “So when GRMA was considered by retailers, the goal was to have a singular audit to the absolute highest standards, giving retailers and brand owners the confidence that a singular audit done to that scheme would allow the manufacturer to prepare and respond to that singular audit, and because of the depth and scope of that audit, the retailer will be able to rely on that singular audit score and not have the need to request additional audits of the manufacturing partner.”

Certifying bodies who want to participate in the audit process must be members of GRMA, then certified by the governance board that they meet GRMAs qualifications and the capacity to conduct the audits. Once they are approved by GRMA to conduct audits, auditors are trained in the audit scheme and the standards of the different scopes.

Pilot audits are currently underway with three different audit groups. Each audit team consists of a retailer, a manufacturer, and a certifying body, as well as observers from GRMA and ANSI. Pilot auditor training was completed in October, with the first audits taking place in late October. “Once the final pilot audit is done, it will take about a month to use all that rich information we got to enhance the training, the auditor tool, and all the different components of what we do as scheme owners to ensure high-quality audits,” says Slikkers. “Full auditor training is now scheduled for the last week of January. At the completion of that training, the auditors are then tested and certified. Manufacturers will be able to request audits starting February 5.”

**An Independent Nonprofit**
Remaining independent is a crucial part of the GRMA to demonstrate impartiality and dedication to the highest standards possible. “We wanted people to understand that GRMA was not just an arm of NSF, and we’re not controlled by a small group of retailers or manufacturers,” explains Slikkers. “It really needed to be this independent body. So, in January of 2018, we became a nonprofit organization. In order to fulfill the legal obligations of a nonprofit organization, you have to have a governance board. That board has to operate in the manner of a nonprofit in that they’re making decisions that are best for the nonprofit, not the companies they work for. There is a legal standard for the duty of care, the duty of loyalty, and the duty of obedience.”

“The governance board manages the [audit] scheme and helps promulgate improvements and adjustments to the standards as things occur,” says Finamore. “If we see issues that continue to pop up, we can offer guidance documents or approach the standard’s joint committee with the opportunity to improve the standard or offer different definitions. We will also conduct annual meetings and roundtables where we’re able not only focus on the [existing scopes], but have additional related standards brought to the fore. So, it’s foundational to manage the scheme, and also providing us the foundation to grow as we move forward.”
People-to-Watch Directory

A Who’s Who of the natural products industry
Anurag Pande, PhD, Vice President – Scientific Affairs
Sabinsa Corp. • East Windsor, NJ

Anurag completed his M.Sc in organic chemistry from Lucknow University. He joined the National Botanical Research Institute, a CSIR institute, as a research fellow and completed his PhD from RML Awadh University. His research interest is related to traditional Indian medicinal plants and their antioxidant and nutraceutical potential. After completing his PhD, Anurag joined the Sami Labs/Sabinsa group as a research scientist in 2004 and worked at a research facility at Sami Labs, Bangalore, on various nutritional and cosmeceutical projects. He later joined the technical support group at Sami Labs responsible for providing interface between R&D and various Sabinsa marketing offices located globally. After a brief stint at Sabinsa Europe GmbH, where he was exposed to the European market, in 2007 he joined Sabinsa Japan Corp., Tokyo, as senior manager, technical affairs, and was responsible for handling the technical and regulatory requirements of the Japanese as well as Korean markets. In 2011, he joined Sabinsa Corp., New Jersey, as vice president, scientific affairs, and explores new product concepts as well as technical and regulatory matters related to the U.S. and Canadian markets. He has been a speaker at various internationally held conferences, such as the Sustainable Cosmetics Summit, the SuppliSide Science Tour, FI Korea, HBA, and the CME group of the American Chemical Society. He is passionate about Sabinsa products and loves to talk to R&D and product development groups about the innovation and science behind the products.

www.sabinsa.com

Steve Holtby, President and CEO
Soft Gel Technologies Inc. • Los Angeles, CA

Steve Holtby has been involved in the natural products industry for over two decades. In August 2008, Steve took over the role of president and CEO of Soft Gel Technologies Inc. (SGTI). He formerly held the position of national sales director for SGTI and vice president of sales for OptiPure. Steve has been with the company since 1998. Prior to joining Soft Gel Technologies, Steve worked in marketing as a brand manager for Nature’s Way. While there, he oversaw the introduction of their vitamin line. The Nature’s Way vitamin line was the first entire line of products in the natural products marketplace to carry the newly introduced structure/function claims and was a bold entry into that segment for the company that had previously focused on the herbal segment of the market.

www.soft-gel.com

Steve Geiger, Vice President – Sales
Vidya Herbs • Red Bank, NJ

With over 25 years of experience in the nutritional industry under his belt, Steve Geiger brings in a vast array of experience to his role as vice president of sales at Vidya Herbs Inc. He leads the fast-growing U.S. sales office based in Red Bank, NJ. Closing out his debut year at Vidya Herbs, Steve is already making a splash at the global company with fast-growing sales numbers and launching new, patented products in the U.S. such as “fat-burning” CGA-7™ and the “beauty from within” ingredient, SkinCera™. Steve is passionate about bringing high-quality, natural extracts to clients in the U.S. market and is committed to providing innovative solutions for product development across the food, beverage, nutraceutical, and supplement industries.

