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Do GMO and Prop 65 Labeling Violate the First Amendment?

More U.S. food firms are invoking free speech as reason not to comply with government-mandated labeling disclosures. Their argument: the government cannot force the company to make a claim the company disagrees with. Two high-profile lawsuits may soon become the first to deliver a judgment on the constitutionality of requiring labeling of genetically modified organisms (GMOs) and Proposition 65 chemicals in food products.

Effective July 2016, the state of Vermont’s GMO-labeling law will be the first in the nation to require packaged foods to disclose GMO content. Prop 65 regulations, now being revised by California’s Office of Environmental Health Hazard Assessment (OEHHA), require products sold in California to warn about the presence of Prop 65–list chemicals. OEHHA has proposed new wording, too: “Warning: This product can expose you to a chemical [or chemicals] known to the State of California to cause [cancer]/[birth defects or other reproductive harm].”

Food companies fear (understandably so) that these warnings scare off customers when in fact a product may not actually be dangerous. After all, depending on whom you talk to, there isn’t yet sweeping consensus that GMOs endanger human health. (In the case of GMO labeling, even the factual statement “contains GMOs,” with no explicit warning attached, is likely to appear ominous, firms say.) The same can be said about Prop 65 chemicals, because some chemicals may be present at such low levels in a product that risk to human health is negligible.

Does the government have the right to compel corporate speech if the company doesn’t stand behind what’s being said? Moreover, must the government be required to definitively prove that the potential for harm exists in order to justify the need for a disclosure? Answers aren’t easy, which is why many will be watching these cases very closely.

In the aforementioned GMO-labeling suit led by food industry groups, Vermont will likely need to show that GMOs actually risk human health in order to uphold the reason for a disclosure. Similarly, in the Prop 65 case brought by the Council for Education and Research on Toxics against coffee merchants, both sides spent last fall arguing over whether or not the acrylamide in coffee causes cancer in humans. As of press time, both cases were ongoing. A decision in the Prop 65 case is expected soon.

Businesses have never received complete First Amendment protection. While the First Amendment protects non-commercial speech (religion, freedom of the press, etc.), commercial speech still faces some government regulation in order to protect the public. If a company engages in food and supplement commerce, it can fully expect to abide by FDA’s Federal Food, Drug, and Cosmetic Act (FD&C Act), which in a manner limits free speech by prohibiting companies from making false and misleading label claims. (Companies, by the way, have used this very argument against mandated disclosure, stating that the government is forcing companies to make what they believe are false and misleading claims, thereby violating the FD&C Act.)

University of California Berkeley law professor Stephen D. Sugarman made some interesting points in an article in the FDLI journal Food and Drug Policy Forum (vol. 5, no. 4; April 29, 2015). Sugarman wrote, “The central justification the Supreme Court has given for applying the free speech clause to commercial speech is the right of consumers to receive truthful information… I find it highly ironic that the Supreme Court and lower courts are now using the ‘compelled speech’ concept… to keep consumers from getting information that many of them clearly want to have (and which regulators have tried to assure they can obtain).”

Consumers voted in a ballot initiative like Prop 65 because they wanted mandatory disclosures. Do food companies have the right to block that? In what some will see as a controversial stance, Sugarman wrote: “In my view, regardless of what the mainstream scientific findings are, if these voters can get the appropriate legislative or executive body to pass a law or adopt a regulation that will give them the information they want about the content of food they will eat, then I say that disclosure requirement should be upheld.” Do you agree? Contact me and let me know.

Jennifer Grebow
Editor-in-Chief

My thanks to the American Herbal Products Association, whose May webcast “Proposition 65: What’s Going On?” addressed this issue.
Big news in the nutraceutical world.

J+D Labs, one of America’s premier custom nutraceutical manufacturers, is proud to announce the opening of J+D NutraStock™—our new line of high quality, made-in-the-USA bulk stock softgels, tablets and capsules.

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Welch’s Brings Grape Ingredients to Market

Grape juice giant Welch's is entering new territory in the ingredients realm. Taura Natural Ingredients (Winchester, VA), which produces fruit pieces, flakes, and pastes for manufacturers to use in bakery, nutrition bar, and other food items, will now produce concentrated pieces and pastes from Welch's Concord grape juice and puree.

Manufacturers will now be able to feature the Welch’s products in their own finished foods. “Welch’s mission is to bring the great taste of the Concord grape to more places and to more people,” said Wayne Lutomski, Welch’s vice president, international and global ingredients, in a press announcement. “Through our partnership with Taura Natural Ingredients and its unique URC process, we will be able to take Concord grapes into applications never before imagined,” including chocolates or combinations with ancient grains in breakfast cereals, the firms said.

Taura’s patented URC process quickly removes water from fruits, which helps limit water activity and moisture transfer in finished products, extending performance and shelf life. This is especially key for dry goods like bakery, cereal, and snack items, in which additional moisture can be detrimental.

According to Taura, its URC technology concentrates fruit purees and blends to below 10% moisture content in less than 60 seconds. “However, it is not the absolute moisture content that decides whether ingredients can be used successfully in tricky applications,” the company further explains on its website. “The crucial parameter is water activity, which is a measure of the ability of water to migrate from a given ingredient into the surrounding food matrix.” URC sidesteps this problem, it says.

Taura adds that the Concord grape is typically a challenging fruit to work with in the inclusion process, attributing the difficulty to the grape’s “slip skin and large seeds.” Welch’s and Taura Natural Ingredients will both market the Welch’s inclusion and paste line, now branded as FruitWorx. Initial rollout is in North America, Japan, and South Korea, with plans for expansion.

Manufacturers will also appreciate the name recognition the Welch’s brand brings. “Food manufacturers can leverage this brand equity by using FruitWorx inclusions in their own products,” said Richard Croad, COO and president of Taura North America.

Broccoli-Antioxidant Action Lasts Longer than Other Antioxidants’, Glanbia Explains

Ingredient distributor Glanbia Nutritionals (Carlsbad, CA) has welcomed to its lineup broccoli-based antioxidant Truebroc from Brassica Protection Products. Elaine Drummond, PhD, Glanbia’s clinical and technology development specialist, explains why the distributor believes that glucoraphanin, the antioxidant derived from broccoli seeds, is superior to other naturally derived antioxidants and why it holds promise for the supplement and food industries.

Unlike “more traditional” antioxidants like vitamin C and polyphenols, glucoraphanin activates “continuous” antioxidant benefits in the body, Drummond says. “Glucoraphanin triggers a natural, continuous antioxidant stream in the body that renews itself over and over for up to three days,” she says. “Even after glucoraphanin has been consumed, the antioxidant pathway it stimulates keeps on going. Other antioxidant nutrients act in a ‘one-and-done’ fashion. They go in, perform their duty, and are depleted, and once they are gone, the oxidative process can continue, causing damage to tissues and organs.”

Glanbia will highlight this difference and position Truebroc as a natural antioxidant source. “While synthetic antioxidants dominate the food-processing applications industry, natural ones are the preferred source in nutritional supplements,” according to Drummond.

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Growing awareness of vitamin K2’s benefits for bone and heart health is pushing new product activity in dietary supplements, functional foods, and beverages. But vitamin K2, especially when combined with minerals and also with multivitamins and nutritional oils like krill oil, can present stability problems, says vitamin K2 supplier Kappa Biosciences AS (Oslo, Norway). As such, the company recently completed a year-long stability study demonstrating that its recently launched K2Vital Delta microencapsulated ingredient maintains its potency.

The company introduced K2Vital Delta vitamin K2 MK-7 last May during the Vitafoods Europe trade show. Kappa Biosciences CEO Egil Greve explains that K2Vital Delta’s “double microencapsulated” beadlet technology is the “only one of its kind” and helps keep the ingredient stable when mixed in multivitamin and mineral formulations.

“The double coating is with gum arabic and starch, but the real benefit of the technology developed by a leading international life sciences company is the trapped air in these beadlets, which ensures unique stability,” he says.

In the recently concluded year-long shelf-life stability study, K2Vital Delta was tested at 25°C and lost less than 4% of its original activity, even when combined with minerals, the company says. It attributes this “strong stability” to the ingredient’s microencapsulation; by contrast, non-microencapsulated fat-soluble ingredients may find stability more challenging. For instance, the company says in its press materials, “The porous structure of calcium can have a detrimental effect on unprotected nutrients. One of the most common sources is calcium carbonate. Calcium carbonate is an alkaline compound and holds one of the highest concentrations of elemental calcium. Calcium carbonate is available in different quality levels, which have varying degrees of influence on MK-7 stability.”

Greve says that K2Vital Delta’s demonstrated stability “provides a unique freedom” to product developers, who can use the ingredient in a wide range of product formulas. It also may result in cost savings, Greve adds, because there is less loss of ingredient activity and thus less overage required during formulation in order to meet end-label claims.

All of Kappa Biosciences’ K2Vital vitamin K2 MK-7 ingredients are nature-identical. “The source material for all K2Vital products are of plant origin, followed by an organic synthesis, which is the only way to enable a nature-identical molecule to the vitamin found in nature,” Greve says.

The company cites K2Vital Delta as the fastest-growing ingredient its K2Vital line, with sales increasing over 500% since last April.

Greve points to high growth and “enormous increased interest” in the vitamin K2 market in general. The company itself estimates that the vitamin K2 retail market will see a CAGR of 50% over the next five years. Greve adds, “I think this also goes for other K2 manufacturers, but due to the still-young industry segment, [there] are no general industry growth figures available.”

“Vitamin K2 is the link between calcium and vitamin D3, helping to ensure optimal absorption and binding of calcium into the bone matrix,” the company says. “Vitamin D3 increases the uptake of calcium from the intestine, and vitamin K2 helps incorporate...
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calcium into the bone structure. These three—calcium, vitamin K2, and vitamin D3—could in fact be called the tri-essentials of bone health.”

Herbal Ingredients Target Metabolic Syndrome

More dietary supplement ingredient suppliers are focusing on metabolic syndrome, an increasingly prevalent condition encompassing high blood pressure and cholesterol, high blood sugar, and obesity that can lead to type 2 diabetes and heart disease. The latest come from supplier Monteloeder in Spain and from distributor SourceOne Global Partners (Chicago) and its supplier-partner Santal Solutions (Appleton, WI).

Monteloeder’s new MetabolAid ingredient marries hibiscus species Hibiscus sabdariffa and lemon verbena (Aloysia triphylla). According to the company, the ingredient was four years in development. So far, the company has completed preclinical animal studies that it says demonstrated that MetabolAid helped activate PPAR-alpha, a receptor that promotes fat breakdown and helps lower cholesterol, while also activating the calorie-burning protein AMPK. In the mice, researchers also observed inhibition of FASN, which is an enzyme promoting fat creation.

The company has now embarked on a 50-subject placebo-controlled pilot clinical study in Spain on “overweight and moderately obese” human volunteers, reporting that “preliminary outcomes are very promising” following dosages of 500 mg of MetabolAid. Specifically, early reports show the MetabolAid group experiencing a greater reduction in blood pressure, higher levels of HDL cholesterol, and a reduction in LDL cholesterol.

