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Definitions: What’s at Stake?

Definitions matter. While the average consumer might not think about how the foods they eat—or the dietary supplements they ingest—are defined by law, the bottom line is that regulatory definitions set the stage for how entire segments of consumer markets will be able to innovate, survive, and thrive in the real world.

In this issue, for instance, *Nutritional Outlook*’s Kim Decker writes about FDA’s current efforts to determine whether or not alternative dairy products—e.g., all of those plant-based milks taking the supermarket aisle by storm—can define themselves as “milk” just as dairy milks can. It’s a complicated issue, one that raises significant questions such as whether or not consumers would still buy soymilk if it were called something else.

In the case of dietary supplements, the definition of the term *dietary ingredient*—the ingredients used to make dietary supplements—is hopefully something that FDA is considering, or reconsidering, now.

A bit of background: The law regulating dietary supplements in the U.S., the Dietary Supplement Health and Education Act of 1994 (DSHEA), defines a dietary ingredient as “a vitamin; mineral; herb or other botanical; amino acid; dietary substance for use by man to supplement the diet by increasing the total dietary intake...” Under this definition, an entire dietary supplement industry was born to include a wide swath of supplement products that you see on store shelves today, from vitamins and amino acids to herbal supplements and more.

However, that definition does not match how FDA narrowly defined a dietary substance in its revised New Dietary Ingredient (NDI) draft guidance, released in August 2016. Although draft guidance is not law (unlike DSHEA, which is the law), it is meant to reflect FDA’s thinking when the agency is determining which ingredients are required to submit NDI notifications. In the draft guidance (page 38), FDA states that “dietary substance ‘is intended to mean foods and food components that humans eat as part of their usual diet.” FDA also states that allowable supplement categories, such as vitamins, minerals, and amino acids, “are recognized as dietary ingredients because [they are] defined by [their] nutrition function”—i.e., they provide nutrition to the human body.

The definition of a *dietary substance* in the draft guidance differs greatly from the definition of a *dietary ingredient* under DSHEA, the actual law governing supplements. If FDA stands by its definition in the draft guidance, it could mean that the agency might not give the thumbs-up to ingredients that aren’t regularly consumed in the diet or that aren’t nutritional in purpose. And this would put in limbo, or immobilized. These innovative products will no longer be available to consumers who seek them for their health.

In May, FDA held a public meeting to discuss this and other issues plaguing FDA’s ability to effectively regulate supplements. One of the speakers at the meeting was Scott Bass, a partner at the law firm Sidley Austin LLP. In this public forum, Bass spoke about how FDA’s “unlawful interpretation” of a dietary substance in the NDI guidance will actually harm consumers in two important ways. First, he pointed out, many of the important health-promoting ingredients in dietary supplements are not, in fact, purely nutritional. If none of these ingredients are allowed in dietary supplements, he said, then a large segment of the dietary supplement industry—and the innovation within—will be immobilized. These innovative products will no longer be available to consumers who seek them for their health.

According to Bass, the second important way that public health is compromised is if companies don’t see a way to comply with FDA’s NDI draft guidance thinking—that is, they can’t find a way to get their ingredients to be considered dietary ingredients as prescribed by the guidance. In that case, companies might try an alternate route of compliance. They might instead pursue independent Generally Recognized as Safe (GRAS) self-affirmations, which FDA has said might eliminate the need for companies to submit NDI notifications. The GRAS process, however, has its share of critics, and some don’t see it as a suitable replacement for an NDI notification.

Bass has spoken about the issue of the draft guidance’s problematic definitions before, including in *Nutritional Outlook*. I asked Bass recently about how he thinks this problem that he and other industry leaders pointed out resonated with the members of FDA as well as non-industry attendees of the FDA meeting in May.

Bass said “that was not the first time I’ve communicated with the FDA about this issue...but rather it’s the first time it was brought up in a public forum.” He said he credits FDA with calling the meeting in the first place in order to open discussion about how to strengthen supplement regulations. “The reaction I got from FDA and industry people at the meeting would indicate, yes, it was definitely received,” he said.

Whether that reception translates into an actual change of the NDI guidance’s definition remains to be seen. It’s notable that as recently as this May’s FDA meeting, Cara Welch, acting special assistant to the deputy commissioner for policy, legislation, and international affairs, for the Office of the Commissioner at FDA, stated that at least one class of ingredients—synthetic botanicals—may not be considered as dietary ingredients by FDA today.

Still, Bass and others wonder whether FDA could still one day pull back from the problematic definition of a dietary ingredient in the draft guidance. And if FDA were to amend its definition of a dietary substance in its draft guidance, could it also change its stance on ingredients like synthetic botanicals and probiotics, which FDA currently says it does not consider dietary ingredients? Bass said he thinks it could. “I’m very hopeful,” he said.

So, again, what’s in a definition? Hopefully not a threat to the industry.

Jennifer Grebow
Editor-in-Chief
NDI Problems Take Center Stage at FDA Public Meeting

Dietary supplement industry leaders and consumer advocacy groups turned out in force at a hotly anticipated public meeting with FDA in May to discuss federal regulation of dietary supplements. The meeting follows an FDA announcement back in February that the agency is seeking ways to “strengthen the regulation of dietary supplements by modernizing and reforming its oversight.” When FDA announced the public meeting—which took place on Thursday, May 16, and was titled “Responsible Innovation in Dietary Supplements”—it said: “The purpose of the public meeting is to give interested parties an opportunity to present ideas for facilitating responsible innovation in the dietary supplement industry while preserving the FDA’s ability to protect the public from unsafe, misbranded, or otherwise unlawful dietary supplements.”

At the May meeting, dietary supplement leaders spoke about some of their biggest concerns regarding dietary supplement regulations—and, primarily, their concerns regarding new dietary ingredient (NDI) notifications. Under the Federal Food, Drug, and Cosmetic Act governing dietary supplements, manufacturers are required to notify FDA, via an NDI notification filing, if they are marketing an ingredient that was not on the market prior to October 15, 1994.

A civil affair, the meeting saw panelists take turns at the podium raising their concerns about dietary supplement regulations and providing suggestions for the best course of action. Below are some of the topline concerns.

NDIs and Synthetic Botanicals

Larisa Pavlick, vice president, global regulatory and compliance for the supplement association the United Natural Products Alliance (Salt Lake City), spoke on behalf of the group’s president, Loren Israelsen, about concerns over the treatment of synthetic botanicals in FDA’s most recent NDI draft guidance, which the agency published in August 2016.

FDA’s 2016 draft guidance for NDI notifications excludes synthetic botanicals from being considered dietary ingredients, prohibiting their use in the market. At the meeting, Cara Welch, acting special assistant to the deputy commissioner for policy, legislation, and international affairs, for the Office of the Commissioner at FDA, who moderated the first two sessions of the meeting, went so far as to say that there is no such thing as a synthetic botanical. She argued that because a synthetic botanical doesn’t come from a plant, it cannot be considered a true botanical and should be referred to using the terminology “synthetic copy of a botanical constituent.”

Whatever the preferred terminology, the exclusion of synthetic botanicals from qualifying as dietary ingredients has been a major point of objection of industry.

Pavlick, in her presentation, questioned why synthetic botanicals would be excluded from consideration as dietary ingredients when a number of synthetic compounds used in dietary supplements already exist, such as CoQ10. Their exclusion contradicts the intentions of DSHEA, she argued. Pavlick likened FDA’s rationale for this decision back to FDA’s thinking surrounding its decision to ban Ephedra in 2004, a period during which Pavlick said she believes the agency blamed the synthetic alkaloid in the drug for the adverse effects experienced by the public rather than considering the misuse of the synthetic alkaloid by manufacturers.

Pavlick did acknowledge one way in which synthetic botanicals may be linked to problems in the market. She noted that synthetic botanicals are causing economic disruption in the marketplace because they are cheaper to manufacture. This results in adulteration of products whereby manufacturers top off botanical formulations with synthetics, which are not disclosed on products. Adulteration, she stated, typically ranges from the use of 5% of a synthetic all the way to 16% in a product. To address this, Pavlick recommended that instead of excluding synthetic botanicals for dietary ingredient stature altogether, FDA should allow synthetic botanicals to be subject to NDI notification requirements, and that the agency should require manufacturers to disclose the presence of synthetic botanicals in finished products.

When Is an NDI Notification Required?

Industry leaders also said the industry remains confused about when an NDI notification is required. According to the most recent NDI draft guidance, “A notification is not required when the NDI and all other dietary ingredients in the dietary supplement have been present in the food supply as articles used for food in a form in which the food has not been chemically altered.”

A great deal of confusion still remains about what constitutes chemical alteration, stated Michael McGuffin, president of the American Herbal Products Association (Silver Spring, MD). For example, in the case of botanical ingredients, McGuffin expressed the need for clarification in cases where there is a change in agricultural practices, such as picking a botanical at a different stage of life, after which the end product may have a different chemical composition. Does this constitute chemical alteration, he asked?
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Compliance
Unresolved issues such as these may be affecting current compliance with NDI notification laws. Steven Tave, director, Office of Dietary Supplement Programs, Center for Food Safety and Applied Nutrition for FDA, stated that the number of NDI notifications submitted since the 1994 passage of the Dietary Supplement Health and Education Act (DSHEA), the law governing dietary supplements and requiring NDI notifications, is low. He noted that the number of actual NDI filings with FDA compared to the number of products currently on the market seems mismatched. According to statistics he cited, there are between 50,000 and 80,000 dietary supplement products currently on the market, while only 4,000 products existed in the market when DSHEA passed. That is a large increase in products, and while clearly not all of these would require NDI notifications, 1,100 filings, the number of filings that Tave said currently exist, is a relatively small amount.

