U.S. shoppers already have a federal non-GMO label in the form of the USDA Organic seal. So why do we need another? p. 32
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Is Non-GMO Riding Organic’s Coattails?

It’s no secret that the food industry teeters on label overload. U.S. food shoppers who want to make socially conscious choices today must wade through numerous packaging claims and certification seals. Eager to join these is the Safe and Accurate Food Labeling Act’s (SAFE; H.R. 1599) proposed voluntary federal seal for non-genetically modified organisms (GMO). Passed by the U.S. House in July, SAFE was in the hands of the Senate as this issue went to press.

On page 32, I weigh potential overlap between SAFE and the USDA’s National Organic Program (NOP) and other existing non-GMO certification seals. I also question whether SAFE would increase consumer confusion. Is there so much clutter that we’ve rendered these seals meaningless to the everyday consumer?

The answer, sadly, is that regardless of SAFE or any other GMO-labeling law, consumers are already confused about GMOs to begin with. In June, the Hartman Group estimated that just over half of the U.S. understands what a GMO is. Not only that, but a mere 9% know that certified-organic food is inherently non-GMO.1

More outreach would educate consumers about what organic is, what non-GMO is, and what their regulations mean. Even Gwendolyn Wyard, senior director of technical and regulatory affairs for the Organic Trade Association (Washington, DC), who believes that consumers are generally aware that USDA Organic certification excludes GMOs, agrees that “more education is needed.” For the record, a USDA spokesperson calls the agency “committed to ensuring consumers understand the USDA organic label and its requirements.”

The USDA Organic label, after all, has a lot to be proud of, banning both pesticides and GMOs—something that most GMO-certification programs do not. Put another way, “Organic is by definition non-GMO, but non-GMO may or may not be organic,” says David Carter, CEO of FoodChain ID (Fairfield, IA). “Whereas organic addresses a wide range of issues, including use of pesticides, synthetic chemicals, antibiotics, hormones, sustainable agronomic practices, etc., non-GMO addresses a single aspect of food and agricultural production.”

At least one person suggests that non-GMO labels might actually benefit from consumers’ inability to distinguish between organic and non-GMO. In a February story titled, “Why the ‘Non-GMO’ Label Is Organic’s Frenemy,” NPR food and agriculture correspondent Dan Charles quoted Cornucopia Institute cofounder Mark Kastel as describing non-GMO labels as “a potent marketing vehicle designed to blur the line between organic and nonorganic.” In short, Charles wrote that some food marketers see non-GMO as a less-expensive certification that delivers the same benefits as organic certification in the minds of consumers who don’t know the difference.

One organic certifier is trying to change that. California Certified Organic Farmers (CCOF) rolled out a new certification seal this March that highlights organic’s benefits in relation to non-GMO. As reported by NPR writer Peggy Lowe in August, CCOF calls its new seal “Organic Is Non-GMO & More.” According to CCOF, this seal “underscores the prohibition of GMOs in organic and recognizes the many contributions of organic to a healthier world.” In a March 2015 press release, Philip LaRocca, chairman of CCOF Inc., stated, “CCOF firmly believes that organic is the champion of non-GMO” because it provides assurance not just of non-GMO but also for “enhancing soil health and biodiversity, supporting animal welfare, and providing traceability of products produced without synthetic fertilizers or persistent pesticides.”

If leveraged effectively, food-certification seals are extremely valuable for both education and marketing. If successful, they provide consumers with meaningful and easily understandable information about what’s in their food. If not, the situation clouds, and it’s the consumer seeking truthful information who suffers at the end of the day. As the organic industry observes the skyrocketing success that the non-GMO industry is enjoying, it will become even more important for organic proponents to not only stand up for USDA Organic certification but also to teach consumers about what the seal really means.

Jennifer Grebow
Editor-in-Chief

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FDA has yet another suggestion for giving consumers more information about the added sugar contained in food and drink: add a percent daily value for added sugar to the nutrition facts label. FDA officially pitched the idea in the Federal Register on July 24. The agency’s proposal supplements its original March 3, 2014, bid to drastically reform the nutrition facts label, including changing the way the label lists serving sizes and calorie content.

Back in March 2014, FDA already made one proposal to change the way sugar is listed. Current labels list a product’s sugar content as one value that reflects the combined amount of naturally occurring and added sugar. (As opposed to sugars naturally occurring in foods like fruits and vegetables, added sugars are sugars and syrups put into packaged foods and beverages during food manufacture.) Instead, FDA said, it would add a separate line to specifically reflect the quantity of added sugar in an effort to get consumers to choose products lower in added sugar. If this proposal takes effect, nutrition facts labels would list two sugar values: one for total sugar (natural and added) and a sub-listing for added sugar only.