SourceOne Global Partners has teamed up with Santal Solutions on Santal’s LeptiPure ingredient for metabolic health. LeptiPure combines two herbal extracts, Gymnema sylvestre and Tinospora cordifolia. The Gymnema sylvestre extract in LeptiPure is an existing patented ingredient, Gymnepure, that SourceOne says is more bioavailable and bioactive than standard Gymnema sylvestre extracts. When marketed alone for blood sugar support, Gymnepure helps increase insulin production and healthy triglyceride and cholesterol levels. Meanwhile, animal studies have shown that Tinospora cordifolia may help maintain healthy glucose and lipid metabolism. When combined, the two ingredients in LeptiPure address many facets of metabolic health, including blood glucose, cytokine and free radical balance, and healthy cholesterol and triglyceride levels, the companies say.

So far, the companies have done initial clinical studies, which they say showed that LeptiPure can increase adiponectin levels by 12% and decrease leptin levels by 25%. Both are hormones implicated in weight management and metabolism. “The initial clinical study results are very encouraging because the science is clear. Improved ratio of leptin to adiponectin levels up to 37% with LeptiPure is directly related to healthy metabolic flexibility and supporting the body’s natural ability to maintain a healthy weight,” said Santal Solutions’ CEO Arun K. Chatterji, PhD, in a press release.

There is global opportunity for dietary supplement ingredients that address metabolic health, the companies all say. “Metabolic syndrome is a global problem,” said Fernando Cartagena, director of Monteloeder, in a press release. “It is estimated to affect 40% of Americans and 30% of Europeans aged 50 years and over, and a solution to this epidemic is required urgently. However, in spite of this, there’s a surprising lack of approved and effective natural products to address metabolic syndrome.”
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**Will China’s New Law Solve a Messy Supplement System?**

We’ll find out this October.

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

China officially passed its new food-safety law in April. Effective October of this year, the new law establishes a notification-based system for certain dietary supplements—vitamins and minerals only—that allows products containing these ingredients to bypass the China Food and Drug Administration’s (CFDA) registration process. Hopes are high that this new system will smooth a currently complex path by which dietary supplements enter and are sold within the country.

Jeff Crowther, executive director of the U.S.-China Health Products Association (USCHPA; Lewes, DE), says that while he hopes other problematic aspects of China’s supplement laws are eventually addressed, he believes the new law is a good start at helping to boost transparency and eliminate gray area within the China regulatory framework.

**Blue Hat System Will Not Go Away**

But China’s infamous blue hat system will still persist for products containing ingredients other than vitamins and minerals. “At this point, the blue hat system will not go away,” Crowther says. This is the existing CFDA registration process that requires companies selling dietary supplements in China to spend hundreds of thousands of dollars registering their products for China commerce. Besides being prohibitively expensive, the process is lengthy and is required for each finished product.

Although the process for vitamins and minerals is now streamlining, Crowther says it is still unclear whether vitamins and minerals, once notified with CFDA, will still need to receive some type of approval number on a per-finished-product basis. Between now and October, CFDA and China’s National Health and Family Planning Commission (NHFPC), the government agency overseeing health awareness and education, should be releasing guidance documents shedding more light on the specifics of the regulation and its implementation.

But the new law *should* in theory help clear some of the gray area that has transpired over the years, created by companies—especially importers, but also domestic sellers—trying to sidestep the blue hat system.

“In the past, foreign companies would import dietary supplements as food, claiming that the ingredients of the products had a direct relationship to food,” Crowther explains. “So they were able to navigate into the market under food law.”

In customs, this meant that companies would obtain documentation from China’s Administration of Quality Supervision Inspection and Quarantine (AQSIQ). “Each time a shipment was received in customs, the foreign company or domestic importer would have a customs clearance firm help them do the appropriate safety and microtests to obtain import documentation—most importantly, the ‘sanitation certificate,’ which, once obtained, allows the importer to sell in the market,” Crowther explains.

Years ago, CFDA became concerned about this gray area of commerce, made even murkier because CFDA and AQSIQ do not have a good system for communicating, Crowther says. In January 2014, the government stopped the food-import workaround.
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for supplement products, which then left many importers unable to get goods into the country.

Importers and domestic sellers of vitamin and mineral dietary supplement products, at least, will now have a clearer pathway for getting products into China commerce under the new food-safety law.

Still Room for Improvement
Crowther says that while USCHPA applauds China for moving in the “right direction” with these new streamlined regulations, the system still “needs work”—namely, because of all of the non-vitamin and non-mineral ingredients that the new notification process still excludes. “What about all the other ingredients that are used in the overall dietary supplement industry, such as omega-3s, pro/prebiotics, CoQ10, lutein, lycopen, amino acids, plant-based antioxidants, green foods, etc.? ” Crowther asks.

CFDA and NHFPC are together creating a list of ingredients that will be eligible for notification come October 1. Crowther says, “Now that China is working on this list, [USCHPA] would like to see them expand this list to include such ingredients. Many of the above-mentioned ingredients are already accepted as food ingredients in China, but are not currently allowed to be put in a tablet, capsule, or soft gel unless they have the blue hat registration.”

“I personally feel that China will add more ingredients to the list as time goes on and continue opening up the supplement industry,” he says. “However, they will be careful to move slowly, allowing time for domestic industry to mature so as to be competitive with the global industry leaders.”

A Good Move
Crowther says that overall USCHPA is happy that China is changing its regulatory structure.

“The new food-safety law is a good move for China in order to help create a more safe and transparent system,” he says. “Across all industries and Chinese society in general, transparency is something that is sorely lacking, which the current administration is working to rectify. Over the years, this absence of transparency has created a mis-trustful consumer base and a fertile environment for unscrupulous opportunists to cash in on producing unsafe, shoddy, as well as, in some cases, deadly products.

“I personally feel bad for all the Chinese companies that are and have been producing good products,” he continues. “It is difficult for them to rise above the stigma of China’s poor safety record, especially when they are seeking to ‘go global’ with their brand. Nobody wants to buy ‘Made In China’ food products or supplements for that matter. The new food-safety law will hopefully help to lessen this stigma in the coming years. I can remember clearly growing up in the United States that anything ‘Made In Korea’ was viewed as junk; however, that stigma has all but vanished.”

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Gluten-Free’s Mainstream Moves

Today’s consumers have many options when shopping gluten-free.

**BY INNOVA MARKET INSIGHTS**

Across the globe, more consumers are investing in “free from” foods. Gluten-free foods in particular are gaining ground due to rising awareness of gluten intolerance in the diet and the availability of more mainstream, better-tasting gluten-free products. In the global food and drinks market in 2014, products marketed as gluten-free accounted for 9% of total food and drink launches recorded by Innova Market Insights. In the United States, interest is even higher. U.S. gluten-free launches comprised 17% of all food and drink launches in 2014.

**Cereal Products**
The cereal market—encompassing breakfast cereals and cereal bars—is well positioned to cater to the gluten-free trend. Numerous non-gluten cereal options are already available to food manufacturers—most notably oats, long in demand for their fiber content and health benefits for the heart and slow energy release. It’s not surprising then that the percentage of gluten-free launches in the global cereal market—19%—is much higher compared to the percentage of gluten-free launches in the rest of the food and drinks market.

In the cereal aisle, gluten-free cereal bars are especially popular. Two-thirds of gluten-free product launches in 2014 were, in fact, cereal bars, whereas in the overall cereal market, standard cereal bars usually make up just 45% of the overall cereal market. In the United States, more than half of cereal bar launches were gluten-free, compared to the breakfast cereal aisle, where just over a quarter of breakfast cereal launches were gluten-free.

Gluten-free launches by major U.S. brands speak to the gains of this trend, including Kellogg’s Rice Krispies Gluten-Free, one of the first gluten-free cereal launches back in 2011. Kellogg’s more recently introduced a Special K Gluten-Free option. General Mills’ Chex cereals range offers seven out of eight lines gluten-free. The brand also recently extended into gluten-free oatmeal.

In the UK gluten-free market, mainstream market leaders also recently introduced gluten-free cereals. Nestlé’s Cereal Partners business launched Gluten-Free Corn Flakes in the summer of 2014, followed by a launch in Germany in early 2015. Rival Kellogg’s also joined the trend in early 2015 with its first “free from” offering in the UK: Gluten-Free Organic Puffed Corn Cereal. Further afield, Sanitarium launched a gluten-free version of its popular Weet-Bix cereal in Australia, made with sorghum.

**Snacks Market**
The snacks market is also seeing a relatively high proportion of gluten-free launches—approximately 11% of snack launches globally. In the United States, gluten-free snack launches are much more common—one-third of all snack launches are marketed as gluten-free.

The snacks market benefits from the fact that many basic snack ingredients such as potatoes, corn, soy, and nuts are naturally gluten-free, so it is a claim that is relatively easy to achieve in many instances. Gluten-free ingredients used to replace wheat or other cereals in the United States over the past few years include lentils, black beans, navy beans, cassava, brown rice, nuts, sweet potatoes, and a wide variety of other vegetables.

**Bakery**
Interestingly, despite being one of the product categories most strongly associated with wheat—and thus gluten—the bakery sector witnessed a lower-than-average percentage of gluten-free launches, at just over 7% of total global bakery launches recorded in 2014. Still, the actual number of gluten-free bakery launches has grown consistently in recent years. The largest number of gluten-free bakery launches were biscuits (more than 40% of total global bakery launches), ahead of bakery ingredients and mixes (30%) and bread and cakes (at just under 14% each).

As the gluten-free bakery market grows, more brands are shifting focus away from the specialty dietetic sector and onto the mainstream market—a move bolstered by companies’ ongoing quality improvements.
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Bakery brands are also undergoing ongoing consolidation. In the United States, Boulder Brands (formerly Smart Balance) has built up a portfolio of healthy, natural brands in recent years, acquiring a number of gluten-free specialists. The company acquired Glutino in 2011, followed by Udi’s in 2012. Both brands continued launching gluten-free bakery lines in 2014, including a new line of hearty gluten-free breads from Glutino and gluten-free dinner rolls from Udi’s. Udi’s gluten-free sandwich breads are also quite successful. Its ancient grain products, including Millet-Chia and Omega Flax & Fibre, are particularly popular with consumers, and the brand recently added gluten-free tortillas to its line. Boulder Brands also opened the largest gluten-free manufacturing facility in the United States in 2013, reflecting its ongoing commitment to the gluten-free market.

Another leading U.S. natural foods specialist, Hain Celestial, also extended its portfolio in 2014 with the purchase of Rudi’s Organic Bakery, an organic and gluten-free specialist. Under the Rudi’s Gluten-Free Bakery brand, the company offers natural breads, buns, pizza crusts, and tortillas certified by the Gluten-Free Certification Organization (GFCO).

More Opportunity
Consumers no longer cite gluten intolerance as the only reason they buy gluten-free foods. Their reasons now also include overall well-being, digestive health, weight management, and overall nutritional value. The field—and opportunities for food marketers—is widening, and with more-standardized labeling of gluten-free foods and the growing availability of high-quality products with a good sensory profile, the gluten-free sector continues to see big potential market.