There can be a lack of submissions for a number of reasons, such as the lack of clarity about when an NDI notification is required, as well as continued concerns about intellectual property protection following the submission of an NDI notification.

A master file is one possible solution. Industry and the agency have long talked about the potential benefits of a master file which would allow companies to piggyback off of an existing NDI notification, eliminating the need for a company to file a fresh notification.

At the meeting, this idea of a master file was supported by Andrew Shao, interim senior vice president of scientific and regulatory affairs, Council for Responsible Nutrition (Washington, DC), and Jay Sirois, senior director of regulatory and scientific affairs, Consumer Healthcare Products Association (Washington, DC). Through a master file system, a firm would be able to submit an NDI notification with proprietary information kept confidential, and other firms would be required to seek authorization from the owner of that master file to reference the contents of the file in their own NDI notifications. However, FDA has yet to establish such a system.

Enforcement
Another issue cited by panelists such as Shao and Daniel Fabricant, PhD, president and CEO of Natural Products Association (Washington, DC), is what they described as a lack of meaningful enforcement of existing law by FDA. They discussed how enforcement could be handled.

One potential consequence of not filing an NDI notification, suggested Fabricant, could be for FDA to consider the lack of an NDI notification a technical adulteration, similar to how not meeting cGMP standards can result in technical adulteration. He also said that import alerts can be a useful enforcement tool. Fabricant cited a number of import alerts for ingredients such as kratom, which have been held at import for not submitting an NDI notification—something that is currently not done for all new dietary ingredients that have not submitted an NDI notification.
Sometimes you just know in your gut what’s right. That’s how we feel about probiotics. Every day new research indicates that gut health influences our overall health. Ashland has teamed up with a leading global producer of probiotics, Probiotical Healthcare Srl., to bring you premium products and cutting-edge knowledge for nutraceutical applications. Contact us to learn more.

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Shao said he believes recalls can be a useful enforcement tool, although one barrier FDA would face with this option is having to prove a serious adverse health consequence of the ingredient of concern. Both Shao and attorney Scott Bass, head of the global life sciences team for Sidley Austin LLP (Chicago), also discussed the benefits of a mandatory supplement product registry, which would assist FDA in enforcement by allowing the agency to know what products are on the market; however, they noted, a registry system would require associated consequences to deter violators from going to market without registering their products.

**GRAS and NDIs**

There was also some debate about the Generally Recognized as Safe (GRAS) self-affirmation process and whether this process is being abused by firms to get around the requirement to file NDI notifications. FDA has said that ingredients with GRAS affirmations may not need to file an NDI notification.

During the meeting, while speaker Ashish Talati, partner, Amin Talati & Upadhye (Chicago), defended GRAS status as an exception for when companies need to file NDI notifications, Laura MacCleery, policy director for the Center for Science in the Public Interest (Washington, DC), a consumer safety advocacy group, criticized the self-affirmed GRAS process as being secretive and vulnerable to conflicts of interest. She argued that an ingredient’s GRAS status should be publicly listed. MacCleery also said she does not believe that GRAS affirmations are an adequate substitute for NDI notifications because they fail to address, for example, the safety of ingredient mixtures and only look at the use of ingredients in isolation.

**Takeaways**

Overall, the meeting had a lot of recurring themes, such as disagreement on synthetic botanicals, unresolved questions about NDI notifications, and the potential benefits of a mandatory product registry, but it was interesting to see trade groups advocating for actual enforcement of NDI notifications, and the differences in opinion that exist about the value of self-affirmed GRAS status.

Overall, the takeaway industry concern seemed to be about ensuring that FDA can effectively regulate supplements while not stifling the market overall. For instance, Bass was the first industry representative to speak. He criticized the most recent NDI draft guidance for limiting the definition of what ingredients can qualify as dietary ingredients, and disincentivizing companies from innovating and conducting good science.

This meeting mainly served to allow industry members to present ideas and argue their positions, so what FDA does with the information and how they proceed in their discussions with industry moving forward will be the real test for how serious the agency is about finding common ground with industry.
With excess sugar’s role in rising obesity rates a source of concern, product developers are searching for safe, natural, clean, noncaloric sweeteners that make meaningful sugar reductions possible. Allulose, a fructose isomer with 70 percent of sucrose’s sweetness, is one such sweetener, and it’s appeared as a noncaloric, GRAS-status sugar substitute in a number of product formulations already.

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SAY HELL YA TO KETOSESWEET AND HELL NO TO ADDED SUGARS.
DIVIDED LOYALTIES
Does probiotics’ future lie in foods, beverages, supplements—or all three?

BY KIMBERLY J. DECKER

When Nutrition Business Journal released its latest “NBJ Supplement Business Report,” one datum that stuck out among others—and stuck not a little fear into the hearts of industry watchers—was this: probiotic sales growth fell from 17.1% in 2017 to 10.2% a year later, a level far lower than the journal had projected earlier.1

Could it be, pessimists wondered, that this once-powerhouse of a category was on the decline, and that consumers’ fascination with “good gut bugs” had run its course?

Not necessarily. To paraphrase Mark Twain, rumors of probiotics’ death have been greatly exaggerated. For although the growth curve for probiotic supplements may point downward and to the right, probiotic food and beverage sales are looking decidedly up. Indeed, writes Rick Polito in Nutrition Business Journal, “[I]nsider talk suggests the story is more about form and format than a disillusioned consumer...People didn’t give up on probiotics. They just expect them in food and not in a pill.”

Supplements Here to Stay
Even amidst those shifting expectations, probiotic supplements remain a going concern. Counteracting the findings of the NBJ report, Sam Michini, vice president of marketing & strategy, Deerland Probiotics & Enzymes (Kennesaw, GA), points to a recent publication from the International Probiotics Association showing that probiotic supplement sales actually grew from 2013 through 2018, “although growth was modest,” he concedes. The organization predicts 26% growth in supplement delivery from 2018 through 2023.

This doesn’t surprise Michini, as probiotic supplements have their advantages. Consider a formulation designed to deliver a higher colony-forming unit (CFU) payload, he suggests. “The dose in supplements typically is more concentrated. Foods generally provide around 1 billion CFU per serving, while a supplement may deliver up to 50 to 75 billion CFU in one capsule.”

And as Barri Sigvertsen, marketing manager, Lonza Consumer Health & Nutrition (Morristown, NJ), adds, “Formulating with probiotics can be challenging. Humidity, harsh temperatures, and stomach acid all hamper delivery of live and active cultures, and exposure to moisture in packaging can “activate” the bacteria before consumption. “Enhancements in capsule technologies, in particular,” she notes, “enable probiotics to successfully pass through the low-pH environment of the stomach before reaching the intestines, while protecting them from early activation that may result from exposure to environmental humidity.”

Wall of Pills
So three cheers to supplements for supplying a reliable probiotic delivery platform that’s here to stay. Notes John Quilter, vice president and general manager, proactive health, for supplier Kerry’s Ganeden probiotics brand (Mayfield Heights, OH), “The growth in functional foods and beverages hasn’t curtailed the development of the supplement market.”

But, he continues, “We’re seeing more demand for probiotic consumption in easy formats. So consumers are looking for probiotic-formulated foods and beverages throughout the day, whether at breakfast, lunch, dinner, or even a snack.”

Chalk it up to another symptom of pill fatigue. “An increasing number of consumers are turned off by the wall of supplement pills and are on the lookout for innovative products that deliver benefits they consider to be in tune with their lifestyles,” Quilter points out. “Products that can meet that demand will resonate.”

GlobalData research shows that 85% of consumers prefer to consume health-enhancing ingredients through food or beverages, Quilter notes. “And the more mainstream functional foods and beverages become, the more likely consumers of all ages will look for products formulated with probiotics.”
PROBIOTIC FOOD
It Started with a Spore

They have a lot of options to look for. As Quilter explains, “Probiotics debuted commercially in dairy products, and there’s still a close association with that category. Yogurt in particular remains a standard-bearer, with more than half of all yogurts sold being fortified with probiotics.”

But thanks to the emergence of “robust, spore-forming probiotic strains,” manufacturers can formulate probiotics successfully into a wide range of nondairy products, Quilter says. The endospores these bacteria wrap around themselves naturally protect them from environmental threat, and suppliers’ ability to harness that spore-forming capacity through “novel technological approaches has completely transformed the probiotic scene,” Quilter contends. “It’s a big step forward.”

Colonizing New Ground

Spore-formers like his company’s Ganeden-BC30, a patented strain of Bacillus coagulans GBI-30, 6086, resist the extremes of pH, heat, cold, shear, and pressure associated with food production and packaging—not to mention with the human digestive tract—better than do vegetative probiotic cells, ”making them a better fit for fortification of everyday foods and beverages,” Quilter continues.

Stability against HTST and HPP pasteurization “opens up new avenues of innovation because it means the ingredient can be used not just in chilled dairy, but in applications like nondairy beverages, frozen foods, cereals, baked goods, better-for-you snacks, and even hot drinks,” he adds. In-application shelf life for his company’s bacteria can be as long as three years.

Michini notes that his company’s Bacillus subtilis strain DE111, a probiotic spore, also survives passage through the digestive tract and remains viable under a range of temperatures and pH levels encountered in foods and beverages. “In stability testing, DE111 experienced virtually no loss of colony-forming units over 24 months when stored at room temperature, 25°C,” he says.

A “great example” of a groundbreaking application is soda, he says, “which is getting much healthier.” Live Soda, for instance, bills itself “The Probiotic Soda Company.” The product is sugar- and calorie-free and promises more than 1 billion CFU of probiotics per 12-oz can—and it contains DE111.