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People to Watch Directory

Carol Cheow, CEO
Cactus Botanics • Irvine, CA

Carol Cheow, CEO of Cactus Botanics, is a biochemistry expert with more than 15 years’ experience in phytochemistry. She has been concentrated on the extraction of ingredients from marine plants and developed ingredients such as fucoidan and fucoxanthin from Laminaria japonica/Fucus vesiculosus/Undaria pinnatifida; astaxanthin from Haematococcus pluvialis; omega-3 from Schizochytrium sp; etc. In 2016, she invented a new branded ingredient: Fucosea™, which is a glorious gift from sea.

www.cactusbotanics.com

Curtis Whetten, Senior Vice President of Sales
Mount Franklin Nutritionals • Sumter, SC

Curtis Whetten is a highly driven, performance-focused executive with proven expertise in cultivating mutually beneficial relationships with food companies around the globe. Currently, he serves as the senior vice president of sales at Mount Franklin Nutritionals, where he applies his 15 years of experience in mogul production to the company’s gummy nutraceutical and nutritional products. Leveraging his deep experience in the co-manufacturing and private-label worlds, Curtis provides innovative solutions for customers in the rapidly growing nutritionals industry. Curtis holds a Bachelor of Arts degree in international trade with a business management and Spanish double minor, a master’s degree in business administration, and is fluent in both English and Spanish.

www.mfnsccom

Tomo Kirimoto, General Manager/VP of Operations and QA
Soft Gel Technologies Inc. • Los Angeles, CA

Tomo Kirimoto was hired at Soft Gel Technologies Inc. as assistant plant manager in 2001. Prior to joining Soft Gel, Tomo worked at its parent company, Japan-based Kenko Corporation. Tomo now serves as the general manager and the vice president of operations and QA. He is responsible for quality control in the plant as well as overseeing engineering improvements of the factory and machinery. He is also in charge of all aspects of plant management, including overseeing the mechanical facilities and improving the efficiency of the plant. Tomo graduated from the Tokyo Institute of Technology and has a master’s degree in material science. He is an avid golfer and enjoys spending time with his wife and two children.

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The ketogenic diet has come to considerable prominence in recent years, thanks in part to growing adoption among celebrities, media personalities, and professional athletes. Keto is currently the diet of choice of Katie Couric, Halle Berry, LeBron James, and Tim Tebow. Alicia Vikander famously used the keto diet to lose weight and gain muscle in preparation for her role in “Tomb Raider,” and three out of five Kardashians agree that keto is the way to go.

These influencers are going keto for the diet’s energy-boosting and weight-loss health claims, and what originally started as a medical experiment is now a rapidly growing industry full of new opportunities for functional food and nutritional supplement brands. Data provided to Nutritional Outlook by Innova Market Insights show that the number of new food and beverage products with keto claims grew five-fold from 2013 to 2017, with keto products diversifying from the sports nutrition category into all manner of food and beverage products.

Keto now has a strong presence in the functional foods industry, with keto cereal, keto ice cream, keto candy, and even keto chocolate chip cookies coming to market. Innova’s data indicate that ketogenic sports nutrition products now account for just 33% of the market, down from 100% in 2013. As more mainstream consumers adopt the keto diet, expect ketogenic functional foods to continue expanding into more categories and SKUs.

Keto supplements are also growing, with keto diet adherents frequently using exogenous ketones to reduce the impact of the “keto flu” (ill feelings keto adopters sometimes experience at the start of the diet). Exogenous ketones are now available as ketone esters, ketone salts, and ketone oils.

As more consumers adopt the keto diet to meet their functional needs, expect new opportunities to open up in keto foods and supplements. Here are just a few of the emerging trends that brands and manufacturers will want to watch.

The Ketogenic Trend: Medical Diet Gone Mainstream

While William Banting’s December 1863 Letter on Corpulence contained the basic principles of what is now known as keto, the modern ketogenic diet came to the fore in the 1920s. Russell Wilder, MD, was an endocrinologist with the Mayo Clinic leading a team of doctors
who were developing a new dietary regimen for epilepsy patients.\textsuperscript{1} Wilder theorized, and later demonstrated through medical trials, that a high-fat, low-carbohydrate diet mimicked the starvation therapy that, at the time, was the leading remedy for severe childhood epilepsy.\textsuperscript{2} Researchers and clinicians at Johns Hopkins Medicine later built the Ketogenic Diet Center, a clinical and research department dedicated to managing pediatric epilepsy through the ketogenic diet.\textsuperscript{3}

In recent years, though, the ketogenic diet has moved outside of the medical establishment and into the mainstream consumer nutrition market. Functional foods, in particular, are seeing rapid growth of foods that are said to promote ketosis (when the body burns fat for energy).

\textbf{The Rise of the Keto Food Movement}

Mike Salguero, co-founder and CEO of ButcherBox (Cambridge, MA), says the ketogenic trend is growing within the functional food space. He points to new product trends in the Paleo market as evidence.

\textbf{KETO WEARABLES: AN EMERGING INDUSTRY}

Mike Salguero, co-founder and CEO of ButcherBox, says that tools for tracking and monitoring ketone concentrations is one of the areas where the next major opportunities in keto will arise. Keto dieters tend to move in and out of ketosis, and maintaining the benefits of the ketogenic diet will require these consumers to be able to track blood ketone levels.