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A market for gluten-free nutritional supplements exists and is growing. As awareness of and education around celiac disease, the autoimmune condition that causes ingested gluten protein to damage intestinal villi, grows, more individuals are diagnosed via blood test and subsequently prescribed a gluten-free diet. Many of these diagnosed individuals are also advised by clinicians to support their gluten-free diets with supplements to fill nutrient gaps specifically caused by removing gluten from the diet.

And beyond the current 1% of the U.S. population who are believed to have celiac disease, up to 6% of the general population may have non-celiac gluten sensitivity, says Jennifer North, vice president, National Foundation for Celiac Awareness (NFCA). These people would benefit from following a gluten-free diet and a corresponding supplementation regimen, as well.

A third group of what North refers to as "lifestyle eaters" are increasingly trying a gluten-free or reduced-gluten diet because of perceived health benefits or because they feel unwell and are experimenting with diet to try to solve the problem.

These groups combined make up a community of gluten-free consumers who present a distinct market for manufacturers and marketers of nutritional supplements.

Opportunities for Industry
Among the opportunities for supplement manufacturers, the first relates to the individual’s need for supplementation that comes with a new celiac disease diagnosis. Amy Jones, MS, RD, LD, chief clinical dietitian, Mary Rutan Hospital (Bellefontaine, OH), explains that those with celiac disease are "at risk for nutritional deficiencies at the time of diagnosis," which result from "poor absorption of nutrients related to the intestinal villi damage that is the hallmark of celiac disease. Of particular concern to patients," she says, "are calcium, folate, iron, B12, and vitamin D." Jones and North add that if a person has had undiagnosed celiac disease for many years, which is typical, "significant time and proper supplementation" may be required to correct the deficiencies. (See the sidebar on page 28 for more on this.)

Of course, a gluten-free diet requires that dietary supplements be gluten-free. “It is important,” Jones points out, “for patients to feel
confident that the supplementation not only provides the nutrition they need but is also free of gluten itself. I encourage my patients only to buy supplements specifically labeled "gluten-free."

**Gluten-Free Ingredients**

Supplements labeled "gluten-free" must comply with FDA’s rule regarding gluten-free labeling as of August 2014. This rule states, among other things, that the gluten-free label can apply only to foods and supplements that do not contain an ingredient that is: 1) a gluten-containing grain, 2) derived from a gluten-containing grain that has not been processed to remove gluten, or 3) derived from a gluten-containing grain that has been processed to remove gluten if the use of that ingredient results in the presence of 20 ppm or more gluten in the finished food or supplement.

With the growing gluten-free consumer base, North says, comes a huge responsibility for industry. “All of the starches and binders used in supplement manufacturing, anything that comes from a grain-based source, has the potential to be contaminated with a gluten-containing grain because of the way grains are produced and transported in the United States,” North warns. “And,” she adds, “even some non-grain ingredients carry risk. We were talking with a supplement manufacturer who told us its most gluten-contaminated incoming ingredient was orange peel, of all things.”

Increasingly, supplement manufacturers looking to sell to the gluten-free consumer community have options for sourcing gluten-free ingredients, particularly excipients. Lew Hendricks, technical service manager, calciums, at Innophos Inc. (Cranbury, NJ), says that demand for his company’s gluten-free excipients, including the calcium-phosphate–based A-TAB and DI-TAB, is steady, and that Innophos gets many customers asking for the company’s Gluten Free Statement (available at the Innophos website).

Susan Freers, technical manager, Grain Processing Corp. (Muscatine, IA), says there are “actually numerous gluten-free excipients” available for use in vitamin and mineral tablet and capsule formulations. These include maltodextrins, pregelatinized starches, modified starches, and corn-syrup starches. She adds that customer demand for gluten-free excipients has increased in the last five years.
to ten years, and that supplement formulators face fewer challenges than food manufacturers do in producing “totally gluten-free finished products,” as there are more gluten-free ingredient options available in general.

Jungbunzlauer Inc.’s market development manager, health & nutrition, Rocio Aramburo (based in Newton Center, MA), agrees with Freers that formulating gluten-free supplements is “not challenging” and that there is a wealth of ingredients from which to choose that are free of gluten and for which “cross-contamination is not an issue.” Aramburo points to Jungbunzlauer’s tricalcium citrate ingredient, TCC TB, as one such example.

Gluten-free supplement manufacturers must always proceed with caution. “So many variables occur throughout production,” North continues, “but when you market to the gluten-free community and you put gluten-free on your label, you have a responsibility to diligently track every incoming ingredient, to test throughout the production process, and to ensure that any co-manufacturers you are working with understand global food-safety principles and how gluten can impact the production process.”

North’s words aren’t just rhetoric. Gluten presence has historically been detected in products a shopper might reasonably expect to be gluten-free.

On the food side, a 2014 FDA-conducted study published in Food Chemistry, for instance, found that 19.4% of food products tested positive for gluten, in fact when in fact their ingredient labels, while not necessarily declaring “gluten-free,” did exclude wheat, rye, and barley from their ingredient lists. (On a brighter note, of the products that were labeled specifically as gluten-free, FDA testing happily found that an accurate 98.9% did in fact meet the legal definition.)

Turning specifically to dietary supplements, Columbia University (New York City) researchers recently disclosed at the 2015 Digestive Disease Week meeting in Washington, DC, that eight of the probiotic supplements the researchers tested that were labeled as gluten-free actually contained trace amounts of gluten. (The researchers said they tested probiotics specifically because an earlier study conducted by the same team found that probiotics are the most popular dietary supplement celiac disease patients chose to take to aid their symptoms.)

Commenting on these findings, the International Probiotics Association (IPA) released a statement noting that only one of the probiotic products in the study labeled gluten-free contained levels of gluten above FDA’s regulatory threshold of 20 ppm. The IPA also cautioned: “The detection of low levels of gluten using a more sensitive method, however, does not necessarily mean that products present any health risk to people with [celiac] disease. The authors of the study themselves acknowledged that
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there was no risk from the one product they found above the ‘gluten-free’ labeling limit, [noting] “It is unlikely that contaminated probiotics can lead to that amount [that causes intestinal damage] unless patients are ingesting mega-doses.”

The association said it is working with the researchers to “understand the findings and explore into more detail the results” and stated that manufacturers should adhere to accurate gluten-free labeling and use accredited labs and methods to test to ensure that contents remain below gluten-free labeling limits. It also noted the availability of certified ingredients. “Probiotic bacteria require complex growth media that contain a range of ingredients, but these can be controlled for the presence of gluten and other allergens,” it concluded.

Do It Right or Not at All
If there is a consensus most share, it is this. As NFCA’s North summarizes: “If a company wants to be of interest to gluten-free consumers, the bottom line is that they must test their products rigorously and make the gluten-free claim if they can. If they can’t consistently make the claim, then they shouldn’t, and they should train their customer service representatives to know why the claim is not being made.” Considering that the Columbia University researchers found in their initial study that up to 23.6% of 423 Celiac disease patients in the study took dietary supplements to address celiac symptoms, the message is that those with celiac disease are using supplements and need accurate gluten disclosures.

The roughly $10.5-billion gluten-free product market experienced growth of 44% from 2011 to 2013, according to NFCA and market-research group Mintel, and is expected to see growth of 48% through 2016, when sales are forecast to total $15.6 billion. As the gluten-free market grows, successfully and responsibly seizing these opportunities will require industry to invest the time, effort, and resources needed to formulate, manufacture, and market truly gluten-free products that meet the dietary needs of the gluten-free community as well as consumer demand for trustworthiness, transparency, and regulatory compliance.

Maureen Kingsley is a freelance writer, editor, and proofreader based in Los Angeles. She covers a variety of industries, including medical technology, food-ingredient manufacturing, and cinematography.

References
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Gluten is so useful and pervasive that finding suitable substitutes is “very difficult,” Shelke says.

She then suggests addressing each aspect of the gluten-based ingredient individually “and in concert with the other ingredients” before proceeding.

Food science is making steady progress in the gluten-free realm, but challenges remain. Here are four significant hurdles.

**Matching Gluten’s Functionality**
The unique structure of gluten aids in leavening retention and, therefore, creates “the perfect crumb, texture, and volume,” Shelke explains. It also provides the chewiness of breads. Current gluten substitutes do not yet produce dough that matches wheat-flour dough; gluten-free doughs are more batter-like and lack viscosity and elasticity. The result is gluten-free baked goods that don’t yet match the body, crumb, texture, and deliciousness of gluten-based products.

**Ensuring Long Shelf-Life**
Gluten protein provides management and retention of moisture and a relatively long shelf-life. Currently, gluten-free products tend to go stale much more quickly and demonstrate shorter shelf-lives. Upping moisture retention and shelf-life are difficult goals for gluten-free food producers to meet, but their development teams are urged to keep trying.

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of wheat," Shelke contends. Wheat’s nutrients—particularly found in whole-wheat flour—include B vitamins, iron, calcium, vitamin D, vitamin E, fiber, protein, and such minerals as magnesium, copper, and zinc. "People who are on gluten-free diets,“ Shelke says, "especially children, are vulnerable to nutrient deficiencies." The refined starches of gluten-free favorites potato and rice flour can also cause blood sugar issues in consumers: the higher glycemic indices of these substitutes can produce greater spikes in blood sugar than certain wheat products do.

Meeting Eating Quality and Taste Expectations
While these characteristics of gluten-free processed foods are improving as food science advances, wheat is "still without comparison" with regard to deliciousness and eating pleasure, Shelke states. She says that successful and tasty gluten-free alternatives must provide the functional, nutritional, aesthetic, and economic qualities that gluten provides in processed foods.

For example, when making a gluten-free cookie, the product developer must first identify the roles played by the gluten-based ingredient: structure and control of spread. Then, potential substitutions must be found and tried both individually and in combination with other ingredients to create structure in and control spread of the cookie—keeping in mind that cookies are almost always one-third flour, one-third shortening, and one-third sugar plus water.

In this example, the cookie developer must then ensure the spread is consistent and uniform and adjust protein and sugars to bring about the right color. Finally, Shelke says, the level of fat must be tweaked to create an acceptable texture.

Most gluten-free doughs still don’t match wheat-flour dough. The dough is often more batter-like and lacks viscosity and elasticity.
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Enzymes: Safe for Celiacs?

As gluten-free dieters seek enzymes for digestive support, one question remains: Are enzymes derived from gluten-containing sources truly gluten-free?

BY MELISSA KVIDAHL

Scan the shelves of any grocery store, and it quickly becomes obvious that gluten-free foods have stepped out of the specialty realm and into the commonplace. According to new data from Packaged Facts, sales of gluten-free products grew 34% annually in the years leading up to 2014, reaching $973 million in that year alone. By 2019, it is expected that total sales will reach $2.34 billion. And the audience is as wide as the product selection.