Not everyone is happy about the agency’s latest suggestion to also include a percent daily value for added sugar, which would measure the percentage of a packaged good’s sugar content against the total added-sugar intake recommended for a day’s diet.

Commenting on the latest percent daily value proposal, the International Food Information Council Foundation (IFIC) reiterated its earlier position that the way in which FDA proposes to list added sugars confuses consumers. IFIC is basing its opinion on consumer research the foundation supported, which determined that consumers had difficulty identifying the amount of total sugar in a product when information about added sugar was also included—in part because many consumers don’t even understand what added sugar is.

“The short (and sweet) answer...providing added-sugars information significantly decreases the ability for consumers to accurately identify the total amount of sugars in a product,” stated Kris Sollid, RD, IFIC’s director of nutrients communications, who co-authored a paper on IFIC’s consumer-study findings now published in the Journal of the Academy of Nutrition and Dietetics.

But FDA accompanied its July 24th percent daily value proposal with findings of its own about how consumers understand sugar listings on the nutrition facts label. FDA’s conclusions are based on a 2014 study the agency undertook to evaluate how its proposed labeling changes would impact consumers’ label comprehension.

According to FDA, a majority of subjects in its assessment were able to correctly report the amount of added sugars when declarations for both total and added sugars were featured. (The label tested did not include an added-sugar percent daily value, however.) FDA further reported that “when declared, higher amounts of added sugars tended to produce more negative judgments about the product’s healthfulness.”

However, the agency concurs that consumers still don’t seem to wholly grasp the difference between added and total sugar. In the report, the agency said, “Although the majority of the respondents correctly identified the total amount of sugars in a serving of food with each label presented that included an added-sugars declaration, the added-sugars experiment results show that a number of participants were confused about the distinction between sugars and added sugars, regardless of whether added-sugars declarations appeared on the nutrition facts label. When participants were viewing nutrition facts labels without added-sugars declarations, they could not accurately determine the amount of added sugars in the products, with the majority reporting that the total sugars amount was the amount of added sugars.”

Still, given its latest daily-value proposal, it appears that FDA will continue to focus on pushing for new ways to list added sugar on the nutrition facts label in an effort to inspire consumers to make healthier choices.
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FDA says it did not include the recommendation for a percent daily value for added sugars when it released its broader March 2014 proposal because the agency did not have a "scientifically supported quantitative intake recommendation for added sugars, based on a biomarker of risk of disease or other public health endpoint, on which a DRV [daily reference value] for added sugars could be derived."

Since then, the agency says, the latest data from the 2015 Dietary Guidelines Advisory Committee (DGAC)—data that will inform the impending final 2015 Dietary Guidelines for Americans—has provided more insight on the link between added sugars and an increase in heart disease and other diseases that gives FDA reason to “tentatively conclude that the 2015 DGAC report and the scientific information on which it relies provide a basis for FDA to establish a DRV reference point for the added-sugars declaration at 10% of calories that is based on a public health endpoint and is necessary to assist consumers to maintain healthy dietary practices.”

FDA’s director of the Center for Food Safety and Applied Nutrition, Susan Mayne, PhD, issued this statement in July: “FDA considered the evidence and determined that it supports setting a daily value for added sugars. The daily value, which is used to calculate the percent daily value that consumers see on the nutrition facts label, would be 50 g of added sugars for adults and children four years of age and older and 25 g for children one through three years.”

In its 2015 report, the DGAC recommends that Americans limit their intake of added sugar to less than 10% of their total daily calorie intake and also stresses that added-sugar intake above the 10% mark makes it difficult for individuals to meet their daily nutrient requirements while staying within parameters for healthy calorie intake.

The 2015 DGAC estimates that 90% of the U.S. population currently exceeds the recommended daily limits for solid fats and added sugars.

Some good news did come out of the committee’s report, however. The committee said that although intake of added sugar is still above the recommended limit, that intake did decrease between 2001–2004 and 2007–2010.

“Some improvements have been made in added-sugars intake, with noticeable declines in mean intakes for all age groups and among both males and females when comparing 2007–2010 data with 2001–2004 data,” the committee said. “The improvements,” it added, "provide some optimism for improved diets.”