“The die-hard ketogenic people say that the only way you know you’re in ketosis is by taking your blood,” Salguero says. “That’s out of the Tim Ferriss [author and podcast host] school of thought where, if you’re going to be on a ketogenic diet, you can’t just eat fat and hope for the best. I think there’s going to be more of this, because more and more people are getting into the biohacking and wearables trends.”
Ketogenic Supplements Address the “Keto Flu”
Thom King, president and CEO of Icon Foods (Portland, OR), says the keto trend has given rise to demand for a new kind of supplement: a supplement that serves as a shortcut to ketosis. The ketogenic diet, King says, requires its adherents to work harder to stay hydrated, especially in the early stages. Switching to a ketogenic diet also places stress on the body as the body learns to stop burning sugar for fuel and start burning fat. For the first several days of a keto diet, dieters commonly report flu-like symptoms for this reason.

“Staying hydrated is critical, and so is making sure you have plenty of electrolytes,” King says. “That’s why there are more and more keto RTDs and drink mix packets that contain sodium chloride, potassium chloride, and other electrolytes. Many consumers are also looking for shortcuts to get them deeper into ketosis. There are exogenous ketone salts like BHB (beta-hydroxybutyrate), but the most effective supplement by far is exogenous ketone esters.”

Ketogenic supplement brands like Perfect Keto (Austin, TX) offer consumers multiple kinds of supplements that claim to ease the keto flu, ranging from ketone salts to esters to oils. Other brands, like Sated (Cambridge, MA), have formulated such ingredients into ketogenic powders and RTD shakes. Sated founder and CEO Ted Tieken says the keto flu is usually the result of one of two potential causes: either the body is resisting the switch to burning fat instead of sugar, which typically lasts for the first four days of a keto diet, or the consumer is suffering from low electrolytes.

“In the first case, there’s not really much you can do,” Tieken says. “In the second case, many keto brands, Sated included, have incorporated electrolytes into their products.”

The keto industry’s future growth may depend on making consumer transitions to keto diets easier. Expect electrolyte-enriched products and keto flu–busting supplements to continue gaining popularity.

WHAT DON’T WE KNOW ABOUT KETO?
The ketogenic diet may have originated within the medical establishment, but there’s still a lot we don’t know about it. Animal studies have shown that the keto diet can reduce brain inflammation and extend lifespan in mice with brain injuries. Outside of seizure prevention, though, it’s unknown what long-term effects keto may have in humans. The ketogenic diet is thought to have neuroprotective and anti-inflammatory properties due to its success as a remedy for pediatric epilepsy in the 1920s; however, modern clinical trials on healthy human subjects are few and far between. Additionally, the relationship between the ketogenic diet and major side effects like cardiomyopathy is still unknown.

Further clinical research is needed to determine whether the ketogenic diet is safe for healthy adults as a standard long-term dietary practice.

The Future of Keto: Into the Mainstream
The ketogenic food trend is seeing rapid growth, King says, and popular innovations like fat bombs, ketogenic jerky, and MCT-enriched coffees are all making keto more accessible for the mainstream consumer. To gain mass-market appeal, though, keto brands will have to be prepared to formulate products that stand out.
“The biggest areas of demand right now are ketogenic cereals, condiments, and baked goods,” King explains. “The RTD and powdered drink mix markets are starting to get crowded. ‘Keto-heads’ are going to want food they can’t normally eat if they want to stay in ketosis, like breads, pastas, and potatoes.”

King says brands can stand out in the keto space with clean ingredient formulations and innovative product formats. He also expects pre-made keto-friendly meal products to be a lucrative niche, as “ready-to-eat meals will be the next to pop.”

Dorian Greenow is the founder of Keto-Mojo (Napa, CA), a company that manufactures blood ketone monitoring systems. Greenow says standing out in the keto space will require brands to create a quality product and then attract first adopters to it. The keto industry is a bottom-up one, he says, and leveraging grassroots social media can be a particularly effective strategy.

“Keto is a very tight community of advocates, but when they touch something that resonates, it’s magic,” Greenow says. “The classic example is FBomb,” a keto-friendly line of high-fat, low-carb nut butters and oils. “The formula for success is simple: make a quality product and be real about what you’re offering.”

The ketogenic space is full of opportunity for savvy manufacturers and marketers. Brands entering the keto space can easily capitalize on this growing trend by investing in high-quality ingredients, coming up with innovative new product formats, and building strong communities around their products.

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If you’re wondering why supermarket freezer cases give over ever more space to sumptuous, indulgently flavored treats that also happen to be low in sugar and calories, high in protein and fiber, and scrupulously clean of label, blame Halo Top.

Halo Top, of course, is the sweet sensation that broke the frozen-dessert mold with its healthful bona fides, 2500% growth, and $342.2 million in 2016 sales—elevating it to 2017’s top-selling new food brand, according to IRI data.

And that explains why Max Maxwell, manager, market intelligence, Glanbia Nutritional (Chicago, IL), insists that "Halo Top was the tipping point, is the tipping point, and continues to be the tipping point. The healthy frozen-dessert category is poised to grow much further than it already has, and it largely began with Halo Top."

The Halo Effect
As far as Maxwell is concerned, the reasons are obvious. "Halo Top delivers the combination of attributes consumers have shown they want: better for you, indulgent, great tasting, convenient, and no guilt," he says. "Think about it: One whole pint of Halo Top is just 280 calories, and a consumer could eat any portion, including that whole pint, without feeling bad about it—in fact, feeling quite good because they’re getting protein while they enjoy it. And that could very well be the definition of ‘healthy’ in terms of what drives consumers’ purchase decisions today: guilt-free indulgence with added nutrition."

The brand’s success has inspired, or pressured, other brands to follow suit with formulation “upgrades” that involve added protein or “clean” sugar reduction, all of which leaves Thom King, president and CEO, Icon Foods (Portland, OR), with the impression that the "Halo effect" is "spreading like wildfire."