According to the National Foundation for Celiac Awareness, just 1% of Americans have celiac disease, a chronic autoimmune disease that leads to small intestine damage, an inability to absorb nutrients, and other health issues when gluten protein is consumed. But about six times that amount suffer from gluten sensitivity—that’s 18 million Americans who test negative for celiac disease but still experience discomfort when they consume gluten. Still others have wheat allergies. And that’s not to mention the scores of trend watchers who have no physical aversion to gluten, but seek out a gluten-free diet for perceived health benefits.

Indeed, gluten is having its moment in the limelight. And since gluten intolerance, in its various forms, causes unpleasant digestive symptoms like cramping, constipation, and diarrhea, digestive enzymes are often sought for relief. Of course, a major concern for formulators and consumers, then, is ensuring that these enzyme products are also gluten-free.

The good news, according to Tony Pavel, general counsel and secretary of the Enzyme Technical Association, is that enzymes do not typically present such a challenge. “Enzyme proteins themselves do not contain a gluten constituent,” he declares.

“Enzymes are produced from microbial fermentation,” agrees Scott Ravech, CEO of Deerland Enzymes (Kennesaw, GA), “and the nutrient media used to feed these microorganisms may contain minimal amounts of protein from gluten-containing sources.”

But according to Ravech, even this is rarely an issue that affects a product’s final gluten status, and for many reasons. First, he explains, the protein source used—in this case, the gluten-containing source—is generally the most expensive of the macronutrients contained in the media, so its level of use is tightly controlled—and, regardless, it is consumed by the organism during fermentation. “It is the intent of the manufacturer that these raw materials are added to the fermentation as food to be consumed by the microorganism,” adds Pavel, “and are not added as formulation ingredients of the final commercial product.” Adding them as formulation ingredients in larger quantities could, of course, compromise gluten-free status.

But even if the substrate is not gluten-free, the enzyme resulting from the overall process often is, says Ravech, because the insoluble media at the end of the process is filtered out, leaving only a very small amount post-filtration. “Following fermentation,” explains Pavel, “the enzymes are subject to recovery where they are further separated and filtered to remove the production organisms and fermentation materials/growth substrate from the final enzyme preparation.”

“It is through the combined processes of microbial consumption and digestion, separation, and filtration that any gluten-containing source’s starting material is processed such that the final enzyme product contains gluten at less than the 20 ppm threshold required to allow gluten-free labeling,” concludes Ravech. “The good news is that even many enzymes that use small amounts of gluten in the fermentation media will, in many cases, still yield a final product well below the 20 ppm level needed to claim gluten-free.”

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

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Clean Label

Everyone’s doing it.

By Kimberly J. Decker

The biggest names in food are committing to clean label these days.

In February, Nestlé USA announced that it will banish artificial colors and flavors from its chocolate candies and Nesquik powdered drink mixes. Hershey soon thereafter said it aims to reformulate all its candies to contain “ingredients that are simple and easy to understand.” Then Kraft committed itself to replacing synthetic colorants in its flagship Macaroni and Cheese with colors derived from spices like paprika, annatto, and turmeric. PepsiCo got into the act by pledging to swap out aspartame, the artificial sweetener in its Diet Pepsi, with the equally artificial, but apparently more acceptable, sucralose. Even quick-service giant McDonald’s announced that it will no longer serve chicken treated with human antibiotics, while more obviously progressive foodservice brands Chipotle Mexican Grill and Panera Bread made headlines by, in the former’s case, banning genetically modified (GMO) ingredients from its menus and, in the latter’s, releasing a “No-No List” of ingredients that the chain will phase out of its kitchens by the end of 2016.

Those are starring examples of what experts predict will be the product development imperative of our age, both for mainstream and small brands alike.

As the clean-label movement creates both opportunities and challenges for suppliers and retailers, the food industry’s ability “to help influence and educate consumers will be pivotal when it comes to how clean label ultimately gets defined” and implemented, says Barb Murphy, director, marketing communications and market insights, Corbion Caravan (Lenexa, KS).

Driving the Discussion

The rise of the clean label comes as no surprise to Angelina De Castro. “We’ve seen a fundamental shift in the food industry toward simpler ingredients,” says the senior manager, marketing, Wholesome, Ingredion Inc. (Westchester, IL). “This is no longer only relevant for natural or organic brands, but includes major consumer brands.”

Michael Swenson, director of business development, Sensient Natural Ingredients (Turlock, CA), agrees, noting that the clean-label question “is now a part of every customer-supplier dialogue.” He traces the public’s awakening to journalists like Michael Pollan, whose books The Omnivore’s Dilemma, In Defense of Food, and Food Rules give readers simple strategies for eating wisely, such as “If you can’t say it, don’t eat it” and “No more than five ingredients per label.” But Pollan’s voice isn’t alone. “There are many other individuals, food manufacturers, and retail chains that participate in the discussions,” Swenson notes.

Thanks to social media, “a single consumer advocate or blogger can have tremendous influence on consumers, suppliers, and manufacturers,” Murphy says. (We’re looking at you, Food Babe.) “While the information isn’t always accurate,” Murphy notes, “it does reach a wide audience and has proven to be a source of leverage to promote change—good or bad.”

What Clean Means

No change would get off the ground, however, were shoppers not hungry for it in the first place. Which is why De Castro believes that clean labeling “is strongly driven by consumers, who are paying more attention to ingredient lists and dietary habits.” The challenge for manufacturers, retailers, and consumers, she says, “will be in determining what defines a product as clean label.”

That’s a question weighing on the minds of everyone—except, it appears, regulators.
at FDA, the USDA, and local agriculture departments, who, as far as Thom King, CEO and president, Steviva Ingredients (Portland, OR), can tell, "haven't guided us on any definition of clean label." Rather, he observes, "The actual definition of clean label is a bit of an enigma, not unlike 'natural.'"

That leaves manufacturers casting about for some sort of lodestar to direct their reformulations. Not infrequently, the one they follow "is associated with short ingredient lists and minimally processed ingredients that might be found in an average kitchen cupboard," says Nicole Rees, business development manager, Glanbia Nutritionals Ingredient Technologies (Fitchburg, WI).

A consequence has been that clean labels often resemble liberated ones, trumpeting their "freedom" from whatever ingredients their audience rejects. Indeed, says De Castro, "Free from" is one of the most common clean-label front-of-pack claims. She cites the 2013 Natural Study by Health Focus International as finding that the majority of shoppers link "natural" to what's left out of a product, "explaining why "free from" claims strongly resonate with consumers," she says.

GMO-free serves as a "purity" attribute that also signals a label's cleanliness, with GMO-free new-product launches in 2014 tripling their 2012 level, per the Mintel Global New Products Database, De Castro points out. Clean can signal transparency and sustainability, too, which are major selling points for Millennials and younger teenagers, Rees says. "These generations ask what manufacturers mean by 'pasture raised,' 'humane,' 'cage free,' and 'grass fed,' and they want to understand the implications behind their choices," she notes. In that spirit, Swenson adds, suppliers like his company base their standard not just on being clean label, but on being clean conscience. He says, "Our labels and documentation show that our products are free of chemicals, clear on the origin, clear on all the tests done and the results obtained and even on the test methods used."

Nevertheless, industry is still trying to pin the tail on the clean-label donkey. And until we do, De Castro points to an interim definition that her company developed in 2010.
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Fortification makes it that much harder to keep labels clean, especially for beverages, because some nutrients like hydrophobic amino acids require emulsifiers and stabilizers to promote dispersion.

Better Baking

Another category where titanium dioxide makes an appearance is bakery, the entirety of which is undergoing some serious clean-label reevaluations. Top candidates for elimination include synthetic dyes and the partially hydrogenated oils that contribute trans fats, as well as plenty of functional aids that, though indispensable in doughs and batters, are roundly unwelcome on labels. With names like potassium bromate, azodicarbonamide (ADA), calcium peroxide, potassium iodate, L-cysteine, and SSL (sodium stearoyl-2-lactylate), CSL (calcium stearoyl-2-lactylate), and DATEM (diacetyl tartaric acid ester of mono- and diglycerides), it’s easy to see why. But chemophobia aside, such ingredients make commercial baking possible.

For example, potassium bromate, calcium peroxide, potassium iodate, and ADA—the last much in the news as the “yoga mat” ingredient previously in Subway sandwich bread—are all oxidizing agents that strengthen dough and increase its tolerance to processing and natural variations in flour quality. L-cysteine is a reducing agent that not only makes dough more extensible—preventing “snap back” in pizza crusts, for instance—but shortens mix times, too. As for SSL, CSL, and DATEM, they’re all emulsifiers that strengthen dough, improve its machinability, and make the finished bread softer.

Murphy says that Corbion Caravan has developed enzyme technologies to help bakers replace these additives without losing valuable functionality. And while the technologies represent a step forward, she concedes that fully scrapping all bakery formulations of “chemicals” without sacrificing functionality remains a work in progress. “While the solutions we have now can reduce the use of strengthening emulsifiers and replace ‘chemicals,’ she says, ‘they’re not able to replace strengthening emulsifiers completely in some whole-grain bread applications. We’re still working to make them even more effective and close the gap between our current clean-label solutions and strengthening emulsifiers.”

In the meantime, baking operations might want to investigate the milled flax ingredients that Glanbia Nutritional offers as “natural” alternatives to emulsifiers, modified starches, and gums. The ingredients “not
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only provide freeze/thaw stability in frozen doughs, batters, and fully baked products,” Rees says, “but manage moisture and mimic the softness and functionality of mono- and diglycerides and other emulsifiers used for texture.”

**Clean Sweetening**

There’s been a mad dash in bakery to clean up sweetener options, too, with high-fructose corn syrup (HFCS) a key sugar that manufacturers hope to remove. Formulators are cutting sugar contents across the board in an attempt to reduce calories, and though that’s traditionally meant reformulating with high-intensity non-nutritive sweeteners, consumer resistance to these “artificial” options is mounting.

“Sugar has the biggest negative dietary impact of all ingredients,” Steviva’s King points out. “Approximately 13% of adults’ total caloric intake comes from added sugars. Thus, more and more food scientists are coming to us inquiring how they can achieve clean-label sugar reduction.” The alternatives that his company offers to sweeteners like sucrose, acesulfame potassium, and aspartame include monk fruit extracts, polyols, inulin, non-GMO crystalline fructose and, the big attention-getter these days, stevia.

But despite being a “natural” high-intensity sweetener, stevia has its drawbacks.

“The key challenge in replacing sugar with high-intensity sweeteners has been to deliver a sweetness profile similar to sucrose,” says Kasi Sundaresan, PhD, senior associate, global sweetener development at Ingredion. For example, a 7%-12% sucrose equivalent would be the target in, say, a beverage formulation, she says, “but some of the challenges of working with stevia are that it has a bitter aftertaste and lingering sweetness.
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that becomes more apparent above 6% sugar equivalence."