In 2018, Deerland launched a highly soluble version of its flagship probiotic designed for easy incorporation in “high-growth natural-product sectors” like hot beverages, functional drinks, and nutritional-supplement gummies, Michini adds. The ingredient mixes easily with liquids and maintains a high CFU count in the finished product.

Know Your Limits

Despite the significant application ground that hardy spore-formers have broken, obstacles to probiotic food and beverage formulations remain.

“Strains and species have their own unique characteristics,” Michini notes. “For example, there are manufacturing limitations with lactobacilli, which are pretty-much restricted to refrigerated and frozen products. Additionally, hydro-activity in processing can cause Lactobacillus to die off, necessitating significant overages to back up CFU live-delivery claims.”

Sigvartsen agrees. “When developing probiotic products, the key challenges are supporting optimal shelf life and stability,” she says. And here, supplements like capsules have an advantage. With their low water content—4%-6% at 50% relative humidity, or less than 9% over the shelf life without protective packaging; versus 13%-16% for hard gelatin capsules—her company’s hydroxypropyl methylcellulose (HPMC) DRcaps protect probiotics against the depredations of formulation and environmental moisture.

With more gellan-gum gelling agent, they “allow for acid-resistant properties that delay the capsule’s dissolution in the stomach’s acidic environment,” she says. They also modify release to promote complete dissolution in the intestines. "An unpublished independent in vivo gamma scintigraphy study completed in 2013 by Bio-Images Research in Glasgow, Scotland, showed the capsules begin to release in a mean time of 52 minutes after ingestion and when they were about to leave the stomach,” she adds.

In fact, Sigvartsen considers capsule delivery superior to functional foods and beverages not only because of their stability and shelf life, but because of their convenience, ability to mask taste and aroma, and formulation flexibility. Case in point: “Many probiotic supplement launches now feature prebiotics,” she says. "Formulating such combination products is challenging, but probiotic supplementation via capsules offers a unique solution: an internal barrier to prevent water penetration and ensure the stability of the probiotic.”

The inner capsule in her company’s DUO-CAP capsule-in-capsule platform typically contains a probiotic, “which is suspended in a solubilized prebiotic formula that’s released first when the outer capsule dissolves and helps feed the probiotic’s growth,” she explains. “The inner capsule with the probiotic cultures dissolves later, improving its ability to reach the intestinal tract.”

People’s Choice

Quilter notes that shelf-stable beverages have proven a consistently tricky application for his company’s spore-former—but that Ganeden’s partners have leveraged cap dispensers and straw technologies as a work-around to deliver an efficacious dose. Their success gives lie to the notion that supplements’ worth is as a backup platform for when food or beverage delivery fails; on the contrary, Quilter believes, supplements’ worth is in “the importance of offering consumers choice.”

“It’s a case of ‘build it and they will come.‘” Michini says. “We feel that although there will be significant development of novel probiotic-containing foods and beverages, this category will also witness strong supplement growth. So all three—foods, beverages, and supplements—will enjoy relevance and consumer loyalty.”

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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Growing consumer demand for products that support a healthy gut, alongside growing interest in alternative delivery methods, has resulted in this: foods and beverages touting gut-friendly ingredients are gaining more attention than ever before. Food and drink formulators are leveraging the health benefits of probiotics, prebiotics—and, increasingly, both together as synbiotics. Ahead, we highlight some of the newest products on the market.

**Prebiotic Bars**

Rowdy Prebiotic Foods was an exciting newcomer to the bar space in January 2018 when the company introduced its prebiotic superfood bars for better digestion and wellness. For Rowdy, yacon root is the source of natural sweetness as well as prebiotics. Today, the low-glycemic, paleo-friendly, non-GMO bars are sold on the brand’s website and at specialty stores nationwide. In 2019, the company unveiled its newest bar flavor: Blueberry Almond Tart. Says Rowdy Prebiotic Foods’ founder Kellie C. Lee: “Rowdy Bars hit the market in January 2018 and has emerged as one of the leading innovators in the natural snack food industry, specializing in nutrient-rich, gut-healthy protein/energy bars. Rowdy’s signature prebiotic superfood, yacon root, is a newly rediscovered ancient food. Hailing from the Andes Mountains, yacon root is a low-calorie, low-glycemic prebiotic powerhouse that has been used by locals in the Peruvian Andes for centuries.”

**Probiotic Bars**

Last summer, the PROBAR brand launched PROBAR Live, a line of fresh, whole-food bars featuring live probiotics. Each PROBAR Live bar contains 1 billion colony forming units (CFU) of probiotics, plus 10 g of plant-based protein. PROBAR’s founder and CEO Jeff Coleman called it “a fresh take on plant-based protein bars by infusing the functional benefits of probiotics into every bite.” The

**Synbiotic Cereal**

Late last year, Kellogg rolled out a new prebiotic and probiotic cereal line called Hi! Happy Inside. The company called the cereal a “three-in-one” solution for supporting digestive health. It features 2.5 g of prebiotics, 1 billion CFU of live probiotics, and 8-9 g of fiber. In a press release, Aleta Chase, marketing director for the brand, said: “This new cereal provides a proactive, real-food solution

**Rowdy Bar is a trailblazer in the prebiotic bar space.**

**Kellogg is banking on synbiotics with its new Hi! Happy Inside breakfast cereal.**

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**Protein + Probiotic Breakfast Pastry**

Earnest Eats, whose mission is to create healthier breakfast options, made a splash with its protein-plus-probiotic oatmeal products. Now, the company is turning its focus to another breakfast item: the toaster pastry. This April at the Natural Products Expo West show, the company debuted Pro Toasty, featuring probiotics and protein and dubbed by the brand as “the first high-performance toaster pastry.” Each serving includes 9-10 g of grass-fed collagen protein plus 1 billion CFU of live probiotics and an almond butter filling. In a press release, Andrew Aussie, president and founder of Earnest Eats, said: “Our new Pro Toasty is shaking up the breakfast categories by offering a higher protein breakfast that is a natural makeover of a sugary indulgence, blast-from-the-past breakfast, crafted with complex carbohydrates, probiotics, and a protein superfood filling to fuel your mornings.”

**Yogurt Drink**

The launch of Danone’s Activia Probiotic Dailies yogurt drink turned heads last year; the company recently took the line further by adding prebiotic fiber. The new Activia Probiotic Dailies with Prebiotic Fiber features “billions of live and active probiotics, prebiotic fiber, and real ginger to support gut health,” the company says. Those who consume the synbiotic drink twice daily for two weeks should see benefits, the company says. Moving forward, Danone is continuing its innovation in the yogurt drink space. This June, it is rolling out a new product: Activia Probiotic Smoothies Lowfat Yogurt Drinks. The drink is a blend of “billions of live and active probiotics with juicy fruit, veggies, and seeds,” the firm says, and supports digestive health when consumed twice daily for two weeks.

**Kombucha**

Wonder Drink Kombucha is shaking up the kombucha category again. Last year, the brand introduced what it called “the first and only kombucha with an organic prebiotic fiber to help promote digestive health.” The Wonder Drink Organic Prebiotic kombucha drink features xylooligosaccharide prebiotic plant fiber. This year, the company took it a step further with condition-specific versions of the drink, called Wonder Drink Organic Prebiotic Plus. The Prebiotic Plus line includes three drinks—“focus,” “hydration,” and “radiance”—and features such ingredients as ashwagandha, cascara, biotin, turmeric, and ginger.

**Refrigerated Prebiotic Pouch**

Gutzy Organic’s products are designed to provide everything that’s good for you, in one pouch. The company’s refrigerated fruit pouches, first introduced in 2017, provide such healthy ingredients as fruit, oats, and prebiotic acacia fiber. This March, the company launched its newest iteration of the pouches: its new Botanicals line. The line is inspired by botanicals such as ginger and dandelion, all while providing the same 5 g of beneficial prebiotic fibers. David Istier, the company’s founder and CEO, says: “We are the first refrigerated organic gut-health prebiotic fruit snack in the market and growing...
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The growth of fresh, healthy snacking and demand for gut-healthy snacks and beverages from consumers is making Gutzy a very unique and compelling offering in the marketplace. Of the company’s prebiotic source, he says: “We see acacia fiber as the purest and most effective prebiotic in the marketplace: it doesn’t lead to gas and bloating, [and it provides] strong gut-health benefits, a great source of fiber, is plant-based, and is easy to mix in manufacturing.”

**Shelf-Stable Prebiotic Pouch**

Another prebiotic pouch brand, also formulated with prebiotics from acacia fiber, is Hyggut. Hyggut launched in December 2018 as “the first shelf-stable prebiotic fiber pouch to market,” the company says. Hyggut’s pouches are shelf stable and contain 5 g of prebiotic fiber alongside fiber from fruits and veggies. Said a company representative: “While there are many ways to take care of your gut, our approach is to nourish the good bacteria that already exist in your gut with prebiotic fiber, giving them the food they need to thrive. We provide a portable, delicious snack that makes good gut health even more accessible for those who lead busy lives but value overall wellness.”
Synbiotic Fruit Bar

Fruit bar brand That’s It took fruit bars to a new realm when, in January of this year, it launched its That’s It Prebiotics + Probiotics Fruit Bars range. The Prebiotics + Probiotics Fruit Bars contain 2 billion live cultures to support digestive and immune health. “The bar contains only two ingredients: 100% real fruit and probiotics,” the company says. “The all-natural fruit acts as a prebiotic, fueling the 2 billion CFU of active cultures contained in each bar.”

Prebiotic Chocolate

Achieving optimal gut health is a delicious proposition when it comes in the form of Gutsii’s chocolates. Designed for those who no longer find appeal in “popping pills, blending potions, brewing broths, and measuring powders,” the low-carb, dairy-free, no-added-sugar dark chocolate bars not only comprise over 33% dietary fiber but offer prebiotic benefits in the form of inulin. The bars, launched in December 2018, are vegan and keto friendly and GMO free.