"Every dairy processor that makes desserts has to be looking at this category," he says. Speaking from his own experience, he says his company’s fielded more clean-label sugar-reduction projects from frozen-dessert customers than from any other category in 2018, "and we do not see that pace slowing down going into 2019."

Even retailers have noticed Halo Top’s success, Maxwell adds, with several introducing similar products in their stores in a bid for some of the brand’s healthy margins. "And when retailers get into the game," he notes, "you know there’s something good going on."

New Trends, New Formulations
Creamy, dreamy Halo Top is a far cry from the “healthy” frozen desserts of yore, which long ran to tired staples like ice milk and gummy-textured low-fat offerings. "The next wave after that was frozen fruit confections and frozen yogurt," Maxwell recalls, "and none of these came close to the success of Halo Top. While some are still on the market and fill a consumer niche, the growth will likely be more in this indulgent, low-cal, high-protein space."

Firms are bridging the healthy-indulgent divide by introducing more of the positives
consumers want—like protein—and eliminating or drastically trimming the negatives, like sugar and artificial anything.

“Currently, most brands are using dairy proteins, but that’s expanding into plant proteins,” Maxwell observes. “They’re taking out sugar, too, using alternatives like stevia or monk fruit, honey, and agave-type sweeteners as replacements. They’re also removing stabilizers, preservatives, artificial flavors, and colors and any ingredients that have more than a couple of syllables or sound like a chemical.”

As a sweetener supplier, Icon Foods’ radar is tuned to shifts away from nutritive sweeteners and chemically synthesized sugar substitutes to alternatives “that consumers can relate to,” King says. But they have to be functional in formulation, too—and many are. “Sweetener blends like stevia and erythritol as well as stevia and allulose lend freezing-point depression,” he says, which helps keep ice cream soft and scoopable, “and allulose really helps with overrun, making for a nice airy and fluffy ice cream.”

He’s also noticed a shift away from hydrocolloids like carrageenan to locust bean gum and natural hydrocolloid blends; indeed, he wagers that today’s hydrocolloids have advanced to the point that the mouthfeel, texture, and overrun of healthy frozen desserts “can be spot-on compared to traditional full-sugar versions,” he says.

Even ice cream inclusions are cleaning up their acts—thanks in part to companies like King’s. “The biggest gain for us is the development of our SweetBitz sugar-free inclusions for frozen desserts,” he notes. “We have sugar-free chocolate chips in 2-m and 4-m sizes. In Q2 of 2019, we’ll be adding inclusions such as sugar-free white chocolate chips, sugar-free butterscotch chips, sugar-free cookie bits, birthday-cake multi-colored sprinkles, and more. Stay tuned!”

**Having Their Ice Cream Cake and Eating It**

It’s just another sign that no matter how high up the ranking “healthiness” rises, a frozen dessert is still a frozen dessert. So it had better 1) be fun, and 2) taste great.

Notes Terri Rexroat, vice president, team lead, Latin America, U.S. Dairy Export Counsel (USDEC: Arlington, VA), “Consumers are looking for healthier options in this category, but even with the demand for clean labels and convenience, taste is still king. Consumers won’t compromise flavor or texture, even for nutritional benefits. So the sweet spot for formulators is ‘healthy indulgence.’”

This even applies to the exalted Halo Top. “One of the factors that made Halo Top so successful was its healthier proposition,” Maxwell argues. “The brand calls out its high protein and low sugar on the label, which falls right in line with the macro consumer trends—it’s taking a traditionally indulgent product and makes it healthier. But what also makes it so successful is that it tastes good.”

Which is what this burgeoning category needs to keep growing. “If a healthier frozen dessert doesn’t taste good, it won’t be successful,” Maxwell concludes. “With so many brands competing for market share, consumers are in control of their choices and won’t tolerate poor-tasting frozen desserts.” Even if they have a halo on top.

We quizzed the experts on their top strategies for balancing wellness with “Wow!” in frozen desserts. Here are their tips.

**Accentuate the Positives**

In the past, enjoying a healthy frozen dessert meant “giving up something to gain the benefit,” Glanbia’s Maxwell says—“with that something usually being taste.” The current trend, by contrast, “is toward not having to make any sacrifices, and indeed, to receive nothing but benefits.”

That means cutting out no-nos like added sugars and artificial sweeteners while loading on the pluses like protein and fiber. And it means that formulations have to maintain the taste, flavor profile, and texture that consumers will accept as indulgent.

“We think ‘positives’ have the most long-lasting beneficial impact on a product,” Maxwell concludes. “There are still the ‘nos’ and the ‘lows’ that work—no sugar, low sugar, no artificial ingredients. But the positives have a more powerful appeal, particularly as consumers seek help in making better choices. The ‘nos’ get your brand in the game, but it’s the positives, like high protein or good source of protein, that have great appeal.”

King couldn’t agree more. “As I see it,” he says, “there are no negatives, only positives.”
**Protein on the Plus Side**

Protein is clearly one of the plus-side ingredients that make category watchers bullish. And frozen dessert developers have their pick of proteins to formulate with. “While milk and cream are typically used in ice cream and frozen desserts, additional fortification with dairy protein ingredients can boost nutrition to create consumer appeal,” says Rexroat. “Whey and whey protein ingredients have been used successfully in ice cream and other frozen dairy desserts for the past six decades. Sweet whey, whey protein concentrates at 24%-89% protein, and whey protein isolates at 90% protein are among the most commonly used whey products. Other whey ingredients, such as delactosed and demineralized whey, can also be used.”