To get around this roadblock, especially in beverages, she advises aiming for sugar reduction over replacement, which allows formulators to use nutritive sweeteners like sucrose, fructose, or dextrose in conjunction with stevia. If a zero-calorie beverage is a must, “Formulators can add erythritol at a max level of 3.5% to get a 2.4% sweetness equivalent along with stevia to reach the 7%-12% sweetness-equivalent target,” she explains. And as a bonus, erythritol provides bulk and “rounds out” the taste, altering sweetness onset and reducing off notes.

Another stevia companion that boosts sweetness and supplies bulk is monk fruit, Sundaresan continues, adding that blending acids like citric, lactic, tartaric, and malic can balance a stevia-sweetened beverage flavor. “And certain flavors and sweetness enhancers are often used along with stevia for masking off notes and boosting sweetness intensity to give a more sugar-like experience,” she says. (Read more about natural-sweetener blends on page 58.)

Some clean-label ingredient solutions are still a work in progress, such as replacing strengthening emulsifiers completely in whole-grain bread.

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But cleaning up beverages involves swapping out more than just artificial sweeteners. Consider ingredients like brominated vegetable oil (BVO), ester gum, and sucrose acetoisobutyrate (SAIB), all weighting agents that stabilize oil-in-water emulsions, like those that occur in beverages flavored or colored with oil-soluble ingredients. Weighting agents are especially useful “when the emulsifier, like modified starch or gum arabic, doesn’t adequately provide the stabilization the beverage needs,” says Dinah Diaz, senior marketing manager, delivery systems, Ingredion. “So with the trend toward delivering natural colors, the use of natural emulsifiers is becoming ever more important.”

Her company produces a clean-label emulsifier—tapping the sustainably grown Chilean Quillaja saponaria tree as its source—that not only eliminates the need for BVO, SAIB, or ester gum, but has a low-enough viscosity to permit the creation of high-load oil emulsions, Diaz says. “Another area where we offer cleaner-label solutions is with foaming stabilizing agents such as propylene glycol alginites, or PGA, which have traditionally been used in beverages,” she continues. They source the line of natural foaming agents from two plants: again, the quillaja tree and Yucca schidigera.

Glanbia’s Rees adds that fortification makes it that much harder to keep functional labels clean—especially on beverages—as some nutrients, like hydrophobic amino acids, require emulsifiers and stabilizers to promote dispersion. “To overcome this, our sports-nutrition scientists have developed a patent-pending process that uses multifunctional ingredients, such as dairy proteins, to deliver these hydrophobic amino acids in soluble form,” she says. The ingredient system “binds specific amino acids—leucine, for example—to whey peptides for improved utilization, a palatable mouthfeel, and a clean label.”

All of this is good news for consumers and product developers alike looking to join the clean-label crowd. For, Rees says, “As the market continues to demand shorter ingredient lists and recognizable, kitchen-cupboard-style ingredients, products that combine great taste and convenience with clean-label appeal are set for success.”

“With the trend toward delivering natural colors, the use of natural emulsifiers is becoming ever more important,” says Ingredion’s Diaz.
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Clean-Label Gums 101

Hydrocolloids are critical to food manufacturers. Which are clean label?

BY KIMBERLY J. DECKER

The biggest challenge with clean-label formulating always comes down to this, says Marshall Fong, consumer insights director, FMC Health and Nutrition (Philadelphia): "Manufacturers must balance consumer preference for healthier foods and beverages with consumer desire for the same taste, texture, and satisfaction they’ve come to expect."

Fortunately, gums, or hydrocolloids, help food formulators strike that balance. They’re staples across the food and beverage spectrum but are especially handy in functional products, where formulators can use them to reduce salt, fat, and sugar, as well as to add vitamins and minerals—all while maintaining product stability, texture, and appearance, Fong says.

Take shelf-stable fortified drinks such as protein shakes and non-dairy milks. These are stars in the functional-beverage firmament, but "the addition of vitamins and minerals can create challenges related to solid-particle suspension and protein interactions that result in stability defects," Fong explains. "Hydrocolloid stabilization systems can provide structure to minimize or eliminate the settling of solid particles and create uniformity so that high-protein beverages remain both appealing and nutritious."

Hydrocolloids also bind moisture, generate viscosity, impede ice crystallization, improve mouthfeel, emulsify, gel—not bad for one family of ingredients. But are they clean?

That depends.

"When there’s not a true standard for natural and clean-label products, it’s hard to qualify which [hydrocolloids] are considered clean label," says Janae Kuc, research and development manager, Gum Technology, a business unit of Penford Food Ingredients (Tucson, AZ). Many hydrocolloids come from natural sources such as seaweed, tree and seed pods, or tubers, which surely increases their clean-label cred, but some also undergo chemical modifications that turn off tougher clean-label customers, she says.

While formulators must take consumers’ clean-label concerns seriously, "above all, we want to affirm the safety and importance of ingredients like hydrocolloids," Fong says. Working with suppliers, formulators can then determine which ingredients will work in their products to create healthier formulations that appeal to customers, and—most importantly—taste good. The following are label-friendly options to get you started.

Pectins

"In general, consumers have a high comfort level with ingredients like pectin," says Andrea Peck Moeller, technical specialist, Cargill Texturizing Solutions (Plymouth, MN). Found primarily in the cell walls of citrus fruits, pears, apples, plums, and more, the polysaccharide is "an ingredient [consumers] may have in their own kitchens, and they understand its role in foods like jams and jellies," where it’s an unbeatable gelling agent.

Carrageenans

Carrageenans—polysaccharides extracted from edible red seaweed—are not without controversy, as some studies associate their degraded form with inflammation. But authorities ranging from FDA and...
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USDA’s National Organic Program to the European Food Safety Authority and a Joint FAO/WHO expert committee on food additives all bless the use of carrageenans in foods, where they’re “natural partners with proteins,” Peck Moeller says. For example? “They help suspend the cocoa in chocolate milk,” she says.

Alginates
Like carrageenans, alginates are also seaweed extracts, although their source is brown seaweed found in abundance off the French coast. Widely used as natural stabilizers, thickeners, and gelling agents, alginates improve the texture of baked goods and the consistency of crème fillings and dairy items like ice cream, custards, and spreads. They even help stabilize processed deli meats and restructured seafood products.

Locust Bean Gum
Locust bean gum is a galactomannan extracted from the seeds of the carob tree—hence its alias, carob gum. LBG for short, it’s “an effective thickener and water-binding agent and is often used in combination with other gums to help minimize water separation in fruit preparations used in yogurts,” Peck Moeller says. Being dispersible in cold and hot water increases its processing appeal, and in addition to human foods, it also shows up in pet foods, paper products, and cosmetics.

Gum Arabic
“There are multiple variations of hydrocolloids that have been minimally processed, such as gum arabic,” says Gum Technology’s Kuc. In fact, gum arabic has a long history in Africa and the Middle East where it’s still harvested as a sap from acacia trees. (It’s also called acacia gum.) By any name, this complex of polysaccharides and glycoproteins is an effective clean-label texturizer and emulsifier in frostings, confections, chewing gum, and beyond.

Cellulose Gum
As far as hydrocolloids go, you can’t get much “cleaner” than cellulose, which “is found in every plant on the planet,” says FMC’s Fong. Turning it into a functional hydrocolloid is "just a matter of using technologies to harvest it and develop customized formulations for unique applications," he says. But be mindful of which cellulose gum you choose, as chemically modified forms like sodium carboxymethyl cellulose may not pass muster with clean-label watchdogs.

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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Health appeal may be a big growth driver in the natural sweeteners market, but taste still triumphs. One of the greatest hurdles for any alternative sweetener to clear is replicating the taste and texture of table sugar that consumers have come to expect. But the fastest-growing natural sweetener on the U.S. market—coconut sugar—may be ideally suited to do just that.

Coconut sugar still holds only a fraction of the sweetener market when compared with stevia, the reigning natural sweetener champ. However, the U.S. market for coconut palm sweeteners has more than doubled in the last year, currently sitting at a little over $22 million, according to SPINS (Schaumburg, IL). By comparison, the market for stevia grew 12.3% in the last year to reach nearly $430 million, and the market for blends of stevia and other artificial sweeteners grew 1.5% to reach nearly $452 million. (Data as of March 22, 2015.)

So how did coconut palm sugar grow 100.4% in one year? A low glycemic index and environmental sustainability are part of the attraction, but the real kicker may be how well coconut sugar substitutes for traditional cane sugar.

**An Ideal Sugar Substitute**

Sourced from the dried nectar of flower blossoms at the top of coconut palm trees, coconut sugar is being billed as a healthier alternative to table sugar, especially for people with diabetes or other health conditions related to blood sugar. Although coconut sugar’s glycemic index range of 35-40 is higher than stevia’s score of 0, it’s still considerably lower than table sugar’s index in the mid-to-high 60s.

The Food and Nutrition Research Institute of the Philippines also found that “unlike processed white sugar, coconut sugar may also contain trace amounts of iron, protein, and vitamin C,” says Dave Rosenberg, food category manager, NOW Foods (Bloomdale, IL). Other coconut sugar purveyors also mention amino acids, potassium, magnesium, zinc, B vitamins, and more as part of coconut sugar’s nutritional profile.

But coconut sugar’s big draw may have less to do with how it differs from cane sugar and more to do with the similarities—specifically, its taste and behavior in formulations.

“The top advantage over many other sweetener alternatives is that in recipes [coconut sugar] behaves just like the bleached cane sugar that people are seeking to replace,” says Mic LeBel, communications manager for coconut sugar retailer Navitas Naturals (Novato, CA). “You can enjoy coconut palm sugar as a 1:1 replacement for cane, and it melts, blends, and generally sweetens in a similar manner and intensity. Therefore, it’s easy for people to adapt to.”

Rosenberg describes coconut sugar as having a “mild caramel flavor and a light coconut aroma” that is similar to brown sugar.

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Sweeteners

He adds that coconut sugar is more versatile than date sugar, maple sugar, and sugar alcohols, as well as liquid sweeteners such as honey and agave syrup.

"Its granular consistency, mild flavor, and light aroma make it easier to work with than many stronger-tasting and darker-colored natural sweeteners," says Rosenberg.

Based on a strong flavor profile—especially its 1:1 replacement potential with cane sugar—coconut sugar’s formulating convenience may well be one factor driving the recent growth.

Sweetening Sustainably

Coconut sugar’s low environmental impact is another element in its favor. According to the website of coconut sugar supplier Big Tree Farms (Ashland, OR), "coconut sugar is considered one of the, if not the most, sustainable sweeteners in the world."

Compared to sugar cane, coconut palm trees require less water, produce more per acre, and support multi-cropping of other coconut products, says Frederick Schilling, cofounder and co-CEO, Big Tree Farms. Coconut palms produce 50%–75% more sugar per acre than sugar cane on average, according to Big Tree Farms.

Slow Production Process

There are, however, a few obstacles to coconut sugar’s ongoing ascent. Environmentally conscious consumers may be happy to hear that coconut sugar is not produced through a mechanized process that pollutes the environment, but the lack of mechanization also slows down production.

"Collecting the flower blossom nectar from the crowns of the coconut trees is very labor intensive, as farmers must climb each tree at least twice a day to collect the fresh nectar," says Schilling. "It is a process that cannot be mechanized. It is harvested the same way it has been for thousands of years."