Guilt-free indulgence? Gutsii chocolate gives consumers gut-health support and a tasty treat all at once.
Everyone loves sugar. Its flavor and performance are responsible for the eating experience we've come to expect from baked goods, confections, and beverages. Excessive sugar consumption, however, has plagued our society with health problems such as obesity and metabolic disease, and this is what is motivating consumers today to drastically cut their intake of sugar. According to proprietary consumer research from ingredient supplier Kerry (Beloit, WI) conducted in 2018, 46% of consumers strongly want to reduce their consumption of sugar, and 71% read the sugar content on ingredient labels.

In fact, according to USDA data, between 2000 and 2016, there was a 17% decline in daily consumption of sweetening agents such as refined sugar and high-fructose corn syrup. According to the group The Consumer Goods Forum, in 2017, 68% of companies reported reducing sugar, a 12% increase compared to 2016. Kerry reports that, as a way to manage sugar consumption, 28% of its survey respondents are opting for reduced-sugar foods and beverages, and 19% are switching to alternative sweetening agents.

Such movement is also impacting the product claims companies are making. For instance, the number of “no added sugar” claims on products grew 2.6% in 2018 compared to the year prior, and the number of “low/no/reduced sugar” claims grew 45% in 2017 compared to 2012, according to data from Mintel. The number of “no artificial sweeteners” claims also grew 4.4% in 2018 compared to the year before, according to Nielsen data cited in the Kerry report, showing that consumers not only want less sugar, but want alternatives that are clean label and natural.

If a product calls for less sugar, but the same sweetness, a natural, high-intensity sweetener such as stevia can solve the sweetness issue; however, replicating sugar’s functionality is no easy task.

“Emerging sweeteners are always compared and evaluated against [sugar’s] performance,” says Akshay Kumar Anugu, PhD, associate, global sweetener development, for Ingredion (Westchester, IL).

Anugu explains that replacing sugar with high-potency sweeteners is challenging for many reasons, such as the fact that differences in the binding ability of sweeteners at T1R2/T1R3 receptors, which are humans’ receptors for sweet flavors, can dictate different flavor delivery and mouthfeel properties, depending on the sweetener.

Says Anugu: “Sucrose not only provides sweet taste, but also imparts functional...
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Sweeteners

“Stevia leaf extracts have become so popular...that close to one in four global beverage launches now contains stevia-based sweeteners,” says Cargill’s Andy Ohmes.

properties such as bulking/mouthfeel. In baked goods, sucrose increases the protein denaturation and starch gelatinization temperatures, acts as a tenderizer by retarding and restricting gluten formation, and also contributes to the volume. In ice cream, sucrose influences freezing point and controls ice crystal formation. In bars, it controls hardness and maintains microbial and physical stability during the shelf life.”

Also, when you ask consumers, not all consider sugar a bad word. In fact, in surveying consumer perceptions, Kerry found that 59% prefer sugar, compared to the 22% who prefer stevia. So, even as consumers may want to limit their consumption of sugar, they also have a positive opinion of it as a sweetener because it is a familiar ingredient.

The challenge now for suppliers and manufacturers is to devise products which give consumers what they want in terms of sugar reduction as well as flavor, all while using alternative ingredients. Their hope is that consumers will begin to recognize products like stevia and choose them because they like the taste.

Given these challenges, today’s sweetener suppliers and manufacturers have developed a number of creative solutions for clean-label sugar reduction. Much of this work involves finding the right combination of high-intensity sweeteners, and bulking agents, to replicate the flavors and textures we get with sucrose.

Stevia

The most ubiquitous natural sweetener on the market today is stevia (Stevia rebaudiana)—more specifically, the steviol glycoside Rebaudioside A (Reb A).

Stevia is significantly sweeter than sugar and is therefore very effective at clean-label sugar reduction, particularly in beverage applications. “Early on, stevia was first embraced by manufacturers in product categories that were on the front lines of the sugar-reduction fallout—chiefly beverages, including juices, flavored waters, and sodas,” explains Andy Ohmes, global director of high-intensity sweeteners, Cargill (Minneapolis, MN). “Stevia leaf extracts have become so popular in these categories that close to one in four global beverage launches now contains stevia-based sweeteners.”

Beverages are a big sugar-reduction target because carbonated soft drinks and juices are notoriously high in sugar. In fact, in Kerry’s consumer survey, carbonated soft drinks were perceived to contain the highest sugar content. That means that consumers will either switch to unsweetened beverages or seek out alternatives, which they hope will be comparable to the real thing.

Meeting this expectation poses some challenges where stevia is concerned. Alone, stevia’s most prominent steviol glycoside, Reb A, will not help formulators eliminate sugar entirely because it has a bitter aftertaste and affects sensory characteristics such as mouthfeel.

At lower sugar-reduction levels, Reb A isn’t as problematic. “Formulators were able to achieve 30%-50% sugar reduction with Reb A in several beverage applications without impacting taste,” says Anugu. “However, Reb A can impart undesirable sensory characteristics, especially above 50% sugar replacement, limiting its application.”

For this reason, the stevia industry’s push to commercialize other, minor steviol glycosides such as Reb M and Reb D, which sidestep some of the undesirable tastes and sensory characteristics of Reb A, has the potential to make a huge impact on sugar reduction. Most often, when aimed at lowering a product’s sugar profile today, these minor glycosides are used either in combination with Reb A or with other steviol glycosides.

Cargill’s ViaTech stevia sweetener portfolio, for example, allows for up to 70% sugar reduction, based on the company’s ability to pinpoint ideal glycoside ratios. “Part of what sets the ViaTech portfolio apart from other stevia sweeteners is Cargill’s proprietary taste-prediction model, which can precisely predict which combination of steviol glycosides deliver optimal taste and sweetness,” explains Ohmes.

“We have found that using Reb D and Reb M as sweetness modulators in very small amounts in tandem with [Reb A sweeteners] RA99 or RA98 works very, very well in masking off-notes while maintaining high intensity,” explains Thom King, president and CEO of Icon Foods (Portland, OR). He adds that even Reb D and Reb M are not without their own off-notes, making combining the steviol glycosides ideal.

Combining a variety of different steviol glycosides is also more cost effective for several reasons. Reb M and Reb D are called minor steviol glycosides because they are present in lesser concentrations in stevia plants, requiring more work and starting material to...
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extract workable amounts. This translates to a higher price, but as many firms are now pointing out, continuing technological advancements are making the minor steviol glycosides more scalable.

Cargill’s newest stevia sweetener, EverSweet, is a minor steviol glycoside sweetener containing Reb M and Reb D produced through fermentation, without the typical leaf extraction.

Another firm, PureCircle (Chicago, IL), has begun selectively breeding stevia plants so that they have a higher Reb M and Reb D content, compared to conventional stevia plants. “As to cost effectiveness, recent PureCircle advances enable us to significantly boost production of high-grade stevia sweeteners like Reb M,” states PureCircle CEO Maga Malsagov. “This means we can supply stevia sweeteners in amounts that customers need as they expand use of stevia ingredients. Depending on amounts purchased and terms of purchase, companies buying Reb M from PureCircle will find the cost of using it to sweeten a beverage or food equivalent to their cost of using sugar to achieve the same level of sweetening.” This has opened stevia up to greater possibilities in other applications, such as baked goods, ice cream, sauces, and other growth categories, says Malsagov.

**Bulk Sweeteners**

Stevia has a lot of name recognition and a positive connotation among consumers looking for low-glycemic and clean-label products. However, stevia can present notable limitations beyond undesirable aftertaste, such as limitations in mouthfeel and bulking.

Of stevia, Anuga says: “Sensory challenges include creating a sucrose-like sweet response (time intensity and temporal), eliminating non-sucrose taste profile (bitter, astringency, licorice, etc.), and adding back mouthfeel. Processing challenges include solubility, dispersion, foaming, stability (processing/storage), shelf life, etc.”

For these reasons, “Up to this point, there has been a more limited use of stevia in the bakery category,” explains Wade Schmelzer, principal food scientist, Cargill. “Cakes and cookies, for instance, are indulgent products, which consumers often associate as a reward for their other dietary choices. Sugar reduction in these types of applications is more complex, since sugar is highly functional, impacting not only taste, but texture, structure, and color.”

Schmelzer says that replicating the texture of full-sugar bakery products often requires a combination of bulking agents, such as erythritol and fibers, “potentially coupled with starches and hydrocolloids.” Bulk sweeteners such as the polyol erythritol and the rare sugar allulose can impart the desirable functional properties stevia cannot. (Read more about allulose on page 36.)

“Bulking sweeteners can produce viscosity and mouthfeel very similar to sugar,” explains King. The most popular combination, says King, is stevia and erythritol, or even stevia, monk fruit, and erythritol.

Erythritol offers a number of functions across platforms, says Ravi Nana, polyols technical service manager, Cargill. In beverages, erythritol provides mouthfeel, which decreases when sugar decreases. In frozen
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dairy products, it provides freezing-point depression, and in bakery applications, it contributes to bulk and enhances texture.

“For example, in ice cream, sugar is what lowers the freezing point and prevents the formation of large ice crystals, creating the smooth, silky texture expected of a premium ice cream,” says Nana. “Because of its small molecular size (one-third that of sugar), erythritol can fill that void, providing a three-fold freezing-point depression factor. That higher effect on freezing-point depression helps soften reduced-sugar ice creams, creating the scoopable texture consumers crave.”

King says the combination of erythritol, stevia, and monk fruit is ideal for sweetening bars and powdered drink mixes, particularly 100-mesh or fine-powder formats that allow for immediate dispersion into solutions or formulas.