To make protein-packed formulation even easier, King’s company launched its HiPro Ice Cream Dry Mix as “a plug-in solution to take the guesswork out of creating a superior product with fewer than 80 calories per serving,” he says. A proprietary blend of milk protein concentrates, natural sweeteners, and natural gums and stabilizers, it produces a “home-style” ice cream with 5 g of protein and 8.3 g of carbs per serving.

The company even supplies a vegan version that King says is grabbing attention. And that makes sense to Maxwell, who notes that “what started with Halo Top in the frozen dairy space could well expand into plant-based frozen desserts. Imagine a pea protein—or bean protein–based dessert, maybe even with a probiotic. We’re just at the beginning of the growth and expansion of this category.”

**How Sweet It’s Not**

Yes, one of the key characteristics of a healthy frozen dessert is a sugar level that’s dwarfed by what you’d find in a less-virtuous counterpart. Consider that a half-cup serving of Halo Top’s vanilla bean ice cream has 6 g of sugar compared to the 20 g you’ll find in both Häagen-Dazs and Ben & Jerry’s vanilla varieties, or the 13 g in Dreyer’s Slow Churned vanilla bean.

But the trend in healthy frozen desserts isn’t just about keeping sweetener grams low; attitudes about sweetness perception are changing, too.

Says Maxwell, “It’s interesting what’s going on with sweetness levels in frozen desserts. A lot of people don’t want their treats to be overly sweet, and the range of alternative sweeteners makes it easier for brands to create products at sweetness levels that don’t overwhelm—and, again, give the impression to the consumer of a healthier product.”

He believes that as the crop of clean-label alternative sweeteners gains greater consumer acceptance, and as products ratchet down sugar levels of the past, “consumers’ openness to a range of sweetness levels will create opportunities for other brands to provide a range of flavors and sweetness levels.”

**Good Things Come in Single-Serve Packages**

Less sugar, more protein, and a “clean” deck of ingredients qualify a frozen dessert as healthy. But so, too, does a serving size that makes it easier for consumers to exercise restraint. After all, even too much Halo Top is... too much.

So one way that brands are helping consumers make healthier choices is by delivering frozen desserts in formats with an obvious endpoint. Maxwell notes that his team has worked with frozen-dessert customers in developing a range of different formats, “but primarily on the smaller pint sizes” that are just right for a single-serve treat.

And when asked what formats she thinks help consumers know when it’s time to stop, Nina Hughes Likins, global marketing director, Prinova (Carol Stream, IL), says, “All of them! Popsicles, ice cream bars, pushups, sandwiches, and single-serve products have all been innovations that resonate with consumers’ demand for a healthier version of frozen desserts and ice cream.” And one that lets you know that when you’re done, you’re done.

**From Idea to Ice Pop**

“Overall, the healthy frozen-dessert category continues to innovate to help consumers enjoy better-for-you indulgences that meet developing demand for global tastes,” Rexroat concludes.

To bring this notion to life in on-trend, on-the-go applications, USDEC, in partnership with the Midwest Dairy Foods Research Center at the University of Minnesota, developed a prototype for the 2018 Institute of Food Technologists Annual Meeting & Food Expo that blended nutritional benefits from domestic dairy with "the international flavor profiles consumers desire,” she said.

The concept: a lemon-ginger ice pop with whey protein. “An adult spin on a classic kid treat,” as Rexroat describes it, the novelty packed 10 g of protein from U.S. whey protein isolate and fewer than 100 calories per pop. “It would make a great, portable option for healthy snacking between meals or post-workout,” Rexroat suggests. 

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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ORGANIC BY NATURE. CLEAN BY DESIGN.
Whether you formulate dietary supplements or functional foods, the arguments both economic and environmental for sourcing organically are pretty well established. But now that organic production—not to mention fair-trade, sustainable, traceable et al.—is increasingly table stakes for the wellness industry, what’s the next hurdle for companies to clear in demonstrating their commitment to a healthy planet and healthy consumers?

If a growing coalition of brands, farmers, and forward-thinking organizations has anything to do with it, it may involve a progressive approach to farming that seems novel, but that actually dates back generations. That approach, known as regenerative organic agriculture, takes the principles of organic and runs with them, aiming not just at minimized chemical use or sustainability, but at measurably improving the land and water we farm, and the lives of the people and animals involved.

True, regenerative agriculture may not have the cache of organic yet. But the fact that multiple groups are either hammering out or in the process of implementing standards for identifying and certifying its principles in practice means that this enlightened effort at holistic food and fiber production is worth understanding. And for the sake of all of our futures, it’s worth pursuing.

**Regenerative Roots**

If anyone has a stake in regenerative organic agriculture, it’s the team at the Rodale Institute (Kutztown, PA). For it was Robert Rodale himself—son of the institute’s founder, J.I. Rodale—who coined the term “regenerative organic agriculture” to describe a philosophy of farming that surpasses the merely sustainable.
How so? According to the Rodale Institute, regenerative organic agriculture doesn’t just protect and preserve the resources it uses—let alone deplete them, it actually leaves them in better condition than before. That means accounting for the health of the soil and water as well as the health and economic and spiritual wellbeing of farmers, farmworkers, and farm animals.