According to another coconut supplier, Tradin Organic (Amsterdam), its coconut nectar is sieved and boiled for four hours after being collected, with coconut oil added to achieve the right consistency and color. The sugar is then stirred until it becomes dry and granular, before moving on to final processing.

Perhaps as a result of that labor-intensive process, as well as the rapid growth in demand, the market’s supply of coconut sugar has been stretched a little thin. According to Christina Franken, marketing manager, Tradin Organic, the lack of availability of coconut sugar remains a challenge.

And, of course, what about the cost of formulating with coconut sugar compared to other sweeteners?

Franken says coconut sugar is priced a bit higher than alternatives like sugar cane and beet sugar, but in the same price range as many organic syrup sweeteners. For instance, coconut sugar is slightly more expensive than agave, but lower than maple, according to Franken.

Yet, despite the challenges, the booming market suggests there’s definitely an appetite for coconut sugar.\[\]
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IT’S IN THE DETAILS.
Finding the Sweet Spot
Creating the right alternative sweetener blend isn’t a piece of cake.

BY MICHAEL CRANE, ASSOCIATE EDITOR

With everyone, from the World Health Organization to U.S. First Lady Michelle Obama, stressing the perils of a high-sugar diet, alternative sweetener ingredients might seem like an easy sell. But finding the right alternative sweetener blend to replace sugar is no simple feat. Even stevia, the dominant natural sweetener on the U.S. market, has limitations that for years many formulators have strived to offset with precise blends of other sweetener ingredients. And when the goal is for sweetener alternatives to behave just like sugar in a variety of product types, there is no one-size-fits-all solution.

Beyond just balancing low-calorie priorities, formulators also have to consider the taste impact of different sweeteners and the way ingredients function in formulation. But with SPINS reporting that the market for blends of stevia and other sweetener ingredients is currently valued at more than $452 million and growing, the effort is well worth it.

“Too much stevia will impart a bitter aftertaste; too little will result in a final product that is not quite sweet enough,” says Thom King, president and CEO, Steviva Ingredients (Portland, OR), in reference to stevia/erythritol pairings. He adds that including nutritive sweeteners such as fructose, agave, or sucrose may be necessary if the product needs to undergo Maillard browning and caramelization, such as in baked goods.

Blends Do It Better
Despite the incredible growth of the stevia market since the ingredient first achieved GRAS status in 2008, stevia still often needs to be combined with erythritol, monk fruit, agave nectar, or even sucrose to avoid an unpleasant aftertaste. Even with these combinations, it still takes a careful balance to get the right effect.

“Too much stevia will impart a bitter aftertaste; too little will result in a final product that is not quite sweet enough,” says King.
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Monk fruit is another zero-calorie option to consider in sweetener blends, but it can introduce bitterness and a loss of volume in recipes because it is a high-intensity sweetener, says Steviva’s King. However, Steviva has discovered that its blend of stevia, monk fruit, and erythritol—MonkSweet Plus—delivers an ideal balance of taste and volume.

“‘We have found that the combination of stevia and monk fruit with erythritol—or even a combination thereof with nutritive sweeteners—works amazingly well since the monk fruit and stevia mask each other’s off notes,” says King. He adds that the erythritol also makes up for some lost volume because it is a lower-intensity sweetener. Launched last October, MonkSweet Plus is already on pace to be Steviva’s most popular sweetener by the end of this year, says King.

If a few more calories are permissible in a product, then blending stevia with nutritive sweeteners offers additional benefits to certain recipes.

“Utilizing nutritive sweeteners such as honey and agave are good options when the system can allow the calories and traditional floral or sweet brown flavor attributes that accompany those types of sweeteners,” says Ingredion’s Berzins. High-fructose corn syrup and sucrose are also being blended with stevia in recent carbonated soft drink launches, says Berzins, but at the price of a higher calorie count.

That’s where the real balancing act takes place—deciding how to reconcile taste, texture, calorie count, and ingredient perception in a sweetener blend.

“It has been our experience that taste is the most important factor in consumer preference, followed by ingredient preference,” says Steviva’s King. “There is a small segment that has rejected alcohol sugars, just as there is a segment that rejects fructose in any form. Being all things to all people is a hard niche to fill. This is why we offer a vast variety of ingredients that can address our customers’ needs for the mark they target.”

But “natural” appeal is also a big draw, says Carolyn Clark, global senior marketing manager for PureCircle (Oak Brook, IL).

“Our research consistently shows a desire for consumers to move towards more natural products and ingredients,” says Clark. “While some consumers are willing to limit the amount of caloric sweeteners they consume, most want a broader range of natural options that don’t compromise on taste.”

She adds that this interest in natural products is also pushing stevia-blend formulation into new categories such as dairy.

The bottom line when hunting for an alternative to sugar? A diverse portfolio of sweetener blends makes many applications possible.

References

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Blood sugar support

Postprandial Power

Fenugreek and chitosan take on blood sugar in new research.

BY IRFAN QURESHI, ND

Researchers estimate that by the year 2050, one in five adults globally will be diabetic.1 According to the latest U.S. Centers for Disease Control statistics published in the 2014 National Diabetes Statistics Report, more than 29 million Americans—9.3% of the U.S. population—already have diabetes.2 Even more staggering, more than 86 million American adults—more than one in three adults—have prediabetes, a condition in which fasting glucose or glycosylated hemoglobin (HbA1c) levels are high but don’t quite yet meet the criteria for diabetes.3

These numbers are more than alarming. Diabetes is a significant risk factor for many disease conditions. In the realm of blood vessel health, people with diabetes are at increased risk of vascular dysfunction and artery calcification. Emerging research indicates that individuals with prediabetes are at increased risk for heart disease, as well. A recently published study led by Valmore Bermudez and colleagues from Spain and Venezuela analyzing data from 1,378 subjects included in the Maracaibo City Metabolic Syndrome Prevalence Study found increased coronary risk in individuals with impaired levels of fasting glucose.1 The authors also point to further research showing that restoration of normal blood sugar levels in prediabetic individuals reduces risk of heart disease.1

Blood sugar and insulin regulation determine other health parameters, as well. Take cognitive function. Recent studies suggest those with insulin resistance and impaired glucose balance are at higher risk for the development and progression of brain health issues, including Alzheimer’s disease.2 An interesting line of current research for Alzheimer’s prevention involves testing therapies that normalize blood sugar and insulin function.

An additional significant risk factor associated with poorly regulated blood sugar levels is the occurrence of post-meal sugar spikes, or postprandial hyperglycemia. This is a significant elevation of blood sugar shortly after food intake that the body is incapable of lowering in a short amount of time because of insulin resistance.

Studies suggest that postprandial hyperglycemia significantly affects overall blood sugar control, as indicated by its influence on HbA1c levels. HbA1c is a common measurement that provides a snapshot of average blood glucose control over the prior three months. A recent investigation by Xin Kang and colleagues from Sichuan University in Chengdu, China, found that, in people with mildly elevated blood sugar levels, the contribution of postprandial blood sugar spikes to HbA1c readings can be upwards of 50%.3 Furthermore, studies indicate that post-meal sugar spikes are an independent risk factor for atherosclerosis and significantly contribute to vascular endothelial cell damage, even more so than constantly elevated blood sugar.4

Given all of the risks associated with unhealthy blood sugar levels, managing the risks through dietary and lifestyle interventions not only makes sense but is necessary. In 2012 alone, the direct medical costs for diabetes amounted to an estimated $176 billion,2 further highlighting the need for preventive strategies, including a healthy diet and lifestyle. Safer alternative therapies are also required, as many of the conventional approaches carry the risk of significant side effects. In this realm, herbs and other natural ingredients continue to shine and show their promise as effective measures for blood sugar management and for blunting dangerous post-meal blood sugar spikes, offering both therapeutic and preventive benefits for diabetes and prediabetes.

Two such natural ingredients highlighted in recent research include the herb fenugreek and low-molecular-weight chitosan.

Fenugreek

Fenugreek (Trigonella foenum-graecum) is a culinary herb with wide use in India, China, and the Middle East. It has garnered traditional notoriety as an herb that lowers blood sugar levels, and it offers other health benefits. The seeds are rich in fiber and contain several active compounds, including saponins, diox-
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Blood Sugar Support

Recent research into the mechanism of action of diosgenin, a steroid sapogenin contained in fenugreek, yields interesting insights.

In a meta-analysis reviewing evidence from human trials on the effect of fenugreek seeds on parameters of blood sugar control, Nithya Neelakantan and colleagues from the National University of Singapore concluded that clinical trials support the benefits of fenugreek seeds for glycemic control. Their analysis consisted of 10 clinical trials comparing single-herb preparations of fenugreek with placebo or no treatment and included trials evaluating its effects on fasting blood glucose levels, two-hour postprandial glucose levels, HbA1c, or fasting serum insulin levels. In terms of fasting blood sugar levels, the results of the meta-analysis revealed that, on average, a decrease of 0.96 mmol/l (~18 mg/dl) was seen in groups treated with fenugreek as compared to control. The authors also noted a dose-dependent effect of fenugreek, as the amount administered in the studies reviewed varied significantly. The studies using doses greater than 5 g showed the most significant effects on fasting blood sugar levels.

With regard to two-hour postprandial levels of blood sugar, the average reduction from the trials was 2.19 mmol/l (or nearly 40 mg/dl) with fenugreek. Furthermore, three of the 10 studies reported reductions in HbA1c levels with fenugreek that averaged 0.85% compared with control treatments. The authors concluded that, while additional larger studies are required to validate these results, fenugreek is a promising complementary option for the clinical management of diabetes.

Researchers from Universiti Sains Malaysia in Kelantan, Malaysia, led by Sathyasurya Daniel Robert, conducted a study to determine the effect of fenugreek on postprandial blood sugar response. Fourteen overweight or obese individuals were included in the trial and were studied following overnight fasts on four separate occasions. The participants were given 50-g carbohydrate portions of white bread and jam or fried rice, both with and without 5.5 g of fenugreek. Their blood sugar responses were monitored for two hours.
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Blood Sugar Support

hours. The results of the study showed that incorporation of fenugreek seed powder in the test foods blunted the surge in postprandial blood sugar levels and increased satiety in the subjects. Reductions of 14.4 mg/dl and 27 mg/dl were noted at 45 and 60 minutes after consumption of the white bread/jam plus fenugreek combination as compared to the white bread and jam alone, indicating the ability of fenugreek to significantly lower postprandial blood sugar spikes.

Fenugreek contains multiple compounds with blood sugar–lowering potential, including saponins and fiber. However, some recent research into the mechanism of action of diosgenin, a steroid sapogenin contained in fenugreek, has yielded some interesting insights. In the first study, diabetic rats fed a high-fat diet for 30 days were also administered diosgenin. Treatment with diosgenin was found to significantly reduce the increase in body weight seen in the same rats not given diosgenin. In addition, diosgenin significantly normalized the elevated blood sugar levels and elevated insulin levels, while reducing insulin resistance, all of which are hallmarks in diabetic rats.