King also points to the benefits of allulose. “The combination of allulose and stevia makes for a perfect plug-and-play sweetening system for baked goods. Stevia does not participate in the Maillard reaction, nor does it brown or activate leavening. Allulose, since it is a saccharide and participates in Maillard, works wonderfully, and the added sweetness of stevia makes it a very, very replaceable sugar in sweet baked goods and desserts.”

Another advantage of allulose is a recent draft guidance published by FDA that states allulose can be excluded from the added-sugar statement on the Nutrition Facts label. Read more about this on page 38.

Fiber

The use of naturally derived fibers such as inulin from chicory root fiber has become another way to reduce sugar while providing important textural properties, especially when used in combination with other sweeteners.

“We have found inulin very useful in baked goods to be used as a fat emulator, with the added benefit of a fiber label claim,” says King. “It pairs very well with stevia. It participates, albeit very slightly, in Maillard since, by definition, inulin is classified as a fructan, which is a polymer of fructose molecules with a short chain length, known as fructooligosaccharides. We have found that the allulose, stevia, and monk fruit combination is much more effective in baked goods.”

Cargill touts using its Oliggo-Fiber inulin. “While we can often replace sugar’s sweetness with a high-intensity sweetener like stevia, it won’t make up for the loss of bulk or functionality. For those properties, we often opt for Zerose erythritol, a natural, zero-calorie bulk sweetener, and naturally sourced Oliggo-Fiber chicory root fiber,” says Tim Christensen, senior food technologist, R&D, bakery applications, Cargill. “Together, these ingredients help deliver the mouthfeel consumers expect. In many bakery applications, the combination of stevia, erythritol, and chicory root fiber can successfully replace the functionality of sugar, keep cost-of-use in check, and deliver on consumer preferences.” This combination (stevia, erythritol, and chicory), says Christensen, makes it possible to achieve a 15%-20% sugar reduction in cookies, and a 20%-50% sugar reduction in cakes and muffins, with limited effect on overall product performance.

The use of inulin fiber also allows for additional claims in major growth categories. “Chicory root fiber is] a product that can be used in some organic formulations, depending on inclusion levels. It’s gluten free. We see now with the keto and paleo trends that incorporation of fiber has taken off as well,” explains Taylor Halstead, product line manager; specialty carbohydrates; starches, sweeteners, and texturizers business; Cargill. “It’s really just compatible with a number of the label claims that customers want to make to begin with.”

A United Front

There is no one-size-fits-all solution for sugar reduction. Optimizing flavor and texture means tailoring a combination of different sweeteners to a specific product because each product brings its own challenges. It’s clear that consumers want reduced-sugar options, and delivering these options is now more possible than ever.

References

3. Nielsen xAOC Sales Units. 52 weeks ending June 16, 2018. Analyzed among 207 billion units.
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In a market abundant with natural sweetening options, allulose is primed to carve out a hefty market share. This so-called rare sugar is reportedly 70% as sweet as table sugar but with 90% fewer calories and many of the same functional qualities.

But why is it called a rare sugar?

Allulose gets its classification because, despite being present in numerous foods (corn, figs, raisins, jack fruit, and more), it’s found in these foods only in very small amounts. Through enzymatic processes, ingredient suppliers are able to extract significant amounts of allulose from large quantities of plant material. That’s why corn ends up being the preferred plant source for most industrial allulose production worldwide. According to Ingredion Inc. (Westchester, IL), which markets Astraea allulose from corn, sourcing the ingredient from other plants just isn’t economically feasible.

Beyond the simple economics, numerous other factors make allulose a sweetener worth considering for beverages, dairy, baked goods, confectionery, and other food products.

**Functional Benefits of Sugar**

Where allulose separates itself from other alternative sweeteners is in its functional likeness to table sugar. It has the same bulk- ing abilities of sugar and the same browning properties. Allulose is also highly soluble in beverages and not quick to crystallize in high-solid systems. Erythritol, for example, is an alternative sweetener missing several of these characteristics.

Allulose also happens to be particularly useful in frozen food products, such as ice cream, because of its freeze-point depression. “For freezing-point depression in frozen food products, allulose delivers excellent handling in manufacturing, storage stability, and desirable texture and other sensory characteristics,” says Abigail Storms, vice president of sweetener platform and global platform marketing for Tate & Lyle PLC (London), which markets Dolcia Prima allulose.
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Blends
Where many alternative sweeteners are sweeter than sucrose, allulose is less sweet. It’s reportedly 70% as sweet as sucrose, despite providing a similar sweetness onset and linger.

By blending allulose with higher-intensity sweeteners, such as stevia, manufacturers can enhance the sweetness of food products without compromising on allulose’s useful functionality. Keeping this in mind, Icon Foods (Portland, OR) markets Ketosweet allulose and Ketosweet+ blends of allulose combined with stevia and/or monk fruit.

“Buyers sourcing from us get the benefit of savings on logistics since one compound is coming from one location rather than multiple sources,” says Thom King, Icon Foods president and CEO. “Additionally, natural high-intensity sweeteners can be very unforgiving if over-dosed into process. Our blend is consistent each and every time.”

Safety
If the utility of allulose hereto shared is enough to peak your interest in purchasing allulose, consider, too, the safety work that’s been conducted on allulose. A recent study of gastrointestinal tolerance suggests acceptable ranges of use for public safety, and suppliers should also be able to help you determine how much allulose to use in your products safely and effectively.

Though research is shedding light on alternative sweeteners that may, when compared to regular sugar, have favorable effects such as on body weight and metabolism, limiting consumption of any sweetener is a good rule of thumb that both manufacturers and consumers should keep in mind.

Labeling
Until recently in the United States, manufacturers of products containing allulose had to label the ingredient as an “added sugar” on FDA’s Nutrition Facts panel, a requirement that irks some industry members. Since allulose contains so few calories and doesn’t appear to raise blood sugar once ingested, interested members would prefer it if the ingredient wasn’t treated in the same way as sugar. Labeling allulose as “added sugar” can create misperceptions for shoppers, including those for which allulose is most targeted: people
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Sweeteners

with diabetes and those who otherwise want to avoid sugar. In 2015, Tate & Lyle submitted a citizen’s petition to exclude allulose from this mandatory labeling.

Years later, FDA has answered. This April, FDA issued draft guidance indicating that the agency intends to exercise enforcement discretion to allow allulose to be excluded from the total and added-sugar declarations on the Nutrition Facts and Supplement Facts labels.

Susan Mayne, PhD, director of FDA’s Center for Food Safety and Applied Nutrition, acknowledged the different properties ascribed to allulose: “The latest data suggests that allulose is different from other sugars in that it is not metabolized by the human body in the same way as table sugar,” she said in a statement. “It has fewer calories, produces only negligible increases in blood glucose or insulin levels, and does not promote dental decay.”

As reported in April by Nutritional Outlook’s associate editor, Sebastian Krawiec, according to FDA’s draft guidance: “Allulose will continue to count toward the caloric value of food on the label and must still be declared on the ingredients list. According to Mayne, this is the first time FDA has stated its intent to allow a sugar to not be included as part of the total or added-sugars declaration on labels. The guidance document also states the FDA will exercise enforcement discretion to allow manufacturers to use 0.4 calories per gram of allulose when calculating the calories from allulose in a serving, in contrast to the 2016 Nutrition Facts label rule, which stated that allulose must be counted as four calories per gram of sweetener.

Both Ingredion and Tate & Lyle celebrated the news in statements.

Afrouz Naeini, Ingredion’s regional platform leader for sugar reduction in the U.S. and Canada, said in an April 18 press release: “Construction is well underway at Ingredion’s dedicated Astraea allulose manufacturing site in Mexico, and commercial-scale availability of products is expected this year. With the FDA announcement, we can now partner more closely with customers as they look to harness the full potential of Astraea allulose and help them bring winning products to market that meet consumers’ taste and indulgent wants and health and wellness needs.”

In an April 17 press release, Abigail Storms, vice president of global strategic marketing at Tate & Lyle, said, “Leading the commercialization of allulose back in 2015 with Dolcia Prima allulose gave us the opportunity to be the first to work with food and beverage manufacturers on their calorie-reduction challenges using this ingredient. We’ve seen incredible solutions, but the labeling was a challenging hurdle until now. I am excited at the impact we can now make together with our customers on the reduction in sugar consumption in brands across categories in the U.S. This is a breakthrough in our ability to offer consumer- and customer-relevant solutions in the face of today’s obesity and diabetes health crises.”

References


Because allulose isn’t metabolized, it doesn’t raise blood sugar levels.
Novel Combination of Fenugreek and Black Musali
What’s in a name? When that name applies to an oat “milk,” soy “cheese,” or macadamia nut “ice cream,” the answer may be: the seeds of controversy. For with a bumper crop of plant-based dairy alternatives threatening to crowd out the cow’s-milk originals they emulate, some in the dairy industry are questioning if these products can adopt traditional dairy names.

So, too, is FDA. As part of its Nutrition Innovation Strategy, the agency is “modernizing our standards of identity, which define through regulation certain characteristics, ingredients, and quality of specific foods,” said an agency statement from Scott Gottlieb, who was the FDA commissioner at the time of the strategy’s launch.1

The upshot: All those coconut yogurts and hempseed sour creams taking up prime dairy real estate may have to call themselves something different if FDA tightens its name game. And whether or not it does so may depend on who protests the loudest, as FDA gave a veritable open mic to consumers, the dairy industry, and its plant-based disruptors to weigh in on the need for new dairy-naming standards. As you might suspect, it’s been a spirited discussion. So we spoke with a few participants to learn what they think consumers should read when they reach into the dairy case.