Or, per the similar definition devised by Los Angeles–based The Carbon Underground and Regenerative Agriculture Initiative at California State University, Chico, regenerative agriculture incorporates “farming and grazing practices that, among other benefits, reverse climate change by rebuilding soil organic matter and restoring degraded soil biodiversity—resulting in both carbon drawdown and improving the water cycle.”

Regenerative agriculture mirrors organic in emphasizing minimal use of dangerous chemical inputs—thus producing safer food in an environment that’s safer for those who work and live in it. But it differs from, and exceeds, organic’s baseline by committing to broader matters of social justice, community health, and animal welfare, and in aiming at the quantifiable betterment of natural resources for generations to come.

Reclaiming the Regenerative Ground

So when representatives of the Rodale Institute, along with allied organizations and companies like Dr. Bronner’s and Patagonia, began noticing a creeping cooptation of the term regenerative by chemical companies, they realized that if they didn’t reclaim the word and all it stood for, it risked being “greenwashed” outright. Or, as Jeff Moyer, executive director of the Rodale Institute, put it, “If we didn’t act now, other organizations would come in and potentially threaten the larger organic movement.”

So they united as the Regenerative Organic Alliance and began developing a Regenerative Organic Certified (ROC) program that would put all interested parties on the same page as far as regenerative organic farming was concerned.

The Alliance intended for the ROC program to be ambitious, says Diana Martin, director of communications at Rodale: “A holistic agriculture certification encompassing robust, high-bar standards for ensuring soil health and ecological land management, pasture-based animal welfare, and fairness for farmers and workers. It was created to model an ecological and ethical system for agricultural production that addresses the problems of factory farming, climate change, and economic injustice, locally and globally.”

Measurable endpoints include increased soil organic matter over time; improvements in animal welfare, economic stability, and fairness...
While members of the Regenerative Organic Alliance and Regenerative Agriculture Initiative were drawing up guidelines for their respective certification programs, botanical ingredients supplier Sabinsa (East Windsor, NJ) was halfway around the world working with local governments to plant hundreds of acres of land of a medicinal tree that, absent such an effort, ran the risk of dying out.

Some background: Sabinsa has always believed that cultivating medicinal plants is the best way to sustain supplies of quality raw materials—especially in the face of growing interest in herbal and botanical ingredients, says Shaheen Majeed, Sabinsa’s president worldwide. So years ago, the company began instituting cultivation programs to help sustain safe supplies of the herbs that form its product base.

Those programs go beyond planting plants to working with farmers on the ground, in the field. “We teach them good agricultural practices that minimize chemical use and produce top-quality herbs and higher yields,” Majeed says. Further, Sabinsa guarantees its partners’ incomes and even includes a provision in grower agreements that if the harvested material’s value rises, the farmer will get the true price, even if it exceeds the originally agreed-upon one.

“It’s beyond fair trade in that we’re not just making sure they get a living wage,” Majeed says. “We’re helping them have better harvests, improving local schools and infrastructure, and even doing things like giving the village kids jackets, school supplies, and soccer balls they wouldn’t otherwise have. The relationships we build through supporting small farming communities in India surprised and delighted us.”

But despite Sabinsa’s confidence that the careful cultivation fostered through its fair-trade programs could protect supplies of herbal ingredients, “trees,” Majeed notes, “which take decades to reach maturity before becoming available for commercial use, need appropriate strategies to replenish, and long-term thinking to make them available for future generations. Some potent tree species face danger of disappearance because of overexploitation without any conservation measures in place.”

Thus the group has committed to funding a 10-year reforestation project that’ll ensure the planting of more than 166,600 Indian kino (Pterocarpus marsupium, Fabaceae) trees on 250 acres in Madhya Pradesh state. “This species has been used in India’s traditional medicine system of Ayurveda, and the traditionally known antidiabetic properties of Pterocarpus marsupium are being confirmed by modern research,” Majeed says. “So demand will grow. Without this advance planning, the species could have been wiped out by market pressure.”

With the State Forest department fast-tracking the program, the first phase of reforestation was completed within six months of entering into the agreement to identify and prepare suitable forestland for planting; develop desirable planting material, proper fencing, and security measures; and plant at the right season, Majeed says. The group expects to spend about $500,000 on the project, with the payoff being a secure supply of a high-value, multipurpose, threatened Indian species.

Now Sabinsa is meeting with the forest departments of other Indian states to initiate regeneration programs for rare medicinal tree species in those areas, too. “Such commitment will not only help regeneration of rare species, but create awareness amongst users and sensitize them. We hope other companies that harvest and sell trees will follow our example and begin thinking much longer term,” says Majeed.
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for farmers, ranchers, and workers; and the creation of resilient regional ecosystems and communities. "Ultimately," says Martin, "the goal of the ROC is to encourage operations to think about all three modules—soil health, animal welfare, and social fairness—to create a truly regenerative system."

Setting the Standards
In addition to Rodale, the program includes such founding members as Compassion in World Farming, Demeter, Fair World Project, Grain Place Foods, Maple Hill Creamery, and White Oak Pastures and, Martin continues, "has been established to continuously review and update the certification guidelines."

In October, CV Sciences Inc., manufacturer of the PlusCBD Oil hemp extract brand, announced that it is also joining the cause.

Acting as program manager for the ROC is NSF International (Ann Arbor, MI), which facilitated the public comment phase that took place during the protocol’s development. In its current capacity, NSF will lead all efforts to support the program’s implementation, overseeing training and educating of certifying bodies, data collection management of audit information, and reporting.