A second study, also in diabetic rats, looked at the effects of diosgenin on certain key carbohydrate metabolic enzymes that impact the body’s ability to regulate blood sugar control. In the study, the administration of diosgenin led to substantial decreases in blood sugar and increases in insulin levels in the diabetic rats. The researchers found that diosgenin increased the activity of hexokinase, leading to increased glycolysis (the breakdown of glucose to pyruvate ultimately used in energy production). Diosgenin also led to decreased activity of glucose-6-phosphatase and fructose-1,6-bisphosphatase, leading to lowered blood sugar levels. By modulating these important metabolic enzymes, key compounds in fenugreek are able to support healthy blood sugar metabolism.

Low-Molecular-Weight Chitosan

Chitosan is a polysaccharide derived from chitin, the material that comprises the exoskeletons of crustacean shellfish. It consists of randomly distributed molecules of D-glucosamine and N-acetyl-D-glucosamine. Studies suggest that chitosan has benefits for blood pressure, healthy cholesterol, and weight management. Recent research indi-
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Sung-Hoon Jo and colleagues from Korea and the United States investigated the effects of three different molecular-weight samples of chitosan oligosaccharide in vitro for their ability to inhibit carbohydrate-digesting enzymes, and in vivo in rats for the ability to reduce postprandial blood sugar levels. When the activity of the chitosan oligosaccharide samples on the inhibition of both alpha-amylase and alpha-glucosidase were measured, the investigators concluded that all three samples, regardless of molecular weight, inhibited these enzymes equally well.

Because these enzymes are responsible for breaking down large starch molecules into smaller sugars, the inhibition of these enzymes in the digestive tract leads to a reduction in sugar absorption into circulation. In the second phase of the study, rats were administered a sucrose solution along with one of the three chitosan samples or acarbose, a diabetes drug that acts as an inhibitor of alpha-glucosidase. The study also included a control group. The results showed that all treatment groups had blunted blood glucose responses when compared to the control group. Of the three chitosan samples, sample one (the lowest-molecular-weight sample with a molecular weight of <1000 Daltons) reduced blood glucose levels the most, leading to a reduction of 14.3% after one hour. Based on these results, the authors postulate that low-molecular-weight chitosan has a dual effect on blood sugar management by acting at the gastrointestinal level to inhibit carbohydrate-digesting enzymes, as well as at the cellular level by aiding glucose absorption into muscle tissue and fat cells.

Two recently published studies on low-molecular-weight chitosan establish the blood sugar–lowering benefits in humans. The first trial was an acute dosing study in which the research group led by Sung-Hoon Jo assessed the impact of a single 500-mg dose of low-molecular-weight chitosan on postprandial blood sugar levels in 13 healthy individuals with an average age of 28.9 years. On day one of the study, the researchers conducted a control test in which the volunteers consumed a sucrose solution and had their blood glucose levels monitored at the beginning of the experiment (0 minutes) and at 30 minutes, 1 hour, 1.5 hours, and 2 hours following sucrose consumption. On the second day of the study, participants consumed 500 mg of the low-molecular-weight chitosan 20 minutes prior to consuming 75 g of sucrose in 200 ml of distilled water. Blood samples were taken at 0 and 30 minutes, as well as at 1, 1.5, and 2 hours after consumption of the sugar solution. At 30 and 90 minutes after sucrose consumption, low-molecular-weight chitosan intake decreased postprandial blood sugar levels by 13% and 14%, respectively, versus control measurements taken on day one. Thus, low-molecular-weight chitosan was effective at significantly reducing post-meal glucose spikes.

A second study led by Hee Jun Kim of Yonsei University in Seoul, South Korea, was a 12-week randomized double-blind placebo-controlled trial. Sixty individuals aged 20-75...
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with prediabetes (fasting blood sugar levels between 100 and 125 mg/dl and two-hour oral glucose tolerance test readings of 140 mg/dl or greater) were enrolled in the study.

Individuals in the treatment group consumed 1500 mg of the low-molecular-weight chitosan daily in divided doses before each meal, while the placebo group consumed an equivalent amount of roasted barley meal powder. Study subjects were instructed to maintain their usual diet and physical activity during the 12-week study period. A two-hour oral glucose tolerance test was performed at baseline and at the end of 12 weeks. HbA1c, adiponectin levels, and pro-inflammatory cytokines were also assessed at baseline and at 12 weeks. While no change was noted in serum insulin levels before and after treatment with low-molecular-weight chitosan, blood glucose levels were significantly lowered at 30 and 60 minutes in the oral glucose tolerance test versus baseline levels. In addition, HbA1c decreased significantly in the test group versus the placebo group. The inflammatory cytokine IL-6 decreased significantly with treatment, while TNF-alpha also tended to decrease, indicating a reduction of inflammation. Plasma levels of adiponectin, a hormone modulating blood sugar regulation and fatty acid oxidation, showed significant increases with low-molecular-weight chitosan after 12 weeks, a finding associated with better insulin sensitivity and reduced risk of type 2 diabetes.

The results of both human studies described here point to substantial benefits of low-molecular-weight chitosan for reducing post-meal spikes in blood sugar levels, better overall blood sugar control, as well as the ability to reduce inflammation—all positive signs for diabetes prevention.

Turning to Natural Alternatives

With the ever-increasing prevalence of prediabetes and diabetes as well as their related complications, research into preventive options should be front and center. Given the enormous healthcare burden and costs associated with diabetes, and given the impact on quality of life, implementing natural alternatives that show effectiveness in managing healthy blood sugar levels, and specifically post-meal elevations in blood sugar, should be a strong consideration in addition to beneficial dietary and lifestyle tools.

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Irfan Qureshi, ND, is chief regulatory officer for Vitamin Research Products LLC. His current focus includes oversight of product development, regulatory affairs, quality control, and quality assurance.


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Research Ramps Up on Vitamin E

A number of catalysts are now spurring interest in this shortfall nutrient.

BY MELISSA KVIDAHL

The 2015 Dietary Guidelines for Americans report established vitamin E as a shortfall nutrient, alongside six others. In fact, according to Andrea Wong, PhD, vice president of scientific and regulatory affairs at the Council for Responsible Nutrition (CRN; Washington, DC), as many as 93% of Americans fall short on this essential nutrient when it comes to intake from diet alone. “Use of supplements has helped decrease that figure down to about 60%,” she says, “but it’s definitely a nutrient the American population is not getting enough of.” And researchers are interested in the potential fallout.

Cognitive Function

Research out of Oregon State University’s Linus Pauling Institute1 outlined some recent findings—most notably, vitamin E’s significance during fetal development and throughout the first years of life, the correlation between adequate intake and dementia later in life, and the difficulty of evaluating vitamin E adequacy through blood level measurements alone.

The review of multiple studies, published in Advances in Nutrition and led by vitamin E expert Maret Traber, revealed that inadequate vitamin E is associated with increased infection, anemia, stunting of growth, and poor outcomes during pregnancy for both infant and mother, and neurological disorders and muscle deterioration in children with an overt deficiency. On the other hand, increased vitamin E concentrations at birth were associated with improved cognitive function by age two. The nutrient was also found to possibly slow Alzheimer’s progression, increase cognitive function, and even reduce risk of dementia by 47%.

“It’s important all your life, but the most compelling evidence about vitamin E is about a 1000-day window that begins at conception,” Traber said, adding that a multivitamin with the recommended daily allowance of vitamin E could go a long way towards addressing the shortfall.

Heart Health

Further interest in vitamin E is reflected in the Canadian and U.S. government’s Dietary Reference Intake (DRI) review. “Only four nutrients were selected in this review, among a number of different nominations,” explains Wong. “This indicates that the governments recognize that there’s significant and relevant data on this nutrient since the last DRI review and that this research is relevant to public health.”

Specifically, much of the most recent vitamin E research centers on implications for cardiovascular health. One recent study, published in February in the European Journal of Clinical Nutrition2, reviewed 12 human studies conducted between the years of 2000 and 2013. “The goal was to examine the nutrient’s effect on C-reactive protein levels, a marker of chronic inflammation and a predictor of future cardiovascular disease,” says Barrie Tan, president of American River Nutrition Inc. (Hadley, MA). “Approximately half of all vitamin E tocotrienol research of the last 30 years was published in the last five years,” he says, adding that most of this research deals with heart-related diseases, diabetes, and cellular health.

Analysis showed that alpha- and gamma-tocopherols yielded a significant reduction in C-reactive protein levels, to the tune of 0.62mg/l. While the mechanism is not completely known, the conclusion was clear: “It seems that vitamin E supplementation may be a good strategy for decreasing inflammatory conditions in susceptible people,” researchers stated in their report, calling for additional research via a randomized controlled trial.

Another study, published in April in Nutrition, Metabolism & Cardiovascular Diseases3, examined 16 randomized, controlled trials of vitamin E treatment as it relates to cardiovascular events, ranging in size from 100 to over 39,000 participants. The meta-analysis examined supplementation with vitamin E alone (as alpha-tocopherol), as well as its effects when combined with other antioxidant agents like a multivitamin or vitamin A, vitamin C, beta-carotene, polyunsaturated fatty acids, or selenium. Researchers noted a wide variety of effects from vitamin E supplementation when combined with other antioxidants in various studies, ranging from beneficial to harmful.

Researchers found that when supplemented alongside other antioxidants, vitamin E was ineffective in reducing incidence of heart attack, and in some cases, could be considered harmful. But when supplemented alone, vitamin E reduced heart attack by about 20%.

Tocotrienols

Tocopherol isn’t the only player when it comes to vitamin E research. Heightened interest in tocotrienols is also contributing to the increased attention given to vitamin E overall, says Barrie Tan, president of American River Nutrition Inc. (Hadley, MA). “Approximately half of all vitamin E tocotrienol research of the last 30 years was published in the last five years,” he says, adding that most of this research deals with heart-related diseases, diabetes, and cellular health.

One such study, published in the British Journal of Medicine and Medical Research in...
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found that 125–750 mg/day of tocotrienol coupled with a healthy diet can decrease lipid levels significantly after just four weeks. Researchers found that the optimum dose of 250 mg decreased total cholesterol in 31 hypercholesterolemic subjects by 15%, LDL cholesterol by 18%, and triglycerides by 14%.

Another study examining tocotrienols, appearing in the *Journal of Clinical and Experimental Cardiology*, addressed its effect on lipids and inflammation simultaneously. Researchers convened two groups of elderly subjects, one with normal lipid levels and the other with elevated lipid levels. After six weeks of supplementation with tocotrienol, antioxidant polyphenols, and niacin, the group with normal lipid levels experienced a significant drop in inflammatory markers nitric oxide, C-reactive protein, and gamma-glutamyl-transferase, as well as an increase in total antioxidant status. (Nitric oxide, when present in normal levels, is anti-inflammatory, but researchers posit that elevated levels of nitric oxide, especially in the elderly, are pro-inflammatory.) The group with the elevated lipid levels experienced the same effects, in addition to a drop in LDL cholesterol (20%–28%) and triglycerides (11%–18%).