Can of Worms
You almost can’t blame FDA for putting off updating its dairy standards of identity; spelled out exhaustively in 21 CFR 131 through 135, they don’t make for captivating reading. (A sample from the standard for milk: “Milk is the lacteal secretion, practically free from colostrum, obtained by the complete milking of one or more healthy cows. Milk that is in final package form for beverage use shall have been pasteurized or ultrapasteurized, and shall contain not less than 8¼ percent milk solids not fat and not less than 3¼ percent milkfat…”)

But did FDA realize that in proposing this update, it was opening a can of worms? As far as Alan Bjerga, senior vice president, communications, National Milk Producers Federation (NMPF; Arlington, VA), is concerned, “FDA’s ‘can of worms’ is of its own creation. Because the agency hasn’t enforced its standards of..."
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identity for dairy-product labeling for decades, a Wild-West approach that isn’t seen anywhere else in the world has taken hold in grocery aisles.”

**Wild West**

That Wild-West approach is part-and-parcel of the gold rush for plant-based dairy lookalikes that market watchers predict will keep paying dividends into the future. MarketandMarkets projects a CAGR of 11.4% from 2018 to 2023 for the dairy alternative category, taking it from a value of $17.3 billion to $29.6 billion over the forecast period.²

Yet with many of these products packaged almost indistinguishably from their dairy counterparts, there’s room for confusion as to what kind of “milk” a consumer might be buying. So while FDA “supports choice and innovation in the marketplace,” Commissioner Gottlieb’s statement reads, the agency is also mission-bound to “ensure that the labeling of such products does not mislead consumers, especially if this could compromise their health and well-being.”¹

And Bjerga thinks it’s about time. "FDAs belated attention last year, which came in response to the growing public-health problem of consumer confusion over the nutritional content of beverages that inappropriately use dairy terms,” he says was “a welcome corrective to their own inaction.”

**Dairy Down?**

Plant-based partisans proffer a different perspective. “Big Dairy’ has a powerful lobby and it asked FDA to enforce its standards, suspects Adam Lowry, cofounder and co-CEO, Ripple Foods (Emeryville, CA). And that, he continues, “has everything to do with the fact that dairy consumption is declining in the U.S. as more consumers look to plant-based, and the dairy industry is playing defense by trying to take away a product identifier that’s been used forever.”

Daniel Fabricant, PhD, CEO and president, Natural Products Association (NPA; Washington, DC), sees a similar impetus. “The only parts of dairy that are growing are ultra-filtered and A2 milk,” he says. “Dairy’s been declining for a long time. And that’s a big part of this discussion. People want to protect their market share.”

Not so fast, counters Bjerga. “The plant-based industry will say that dairy’s just upset because their sales are slipping and they’re worried about eroding market share. Not true. First, we’ve been advocating FDA action for 40 years, through good times and bad. Second, dairy consumption of all products has actually been rising, with butter at a record.” Cheese, too, is trending slightly up, he adds, “despite the imitators.”

**Bait-and-Switch**

But those imitators are the nut-, seed-, grain-, and legume-based competitors enjoying surprising success at winning over even omnivorous consumers—and it’s worth exploring whether or not they’ve done so by duping shoppers into thinking they’re the “real” dairy deal.

“Consumers are not at all confused about what is dairy and what’s not,” Lowry believes. “In fact there’s case law that proves exactly this, relating to soy milk, where it was shown that no one thinks ‘soymilk’ comes from cows.”

Nor has Fabricant seen data suggesting that the appearance of the term “milk” on plant-based beverages is a bait-and-switch. “I don’t think consumers are necessarily confused” about what’s dairy milk and what isn’t, he contends.

**All Milk Is Not Created Equal**

But if anything confuses shoppers, Fabricant concedes, “that’s the nutrition aspect.” And here, at least, both dairy and plant-based advocates agree.

“The plant-based industry often likes to say that consumers aren’t confused because ‘they know almonds aren’t a dairy product,” Bjerga says. “That’s a red herring. The debate here isn’t over that type of confusion. The debate is

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**MEAT OF THE MATTER**

**Consumer poll reveals surprising attitudes about what’s in a name.**

According to Steve Harman, account director, Ingredient Communications, a provider of PR services to ingredient companies (Crawley, UK), the debate over what plant-based products should call themselves “is an issue that’s been brewing for a few years now, and not just in the U.S.”

Exhibit A: The European Court of Justice recently prohibited the use of identifiers like “milk,” “butter,” and “cheese” for non-dairy products, he says, and France now prevents vegetarian products from labeling themselves in the same way as meat. “Much of this is being driven by a meat industry backlash against the growing popularity of plant-based diets,” he notes. “It’s not surprising that the politician who proposed the French ban is a former cattle farmer.”

So with plant-based naming now a political issue, Ingredient Communications wanted to learn where consumers stand and surveyed 1,000 people in the U.S. and the UK to do just that. “Some of the results were surprising,” Harman says, “in particular the fact that 25% of respondents thought manufacturers of vegetarian products shouldn’t be allowed to use meat-related names.”

Also unexpected: the gulf between vegans and vegetarians in their product-naming preferences. “Vegetarians were the least likely to approve of meat-related names, with only 18% supporting a ban,” Harman says. “However, vegans were even more likely than meat-eaters to oppose meat-free products using meat-related names, with one in three supporting a ban. They were also the group least likely to buy a meat-free product if it was labeled with a word such as sausage, burger, or steak.”

Further, survey results betrayed a certain skepticism among consumers as to companies’ intentions. “We asked why people didn’t approve of words like sausage or burger being used to describe vegetarian products,” Harman notes, “and the most common reason was that they believed it to be misleading.” Ouch.

So what’s the take-home message? That choosing names for plant-based alternatives “isn’t as simple as a straight fight between meat producers and manufacturers of vegetarian products,” Harman concludes. “What’s definitely the case is that there needs to be a debate, and it needs to include the voices of consumers.”

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over confusion on nutritional content—that’s what FDA asked about, and that’s where the facts are on our side.”

Indeed, “Consumer research has repeatedly shown consumers have incorrect perceptions of the relative nutritional merits of dairy versus nondairy products,” Bjerga continues, citing a 2018 IPSOS poll of 2,006 U.S. adults, commissioned by Dairy Management Inc., showing that roughly half mistakenly believe that the main ingredient in plant-based beverages comes from the plant itself (“Such drinks are mostly flavored water,” an NMPF statement counters), while more than a third believe that plant-based beverages have the same or more protein than dairy milk, when the latter can have up to eight times the protein of the alternatives.

FDA’s Role

That said, banning the use of dairy names on nutritionally equivalent nondairy alternatives “would actually create more confusion, not less,” Lowry believes. “The dairy industry wants milk to be solely ‘the lacteal secretion of a hooved mammal.’ That’s not just gross, but wrong.”

Ultimately, he thinks the agency should keep its eyes on the prize. “FDA’s role is to protect consumers,” Lowry points out. And limiting the use of “milk” to plant-based alternatives with equivalent nutrition to dairy milk—as long as labels make explicit that the milk is from plants, not cows—strikes him as an effective solution.

Bjerga also emphasizes consumer protection. “The FDA was established to protect consumers, and they should do so by enforcing their own rules given the clear market confusion and flouting of regulations that’s taken place via their own inaction,” he says.

Truth or Consequences

But what of any agency obligation to promote innovation, or even free speech? “Adding some nuts to water, throwing in a bunch of chemicals, and calling it milk isn’t innovation,” Bjerga says. “It’s dishonest.”

And the free-speech part? The NMPF actually commissioned a study of case law to determine where the boundaries may lie, and in a citizen petition the organization filed with FDA on February 21, it outlined a labeling framework that it feels respects the plant-based industry’s first-amendment arguments.

In a statement regarding the petition, NMPF Executive Vice President Tom Balmer emphasizes that the organization isn’t arguing for any “bans” on speech. Its approach “simply relies on proper disclosures that allow for appropriate, truthful, non-misleading messaging. In the end, products that are ‘milk-like’ or ‘yogurt-like’ are not actual milk or yogurt—and the nutritional distinctions are critical to informed consumer decision-making.”

Fabricant, who used to direct dietary supplement programs at FDA, has valuable insights, too. “The agency’s goal is to protect and promote public health, and you do that with information based on fact, not on feelings,” he says. And that’s what the Nutrition Facts panel is for: “to get factual information
For now, market researchers see no end to dairy alternatives’ growing sales.

into consumers’ hands. I look at this less as a problem with the term ‘milk’ than as a chance for consumer education."

Beyond that, he continues, “While you always have to start with freedom of speech, you can’t hide behind it if you’re going to defraud or confuse consumers."

As it stands, the comment period on the matter has closed, and FDA is combing through the input. While industry insiders are reluctant to spitball FDA’s decision, it never hurts to be optimistic. As Lowry muses, “I think it’ll work out in the end because consumers already know that milk can be dairy or nondairy. Ultimately, it should be the consumer’s call, and no consumer is confused about this. This is entirely industry driven.”

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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For now, market researchers see no end to dairy alternatives’ growing sales.

References

In the never-ending quest for weight-management solutions, ingredient suppliers continue to introduce ingredients to market while substantiating those that are longstanding. The last many months have brought about a number of significant discoveries in terms of new research and new products to market. Whether the manufacturer’s interest lies in botanicals or highly innovative extractions, there’s a vast array of ingredients to consider.

Here we share some scientific highlights from around the dietary supplement industry, all relating to ingredients for weight management.

**Chromium Picolinate**

Some ingredients in the weight-management category have been shown to encourage fat loss. Unfortunately, these ingredients also tend to encourage lean body mass loss. A recent scientific review comparing popular weight-loss ingredients found that chromium picolinate encouraged fat loss alongside the lowest amount of lean body mass.\(^1\) It’s great news for Nutrition 21 LLC (Purchase, NY), which funded the study on its Chromax chromium picolinate ingredient against popular weight-loss ingredients. Besides Chromax, the study included green tea (Camellia sinensis), malabar tamarind (Garcinia cambogia), and African mango (Irvingia gabonensis).