According to Jessica Evans, director of standards development at NSF International, certification requirements will address farming and ranching operations, transportation, slaughter, and certain processing facilities that produce food and fiber.

"Producers can start on the path to ROC from several different places," she explained, "as either a conventional producer, a certified transitional producer, or a USDA National Organic Program (NOP) certified producer. Regardless of where they enter, producers generally move from conventional to transitional organic, then to certified organic, and then to ROC Bronze, Silver, and Gold status.

Above and Beyond
As that progression implies, ROC "builds off the requirements of the USDA NOP certification program and allows producers going above and beyond in animal welfare, soil health, and worker fairness practices to be recognized for their efforts," Evans says.

And as evidenced by the fact that only products that have already achieved USDA NOP certification will get the ROC’s nod, the ROC’s backers didn’t intend for their "above-and-beyond" approach to supplant existing organic standards. Rather, ROC certification supports those standards while encouraging producers to adopt holistic, regenerative practices throughout their operations, especially vis-à-vis animal welfare and farmer and worker fairness.

What’s the next hurdle for companies to clear in demonstrating their commitment to a healthy planet and healthy consumers?

Martin adds that ROC certification need not add to producers’ already growing list of certification burdens, and "was developed to avoid duplication of audits and certifications and even accepts existing high-bar certifications”—Demeter Biodynamic, Global Animal Partnership, and Agricultural Justice Project’s among them—"to fulfill both the animal welfare and fairness for farmers and farmworkers requirements."

The Regenerative Organic Alliance is justly proud of its broad-based approach. As Moyer notes, "There are a lot of companies, farmers, and others talking about regenerative farming. Our certification is the only one that starts with organic, and the only one that also incorporates standards for social fairness and animal welfare."

Climate Action from the Ground Up
As far as soil health is concerned, the ROC accepts USDA NOP organic and other internationally recognized organic certifications as a baseline step. But, says Martin, "There are then additional regenerative requirements to meet, which a farm can tailor to their specific growing region. It’s all part of their journey to ROC."

And the soil component, in particular, helps make the ROC program so important—and so groundbreaking. That’s because "healthy soil is the key to healthy people and a healthy planet," Moyer says. Alas, the planet loses the equivalent of 30 soccer fields of soil every minute, mainly due to industrial farming.

In fact, if the soil destruction caused by decarbonization, erosion, desertification, and chemical pollution continues at current rates, soil scientists predict that "within 50 years we will not only suffer serious damage to public health due to a qualitatively degraded food supply characterized by diminished nutrition and loss of important trace minerals," Martin warns. "We will literally no longer have enough arable topsoil to feed ourselves."

And that’s just the nutrition angle. Soil is critical to absorbing carbon and filtering water. So as soil deteriorates, it stores less carbon, the world grows hotter, and the land further degrades. Moyer calls it "a vicious cycle." Yet generating 3 cm of topsoil takes 1,000 years, and about one-third of the world’s soil has already deteriorated as a direct result of chemical agriculture. That, in turn, "exposes people to toxic chemicals and causes unnecessary suffering to animals that support this system," he concludes.

But all is not lost. If it were, the Alliance behind the ROC program wouldn’t have made its effort in the first place. For, as Moyer says, "As grim as this picture looks, the direct benefits of regenerative organic agriculture are extraordinary": better food and higher-quality fibers, rebuilt topsoil, reduced pollution from chemicals, sequestered carbon—all at once. "As we face environmental catastrophe, this may be the best shot we’ve got at moving the needle," he says.
“Regenerative organic standards and certification offer a path forward that considers the health of the entire system and the planet,” says Jeff Moyer, executive director of the Rodale Institute.

Going Live
The ROC certification program debuted at Natural Products Expo East in 2017, and after a public comment period the official framework went live in early 2018. “Just recently,” Martin says, “ROC entered the pilot phase in which 23 farms and brands will begin to experiment with the practices on the ground so we can test the feasibility of their implementation for a wide range of farm types and climates. We’re hoping that the first ROC-labeled products will be on shelves in 2019.”

It’s an exciting prospect for the program’s supporters and participants, as well as for supplement and functional food brands that consciously seek out ROC-certified ingredients. And “for consumers who value this criteria,” Evans says, “the program provides an easy way to verify label claims and choose products that align with their beliefs.”

Martin agrees. “Consumers purchasing ROC products will know that they’re buying a product that addresses the full suite of supply chain responsibility concerns, from environmental and animal treatment to fair and safe working conditions for farmers and farm workers. Also, since regenerative farming practices enhance carbon sequestration, consumers will be supporting the fight to mitigate climate change.”

But ROC isn’t the only certification standard out there. In March 2018, The Carbon Underground and Green America partnered with Ben & Jerry’s (Unilever), DanoneWave, Annie’s (General Mills), and MegaFood to develop their own global verification standard for food grown regeneratively. Again, the standard will give farmers even more incentive to restore the carbon cycle, build soil health, improve crop resilience, and increase finished-harvest nutrient density.

The work reflects the regenerative agriculture definition created by The Carbon Underground, Cal State Chico, and the Regenerative Agriculture Initiative, which includes 150-plus companies, organizations, and scientists as signatories. And similarly to ROC certification, it will recognize related standards such as USDA NOP, Non-GMO Project Verified, and the like, and will give farmers flexibility in implementation, with credit for outcomes already achieved.

So will consumers know the difference? And will it even matter if everyone’s end goal is fairer farms, healthier soil, and a swing at the climate change piñata?