An Essential Nutrient

“This research and others are definitely promising,” says Wong. “But we have to remember that, primarily, vitamin E is an essential nutrient and we need it for our daily cellular and bodily function. Anytime we see new research that shows an added benefit, whether it’s for heart health or for inflammation, it’s a bonus.”

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Antioxidants

Vitamin E: The Supply Side

As the spotlight brightens on vitamin E research, manufacturers looking to include the nutrient in supplement and functional food formulations have myriad considerations to ponder when it comes to supply.

BY MELISSA KVIDAHL

Currently, the vast majority of natural vitamin E sold in the United States hails from refined soybean oil, which leaves it susceptible to sharp spikes and falls in soybean pricing. Just this year, for example, January saw soybean prices fall nearly 4% due to a record 2014 harvest that yielded more supply than predicted by analysts—about 4 billion bushels in total, according to the U.S. Department of Agriculture (USDA). And the trend doesn’t seem to be stopping; 2015 looks to also hold a higher soybean supply than forecasted.

That’s the good news. The bad news is that drought conditions can change this outlook in an instant; so, too, can consumer demands such as those for allergen- and GMO-free offerings. While FDA exempts highly refined soybean oil from being labeled as an allergen (most individuals with a soy allergy can safely consume it), still other consumers seek to limit their intake, whether it’s because of a severe allergy or a desire to offset its prevalent use in many packaged foods. More concerning is the GMO issue since, according to the USDA, more than 90% of the soybeans grown on American farms each year are genetically engineered. Organic options, on the other hand, are few and far between—less than 1% of the roughly 74 million acres harvested was grown organically by the last count taken in 2011 (and reported in 2013) by the USDA.

Suppliers are answering this concern with alternative approaches. One option, of course, is synthetic vitamin E; however, according to the National Institutes of Health’s Office of Dietary Supplements, lab-made vitamin E is less potent than its natural counterpart, with about 150 IU of synthetic vitamin E needed to reach the same potency attained by 100 IU of natural vitamin E. Manufacturers looking for natural alternatives may be interested in sunflower seed oil, which is not genetically modified and has experienced a relatively flat pricing trend, says Michael Sodaro, vice president of sales at Nutralliance (Yorba Linda, CA). “We believe that although our market share of the extremely large overall vitamin E market is small, it continues to grow at a tremendous rate,” he says of the company’s sunflower-derived offering.

In the end, formulators have a few options: ride out the soybean price fluctuations, switch to synthetic, or explore GMO-free alternatives to meet growing demand. The bottom line is that, however it’s obtained, vitamin E supplementation is greatly needed, says Andrea Wong, PhD, vice president of scientific and regulatory affairs at the Council for Responsible Nutrition (Washington, DC), since just 7% of consumers get enough from diet alone.
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More Evidence that Lecithin Delivery System Boosts Boswellia Bioavailability

The resin of the Boswellia serrata tree and its active boswellic acids are commonly sold in the dietary supplements market as an anti-inflammatory ingredient for joint health. But boswellic acids have historically been poorly bioavailable when ingested orally. Now, ingredient supplier Indena (Milan) says it has new human clinical evidence that its Phytosome bioavailability-enhancing technology can improve Boswellia serrata absorption.

The company presented the data at the 2015 Pharma-Nutrition Conference held in Philadelphia in April. The randomized, double-blind crossover study was conducted in 12 healthy human subjects. According to Indena, study subjects were given either 500 mg of Indena’s Boswellia serrata extract or 500 mg of Casperome, a new ingredient blending the Boswellia serrata extract with Indena’s Phytosome technology.

Bioavailability in the Casperome group was higher. “Plasma levels of the most relevant boswellic acids measured after Casperome administration, in particular beta-boswellic acids, were in the range of expected biological activity, thus representing strong support for a rational dosage regimen in clinical testing,” the company commented.

Casperome is a 1:1 ratio of Boswellia serrata extract and Phytosome, a non-GMO soy lecithin carrier that helps shuttle the active ingredient for enhanced absorption. The company points out that there is a difference between Phytosomes and liposomes, which are commonly used to encapsulate ingredients to make them more bioavailable. While both are micelles, the difference, the company says, is this: “With liposomes, the ingredients are dissolved in the central part of the cavity, with limited possibility of molecular interaction between the surrounding lipid and a hydrophilic substance. In a Phytosome, the ingredient is dispersed into lecithin, a dietary surfactant, and can be compared to an integral part of the lipid membrane.”

Preclinical animal studies, including a January 2013 Fitoterapia study (J Hüsch et al., vol. 84), showed that Phytosome technology helped significantly improve Boswellia serrata absorption in rats. This new human data, which Indena says it is submitting for journal publication, would further support these findings.

Indena has already used Phytosome technology to improve the bioavailability of other herbal extracts, including ginkgo, milk thistle, and green tea, as well as phytochemicals like curcumin and silybin. Casperome, standardized to a minimum of 25% Boswellia serrata triterpenoid acids, was launched earlier this year.

Of the latest human study, Christian Artaria, Indena’s marketing director, said, “We are excited for the results we achieved, as for the first time, with a single dosage of 500 mg of Casperome, relevant plasmatic levels could be reached and measured in humans.”

“Breakthrough” Vitamin K2 MK-7 Study Confirms Heart Benefits


A recently published intervention trial confirms what previous population-based studies have hinted at: that vitamin K2 MK-7 helps to improve arterial flexibility. The study is specifically on NattoPharma’s (Oslo, Norway) MenaQ7 natural vitamin K2 MK-7.

“This is the first study showing that long-term use of vitamin K2 in the form of MK-7 beneficially affects cardiovascular health,” said Cees Vermeer, a scientist from Maastricht University in the Netherlands who led the study’s research team, in a press release. “Previous population-based studies have shown an association between vitamin K2 intake and cardiovascular risk, but this is the first intervention trial focused on vitamin K2 supplementation with cardiovascular endpoints.”

The three-year study, published first online in Thrombosis and Haemostasis, included 244 healthy postmenopausal women aged 55-65 years. Subjects were randomly assigned to either 180 mcg of MenaQ7 daily or placebo. Using pulse wave velocity and ultrasound analysis, researchers determined that vitamin K2 not only inhibited age-related stiffening of artery walls but also achieved “unprecedented statistically significant improvement” in vascular elasticity. Vermeer says these results confirm vitamin K2’s contributions toward improving cardiovascular outcomes.

“The techniques that were used in this study, the pulse wave velocity and the ultrasound, basically take a measurement from the carotid artery to the femoral artery to see how quickly the blood is flowing through this area,” says Kate Quackenbush, director of communications, NattoPharma. “If your arteries are clogged and calcified, your arteries are going to get smaller. You’re not going to have as much free flow. So, again, it’s an early idea about how cardiologists and general practitioners can start to examine that.”

The same cohort in this Thrombosis and Haemostasis cardiovascular study was also featured in a 2013-published bone health study in Osteoporosis International. By activating osteocalcin, vitamin K2 helps to limit calcium buildup in the arteries and shutter it toward bone building instead.

“Both studies are significant because they are long-term—three years of participation and then examination of the results,” said NattoPharma’s CEO Hogne Vik in a press release. “Observing changes in heart health and bone health, for that matter, take time.”
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What’s Next for Aloe?

With *Aloe vera* beverages now stationed in convenience stores and corporate campuses, what’s next for this sweet succulent?

BY MICHAEL CRANE, ASSOCIATE EDITOR

*Aloe vera* may have lotions and creams to thank for its fame, but the growing market for aloe beverages suggests consumers are turning to the herbal ingredient for more than just sunburn relief. With those beverages expanding beyond the natural channel to supermarkets, convenience stores, and gas stations, are aloe foods finally going mainstream?

Yes, says Peter Hafermann, president of aloe supplier Improve USA (Anaheim, CA). “Beverages are where the growth is, from our company’s perspective,” he adds.

Over the last three to five years, aloe beverages gradually gained popularity in the natural channel, but often only as unflavored raw aloe juice, according to aloe supplier Aloecorp (Lacey, WA). “It was mostly people were buying just a bottle of juice, raw juice, plain juice, and they would drink two or three ounces of juice every day,” says Jeff Barrie, regional sales manager, Eastern USA, Aloecorp. “Now these single-serve beverages are getting very popular. There’s a lot of interest in it, and there’s a lot of these products on the market.”

According to SPINS (Schaumburg, IL), the U.S. market for functional aloe juices has grown 25.7% over the last year, reaching a value of more than $47 million as of April.

*ALO Drink* (San Francisco, CA) is one finished product company that has experienced success reaching mainstream consumers. With its flavored, single-serve drinks currently available through retailers such as Chevron, Target, Costco, Safeway, and QuickTrip, *ALO* has been able to grow beyond natural channels in recent years.

“In Detroit, one of ALO’s best customers is a gas station—traditionally a mainstream, male-dominated, grab-and-go channel,” says Henry Chen, founder of *ALO Drink*. Chen adds that the convenience/gas channel “has been identified as a significant growth area for our brand.”

Available in 500-ml and 350-ml single-serve bottles, *ALO Drink* offers flavors such as honey, pomegranate/cranberry, and watermelon/peach. The company also offers blends of coconut water and aloe juice.

Chen claims *ALO* is gaining popularity on corporate campuses as well and has become “one of the most popular drinks available on the Google campus.” *ALO Drink* is also available at the campuses of Facebook, Comcast, Sony, and Lucasfilm, says Chen.

**Remaining Challenges**

But there are still a few obstacles for aloe beverages, including a pulpy texture that many consumers may find unappealing. In response to this, *ALO Drink* launched its pulp-free line earlier this year, which contains the same *Aloe vera* content as ALO’s original line, says Chen.

Mislabeling and adulteration of aloe products can also be an issue. Formulators and consumers should look for the monograph of the International Aloe Science Council (IASC) to know they’re getting authentic aloe, says Ken Jones, vice president and COO, Aloecorp.

“Probably the biggest issue right now is not having enough *Aloe vera* in a product to be efficacious. The IASC requires certain levels—15% minimum—in a product because that’s at least an efficacious level,” says Jones. "If someone has a drink that contains 2% aloe, they still put *Aloe vera* on the label. But unless you drink a case, you won’t get the benefits of aloe.”

Another challenge is educating consumers about the possible benefits of ingesting aloe, such as “promoting healthy digestion, reducing inflammation, and supporting your joints and muscles,” according to *ALO Drink’s* website. Consumers who are accustomed to topical aloe lotions may not be used to the idea that it can also be ingested.

Taking aloe beyond beverages is another trend, although not a big one in the United States.

“If you go to Europe, you’ll find [aloe] in a lot of things that you won’t find it in here. You’ll find it in smoothies and ice creams and things like that,” says Bob Smith, regional sales manager, Western USA, Aloecorp. “Yet, it hasn’t caught on in the U.S.”

But if aloe beverages continue making inroads into U.S. mainstream channels, could other aloe foods really be that far behind?
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