“Healthy muscle mass has been more commonly referred to as the ‘currency of aging,’ likely because without it the body will start to break down, negatively impacting movement and balance,” says Mallory Junggren, senior director of marketing at Nutrition 21. “However, the more lean muscle you can retain, the better your chances are of preserving that mobility.”

An essential nutrient for humans, chromium helps insulin function by more effectively transporting glucose into cells. By improving insulin function, muscle cells get the nutrients they need for proper muscle maintenance. It’s a holistic-sounding approach to weight loss, and one that the company is interested in better understanding with future scientific research.

Chromax is available in powder format for use in tablets, capsules, nutrition bars, and pre-mixed beverages.

**Okra Pod Powder**

Known for its slimy quality in various cooking preparations, okra (Abelmoschus esculentus) has a high mucilage content. The mucilage contains fibers that can bind to fat and, so doing, eliminate fat from the body prior to its absorption. The phenomenon makes okra a unique candidate for weight-management solutions.

Nexira (Rouen Cedex, France) is capitalizing on okra as a fat binder with its new ingredient Okralin, a patented combination of okra pod powder and inulin. According to the company’s latest animal research, Okralin works as a fat binder more effectively than okra itself and more effectively than cactus powder and chitosan, which are both sold commercially for their fat-binding properties. A more recent human study suggests that Okralin promoted weight loss significantly more than a placebo in 12 weeks.\(^2\)

While Nexira’s Okralin is marketed primarily as a fat binder, okra itself is increasing understood as having other properties that are useful in weight and diabetes management.

**A Compound in Shilajit**

Having already created a successful market for shilajit as a healthy aging ingredient, Natreon (New Brunswick, NJ) has more plans for shilajit in the future. In March 2019, the company earned a U.S. patent for an isolated compound in shilajit and “prevention and/or treatment of body weight gain.”
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PATENTS: US 10,085,963; AU2015351423; JP6472453; US 7,063,861; JP4205943; EP1254209; NZ518116; AU773081

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Shilajit is a rock exudate used in Ayurveda and sourced from the Himalayas and other mountain regions. Within the substance, Natreon isolated a compound called urolithin B. The compound is at the center of Natreon’s new U.S. patent, and Nutritional Outlook will learn more about it as Natreon moves closer to marketing. For now, Natreon has developed and identified standardization procedures, biomarker compounds, and undisclosed pharmacological studies to support a future market for the ingredient.

Morning Glory

Unlike other morning glories, Operculina turpethum is a wandering vine with perceived weight-management potential. Cepham Inc. (Somerset, NJ) started marketing the ingredient under the name OperQthin, making it the latest Ayurveda ingredient to come to the mainstream market.

"Over the years, much commercial and application research has been focused on common Ayurvedic herbs like Garcinia, Coleus, and Gymnema," says Cepham president Anand Swareoop, PhD. "While very popular in Indian traditional medicine system, morning glory has not been given its due attention. However, with Cepham’s research initiative on less-known herbal remedies, this product is in focus again."

Right now, supporting science on OperQthin is limited to animal trials that suggest potential anti-diabetic and weight-reduction benefits, but Cepham says a human randomized, controlled trial protocol is in the works for a study that could be completed by late 2020.

Three Gingers

Ginger may support weight management via potential mechanisms such as thermogenesis, appetite control, and inhibition of intestinal fat absorption. Much of the available research, however, is on common yellow ginger (Zingiber officinale). To distinguish its ginger offering from that of other suppliers, Cepham has unveiled GyngerLean, a formula combining yellow ginger, red ginger (Alpinia galangal), and black ginger (Kaempferia parviflora).

Cepham believes its trio of gingers can have a synergistic effect on weight management. An animal trial on GyngerLean is now complete and, once safety studies clear, Cepham will begin a study on GyngerLean in humans.

White Kidney Bean

A new meta-analysis supports the notion that a proprietary extract of white kidney bean (Phaseolus vulgaris) can positively influence body weight and body fat in humans. The extract is Phase 2, a product from Ashland (Kearny, NJ).

White kidney bean is known to contain amylase inhibitors which can block or slow the absorption of carbohydrates from meals. But because historical research on white kidney bean extract has yielded mixed reviews, researchers decided to focus solely on Phase 2 studies for this meta-analysis. In review of 10 studies, they determined that Phase 2, when taken with meals containing carbohydrates, was associated with weight loss compared to placebo.

The meta-analysis, funded by Ashland (previously as Pharmacem Laboratories), suggests that manufacturers should not assume a false equivalence of white kidney bean extracts on the market today. Phase 2 is the most studied of those available.

GOS Prebiotic

Prebiotics and probiotics are often added to foods and dietary supplements with the hope or expectation that they will foster diverse and beneficial bacteria populations in humans. Concerning weight management, obesity, and related health complications such as leaky gut have been associated with low diversity of bacteria present in the gut. Now, prebiotics and probiotics are evaluated for potential use in obese populations, but researchers are also interested in combining these ingredients to create symbiotics that might be more effective in improving health factors. Such was the inspiration for a recent USDA-funded study on one prebiotic and two probiotics.

Researchers assigned humans to consume a prebiotic galactooligosaccharide (GOS) and one of two probiotics, separately and combined. After three weeks, fecal analyses showed that symbiotic combinations did not improve intestinal function, but each ingredient on its own was associated with improvements in gut permeability. It’s still possible, the researchers say, that a higher dose of GOS, combined with probiotics, may have yielded a significant improvement with symbiotics.

FrieslandCampina (Amersfoort, Netherlands) provided GOS for the study.

Brewer’s Yeast

Following up on years of research, Fytexia Corp. (New York City) has expanded its weight-management portfolio with a unique peptide fraction derived from brewer’s yeast (Saccharomyces cerevisiae). Dubbed DYF-10, the ingredient reportedly influences satiety hormones when consumed.

DNF-10 was introduced at SupplySide West in Las Vegas last fall, and the ingredient is backed by numerous animal and human studies showing benefits such as reduced caloric intake to weight loss. Fytexia has future plans to better learn about DYF-10’s mechanisms of action and influence on hormones in different populations. Until future studies are performed, the company continues to analyze its existing data for new understandings.

Fytexia also markets a fat-burner derived from citrus (Sinetrol) and a concentrated polyphenol ingredient equivalent to five portions of fruits and vegetables (Oxxynea).


References

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Healthy-aging marketers have traditionally focused on female consumers, but in recent years, healthy-aging products for men have gained popularity as older men turn to supplementation to help maintain their vitality and fitness levels.

Golan Raz, head of the global health division at Lycored (Secaucus, NJ), says that the healthy-aging space is shifting toward a unisex approach where both women and men are now seeking products that can help them combat the effects of aging. “This is wonderfully demonstrated in the ingestible skincare space,” Raz says. “More and more men are realizing that beautifully aging skin isn’t just the domain of women.”

A recent Lycored survey of 313 men over the age of 50 found that the top health concerns for older men are diabetes and heart disease. Cardio-metabolic wellness, Raz said in a Lycored press release, is a significant source of anxiety for older men. Raz says that living a healthy lifestyle and ensuring proper nutrition are multifunctional activities that support heart, brain, and prostate health—all key areas of concern for aging men.

Demand for male-oriented healthy-aging products has risen, and brands are developing and researching new and established products in response. Ahead, we summarize new research and other new developments in men’s healthy-aging ingredients.

**Fenugreek Extract Increases Strength and Body Mass in Healthy Men**

Mariko Hill, product development executive for Gencor (Irvine, CA), says that men’s concerns around vitality are ensuring that testosterone-oriented ingredients stay at the top of the market. “Ingredients that promote healthy testosterone levels are still dominant in the men’s health supplement space,” Hill says. “Men tend to gravitate toward ingredients that boost muscle mass and promote vitality, which are two elements that testosterone has a huge influence on.”

Gencor recently completed a new, not-yet-published study on its branded fenugreek (Trigonella foenum-graecum) extract Testofen. This double-blind, randomized, dose-response clinical trial followed 138 healthy, non-smoking men for eight weeks. Subjects were randomized to receive either 300 mg or 600 mg of Testofen per day, or a placebo. All subjects in all conditions were assigned an exercise regimen.

After eight weeks, participants in both of the Testofen conditions saw statistically significant increases in leg strength, aerobic capacity, and body composition relative to participants in the placebo condition. The study also found that the effects were dose-dependent, with participants in the 600-mg condition seeing larger gains than those in the 300-mg condition.

Hill says the forthcoming study indicates that Gencor’s fenugreek extract is an effective supplement for improving body composition and muscle strength in aging men. She notes that maintaining healthy testosterone levels is important as men age: “Muscle mass and testosterone levels decrease as men age, which leads to a reduced quality of life due...”
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Men’s Health

Fenugreek Extract Boosts Energy, Stamina, and Testosterone

Testosterone is implicated in bone health, blood health, and even cognition. As testosterone tends to drop starting when men enter their 40s, maintaining healthy testosterone levels is critical for healthy aging in myriad ways.

A recent clinical trial provided to *Nutritional Outlook* by Cepham (Somerset, NJ) found that Cepham’s branded *Trigonella foenum-graecum* extract Testncrease improved free testosterone levels by 6.3 ng/dL, making it over 2.5 times more effective than a placebo. Cepham says the active ingredient in fenugreek extract, protodioscin, is also an effective energy enhancer and mood balancer.

Maca Improves Physical Performance, Sexual Function, and Fatigue

Maca also continues to be a men’s health ingredient of interest, with researchers continuing to study its benefits.