“The market is indeed saturated with certifications that can be confusing to consumers and even to industry experts,” Martin concedes. Speaking for her own organization’s seal of approval, she continues, “Once the certification is a bit more mature, our hope is that consumers will look for it as a way to avoid confusion, knowing that ROC addresses all their concerns.”

Besides, says Moyer, “Isn’t it time we had a higher standard for the way we treat our farmers, farmworkers, and animals? Regenerative organic standards and certification offer a path forward that considers the health of the entire system and the planet.”

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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Tea for You

Tea’s limitless flavor possibilities cater to all reaches of the consumer market.

BY SEBASTIAN KRAWIEC, ASSOCIATE EDITOR

Tea, like coffee, straddles a variety of beverage categories that target particular consumer preferences, from the high-minded loose-leaf tea brewer, to the casual iced-tea drinker grabbing a bottle at the convenience store. Tea has something for everyone: it tastes good, it has functional aspects like energy, but it also has a healthy connotation.

So, while coffee is certainly experiencing a boom, particularly in the ready-to-drink (RTD) cold-brew space, tea, despite being considered a counter-part, does not necessarily compete with coffee, but instead exists in its own space. "Tea has become more the evolution from the carbonated soft drink, sparkling beverage platform, as opposed to coffee, which is more functional," says Shannon Coco, strategic marketing manager, Taste, for ingredient and flavors supplier Kerry North America (Beloit, WI).

Renata Ibarra, senior RD&A director, Taste, for Kerry, agrees, saying, "Tea has a more healthy halo than coffee, so the consumer going after coffee would not necessarily go after tea. We think tea still has a lot of space [to grow] because [of the versatility], from the sweet teas to the unsweetened tea, combined with fruits or varieties like white, green, or black tea."

With tea, the flavor possibilities are virtually endless, and the reasons for drinking tea are not limited to a particular function.

Adapting to Consumer Tastes

RTDs account for 46% of total tea volume, while tea bags account for 44%. According to Nielsen, "liquid tea," or RTDs, was the number-one product category in dollar growth change at the end of 2017, with a dollar percent increase of 18.9%. This was the second year in a row that RTDs took the number-one spot in dollar growth, Nielsen says. Considering the growth of the category, this creates a lot of opportunity for new and innovative flavor solutions as brands chase the ever-changing palates of consumers.

Among the biggest challenges currently in formulating beverages, including tea, is managing sugar content. A recent white paper by Kerry, which surveyed over 1,500 U.S. consumers, found that 46% of American consumers are trying to reduce their sugar consumption, 27% prefer products that are less sweet, and 50% seek out a specific type of sweetening agent in their products. That means a lot of creativity has to go into how a beverage, such as an RTD tea, is formulated in order to develop a low-calorie beverage that also hits all the right flavor and textural notes. This means combining sweeteners, using flavor maskers, or introducing other flavor profiles such as floral or fruit flavors.

For tea, this can mean any number of flavor combinations; it depends on the type of end-product that is being created and who it will be marketed toward. Some will want a tea that is sweet and fruity, while a consumer that is more of a purist will desire a more astringent and authentic tea flavor. Because of the level of customization that an RTD tea product requires, using tea extracts is advantageous.

"The way [extracts] are broken out is that if you like the brighter notes, you can increase those, or you can add them back to a cold-brew tea to get rid of some of the off-notes that may happen from brewing," says Philip Caputo, marketing and consumer insights manager for Virginia Dare (Brooklyn, NY). "We can change the levels of all these to get the taste that you want. You can actually change the taste of the tea while still using all the natural components. If you like the brighter notes, you can increase those, or you can add them back to a cold-brew tea to get rid of some of the off-notes that may happen from brewing."

Synergy Flavors (Wauconda, IL), for example, has a portfolio of extracts and essences that can replicate the experience of drinking freshly brewed tea in an RTD format. "You put [the ingredient] and water into our proprietary system, you draw off the aroma (which is the essence), and what comes out the bottom is the extract. Then you put them together," explains Lindsey Oostema, business development, Synergy Flavors. In an RTD tea format, this creates that full experience of drinking tea by releasing the tea aroma, which will fortify the flavor of tea. Synergy also makes extracts and essences for other flavor profiles, so besides the tea flavors and essences, a hibiscus or lemongrass essence can be incorporated for a more nuanced and robust flavor. One must remember that much of the flavors we perceive comes from our sense of smell.

Part of the diversity of flavors comes from the diversity of the teas themselves. "Something we’ve been pushing is single-origin [flavors]," says Caputo, such as from Assam, Sri Lanka, teas from various regions. "That’s something customers have been frequently requesting, so that is often a selling point. We can make the tea extract just for the single-origin and then flavor pairings; obviously florals, spices, that kind of thing. It really comes down to the type of tea. That’s the kind of flavor we will pair it with."

One flavor profile that has continued to be popular in teas and RTD beverages in general has been tropical flavors, says Caputo. Tropical flavors provide the refreshment RTD tea consumers want, and it’s why citrus flavors continue to sell well and see continued innovation. "Trending and emerging citrus is definitely a platform we’re seeing a lot of traction in," says Coco. "More exotic profiles that take a familiar citrus consumers love [and] bringing in that touch of exoticism—in particular, meyer lemon, yuzu, and calamansi lime are some things we’re seeing traction for in the market and continued interest around from consumers and customers."

View references online at NutritionalOutlook.com/food-beverage/tea-limitless-flavor-possibilities-cater-all-reaches-consumer-market
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