In a study recently published in the *Journal of Exercise and Nutrition*, 22 males and 25 females were randomly assigned to receive either placebo or 2.1 g of a patented Peruvian maca—Lepidamax ingredient from Nutrition 21—for 28 days. Researchers utilized the Shapiro Test to test the effects of maca on grip strength, mood, and sexual functioning, and a Nonparametric

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**Healthy-aging products for men have gained popularity as men turn to supplementation.**

Wilcoxon Rank Test to examine the differences between groups for men and women separately.

Men taking maca had a significant improvement in handgrip strength, sexual function, and a reduction in fatigue, compared to placebo. (Women taking maca saw a significant improvement in fatigue, mood, sexual function, and handgrip compared to baseline, but these improvements were not significant when compared to placebo.)

“We’re excited to see that these clinical study results support Lepidamax’s ability to effectively enhance various end-points related to men’s health, enabling end-users to break through potential performance barriers,” said Joe Weiss, president of Nutrition 21, in a press release. “This study confirms our previous understandings around this ingredient and has exceeded our expectations regarding the possible applications for Lepidamax.”

**Pycnogenol Is Well-Tolerated, Effective for BPH**

In December 2018, Horphag Research (Chicago, IL) announced the results of a new study demonstrating the efficacy of its branded ingredient Pycnogenol, a French maritime pine bark extract, in relieving the symptoms of benign prostatic hypertrophy (BPH).3

The study followed 75 men between the ages of 55 and 75 for eight weeks. Subjects who took 150 mg of Pycnogenol per day saw statistically significant improvements in BPH symptoms, with no significant side effects, compared to those who took a placebo.

The study also found that Pycnogenol was even more effective than pharmaceuticals like finasteride and dutasteride in managing BPH symptoms.

In December, Sebastien Bornet, vice president global sales and marketing for Horphag, told *Nutritional Outlook*’s associate editor Sebastian Krawiec: “This is a big issue. It’s about quality of life. If you have to wake up two, three times during the night, you can’t sleep. If you can’t sleep, you can’t stay healthy, and then it’s a snowball effect and you have other health issues at the end of the day.”

**Product Innovation Makes Drinkable Tongkat Ali Possible**

Tongkat ali (*Eurycoma longifolia*) has a long history as a men’s vitality and sexual health supplement, with applications in sports performance, weight loss, and energy markets. Annie Eng, CEO of HP Ingredients (Bradenton, FL), says that new developments with HP Ingredients’ branded tongkat ali supplement LJ100 have now made it possible to deliver tongkat ali in more delivery formats.

“Tongkat ali by its nature imparts a bitter taste,” Eng says. “The material itself works well in pill forms, but we’ve received several requests from brand marketers who want to use the ingredient in beverage formats.”

Now, Eng says, “Microencapsulation allows for the incorporation of LJ100 into beverages, as microencapsulation successfully masks the bitter edge.” She adds that microencapsulation also allows for slower release of the active ingredient while also offering better ingredient stability and bioavailability.

Last year, HP Ingredients completed a new study of LJ100 that examined the relationship...
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*Based on publisher’s own data.*
between testosterone, physical vigor, emotional well-being, and cognition. The 24-week study⁴, a randomized, double-blind, placebo-controlled parallel study, followed 83 people between the ages of 25 and 65 who had a BMI of 18-30. Participants were randomly assigned to receive either one 50-mg tablet of LJ100 plus a multivitamin per day, or a matching placebo, for 24 weeks. The study authors assessed efficacy after 12 weeks and safety after 24 weeks.

Participants in the LJ100 condition showed a significant decrease in neutrophils that degranulate to release proteases during pathogenesis and stress. The study authors speculate that tongkat ali is an adaptogen that may improve emotional health and vitality by modulating the body’s immune response.

“Supplementation with tongkat ali and a multivitamin was associated with improvements in vigor, cognition, and testosterone levels,” Eng says. “There are more than a dozen studies on LJ100 [and study results like these are why] it’s often positioned for male libido, energy, and sports performance.”

A Better-Tasting Saw Palmetto Powder

Saw palmetto extract has long been a popular men’s health supplement, particularly for prostate health. But one challenge has plagued brands and manufacturers from the start: Saw palmetto simply doesn’t taste very good.

Stephen Hill, vice president of product development and regulatory for Valensa International (Eustis, FL), says that saw palmetto extract’s naturally pungent sensory profile has traditionally limited the supplement’s applications outside of a softgel. But now, delivery format innovations are making it possible to create odorless and flavorless saw palmetto powders that can be used in formulations for bars, chewables, smoothies, and other finished product formats.

“By microencapsulating the lipid extract, Valensa has been able to deliver a more sensory-neutral and functionally superior powderized format,” he says. “We hope this leads to greater reach and compliance by enabling the benefits of saw palmetto to be delivered in new forms and products that men prefer.”

Hill says that saw palmetto extract prevents the conversion of testosterone to dihydrotestosterone by inhibiting the action of 5-alpha-reductase. This means the compound has potential applications in men’s health well beyond its previous use as a prostate health ingredient.

“Valensa views saw palmetto extract as the key to unlocking an active lifestyle without the undesired sexual side effects that men often experience,” he notes. “We’re going to have more to say about this topic soon.”

Men’s Health Ingredients Ready for Innovation

The men’s healthy-aging ingredients market is fertile ground for innovation, with a growing demographic of baby boomers looking to maintain their vitality and keep up an active lifestyle. Recent ingredient developments have shown that there’s still plenty of room for new formats and formulas. As more aging men look to stay fit and healthy, expect new opportunities for men’s health ingredients to emerge.

References

Mike Straus is a freelance writer living in Kelowna, Canada. He has written for publications including Canadian Chiropractor Magazine, UX Booth, and Iconic Concierge Vancouver.
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Clean-label native starches continue to challenge modified starches in function and stability.

BY SEBASTIAN KRAWIEC, ASSOCIATE EDITOR

Clean-label is an important purchase prerequisite for many a consumer these days. Even foods designed for convenience such as frozen, canned, jarred, and instant foods are getting the clean-label treatment. For many consumers, the health benefits they associate with a cleaner label are non-negotiable, no matter the product.

Sharon Chittkusol, associate marketing manager, Clean & Simple, U.S./Canada, for Ingredion Inc. (Westchester, IL), notes similar findings from a survey her company commissioned in 2017 in U.S. and Canadian consumers. The survey found that “consumers in the study believed that ‘natural’ ingredients are better for their health, the environment, and taste better,” she says. “We also confirmed that ingredients gained consumer acceptance when they were recognizable with pronounceable names and were not something unfamiliar or that sounded like they were made in the lab.”

Starches play an important role in foods by providing texture, which plays a significant role in how consumers experience food. Achieving the right texture can be difficult, however, particularly when a food’s processing subjects it to extremes in temperature. “Nowhere is [significance of texture] more evident than [in] frozen foods, where sauces must withstand multiple freeze/thaw cycles,” explains Shiva Elayedath, senior technical services manager for Cargill (Minneapolis). “The sauce tends to break down as ice crystals grow and recede with each cycle. In the past, we relied on modified starches to prevent these sauces from ‘weeping,’ but increasingly, consumers are asking for alternatives.”

Rice flour, rice starch, potato starch, and tapioca starch are among the most common clean-label starch alternatives today. (They are also referred to as functional starches.) Non-GMO corn starch is another clean-label option that is familiar to consumers. “The main goal of functional starches and flours is to deliver viscosity and to offer high stability to heat, acid, and shear during processing and help provide product stability over shelf-life, giving manufacturers the ability to maintain product quality over ambient as well as refrigerated/frozen shelf life,” explains Chittkusol. “Functional starches and flours help products retain a smooth texture and prevent separation after storage.”

Traditionally, chemically modified starches have been the go-to solution for texture and stability, as native, clean-label starches were not reliable for maintaining textural stability in response to harsh conditions such as freezing and high heat. “Traditional single-source native starches exposed to these conditions tend to break down and release water,” explains Elayedath. “They get weepy and transform a thick, creamy sauce into a gloppy mess.”

However, ingredient suppliers have devised ways to physically modify or combine native starches to improve functionality and allow them to replace chemically modified starches. Blends are key, says Elayedath: “Since Cargill began experimenting with different starch blends from various botanical sources, we’ve found native starches can do more than we ever imagined—especially if we blend two or three together. We’re also using basic processing techniques, like controlling moisture and heat, to create more robust starch solutions that better withstand harsh processing conditions, yet still appear on ingredient statements as plant-sourced starches.”

As for Ingredion, says Chittkusol, the company’s functional native starches benefit from a “physical modification process” that can help sidestep processing challenges while remaining clean label. The company also works with customers to adjust formulations or manufacturing processes as needed.

For example, Ingredion’s Novation starch portfolio includes Novation 340 and 350, which are pregelatinized instant starches processed from waxy maize. Novation 350 is for systems with high-dispersion requirements. These starches are ideal for refrigerated dressings, dips, sauces, marinades, pie fillings, and frozen/refrigerated prepared meals. Meanwhile, the firm’s Novation 309 and 609 are organic corn starches that provide cold-temperature stability with the possibility of simplifying labels and reducing expense by eliminating costly hydrocolloids.

Cargill’s SimPure line of clean-label starches includes SimPure 99560, a blend of potato and tapioca starches, and SimPure 99500, a potato starch. “These starches have excellent freeze/thaw stability and deliver great texture and viscosity, holding up to the rigors of modern processing and delivering a consistent end-product in both acidic and neutral pH systems,” says Elayedath.

With the continued innovation in native starches, it’s getting easier than ever to develop the clean-label products consumers want, without having to sacrifice taste and functionality.
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