Regulators still have good reason to be concerned about Americans’ high intake of added sugars. Some estimates say that America’s added-sugar consumption has gone up by a whopping 30% over the past three decades and that 16% of the average American’s daily calories come from added sugar. Studies have shown that high amounts of added sugar can significantly increase the risk of heart disease, diabetes, and obesity.

FDA hopes the nutrition facts label is a way to help consumers become more cognizant about eating added sugar. In her statement, FDA’s Mayne pointed out that “a consumer who drinks a 20-oz sugared beverage may be surprised to know it contains about 66 g of added sugar, which would be listed on the label as 132% of the daily value.”

FDA estimates that 5%–6% of products on the shelf “that significantly contribute added sugars to diets” will be reformulated if its labeling proposal takes hold. Currently, the nutrition facts label lists percent daily values for total fat, saturated fat, cholesterol, sodium, total carbohydrate, dietary fiber, calcium, and iron.

The agency is now accepting comments on its new suggestion to include a percent daily value for added sugar.

Fish Oil Omega-3s May Increase Muscle Mass, Power in Healthy Older Adults

Fish oil–derived omega-3 dietary supplements may increase muscle function and mass in healthy older adults when taken daily, according to a new study by the Center for Human Nutrition, Washington University School of Medicine (St. Louis, MO).

Researchers reported that healthy older adults who received 3.36 g of EPA/DHA omega-3 per day experienced several muscular benefits and also saw improvements in muscle power in their legs when compared with a placebo group.

The double-blind, randomized controlled trial involved 60 men and women aged 60–85 who were given either 3.36 g EPA/DHA omega-3–derived fish oil or a corn oil placebo to take daily for six months. Both the experimental and placebo treatment came in the form of four identical-looking pills.

The omega-3 polyunsaturated fatty acids (PUFA) were derived from fish oil and administered in a daily amount equivalent to 200–400 g of freshwater fatty fish.

“The study indicates that dietary supplementation with marine n-3 PUFAs has significant anabolic and, even more importantly, function-enhancing effects on muscle in older adults,” says Bettina Mittendorfer, PhD, one author of the study.

Body weight, total body fat mass, and intermuscular fat content were not significantly affected by the omega-3 PUFA therapy, but there was a significant increase in thigh muscle volume, hand grip strength, and one-repetition muscle strength. Average isokinetic leg muscle power also tended to increase, according to researchers.

Based on the study results, the researchers concluded that fish oil–derived omega-3 PUFA supplementation “should be considered a therapeutic approach for preventing sarcopenia and maintaining physical independence in older adults.”

“This is an important development and has direct clinical relevance, as currently, besides vitamin D, there are no treatments good enough for the prevention and treatment of sarcopenia aside from regular exercise, which is difficult to adhere to especially in older peoples,” says Mittendorfer.
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GMO Labeling in the Hot Seat

The U.S. House of Representatives passed the Safe and Accurate Food Labeling Act in July. Where are we headed with this, and is federal GMO labeling now imminent?

BY JAMES J. GORMLEY

On July 23, the U.S. House of Representatives passed H.R. 1599, the Safe and Accurate Food Labeling Act (SAFE), also referred to by its critics as DARK, or the “Deny Americans the Right to Know” Act. As SAFE heads toward a Senate vote, stakeholders on both sides of the GMO-labeling divide are at the edge of their seats wondering what’s next.

What the Bill Proposes
SAFE would amend the Federal Food, Drug, and Cosmetic Act in numerous ways.

First, it would require developers of GMOs intended for use in food to submit a premarket biotechnology notification to the FDA. “The premarket notification must include the developer’s determination that food from, containing, or consisting of the GMO (GMO food) is as safe as a comparable non-GMO food,” the bill states.

For the GMO to be sold as food, FDA must not object to the developer’s determination of safety. If FDA determines that there is a material difference between a GMO food and a comparable non-GMO food, the bill says, “FDA can specify labeling that informs consumers of the difference.” H.R. 1599 further stipulates, “No food label can suggest that non-GMO foods are safer than GMO foods.” And the bill states that a food can be labeled as non-GMO even if it is produced with a GMO processing aid or enzyme or is derived from animals fed GMO feed or given GMO drugs.

SAFE also would establish some crossover with USDA’s current National Organic Program (NOP). Under H.R. 1599, products would be allowed to be labeled GMO-free if the ingredients’ supply-chain process controls are NOP certified.

These are only some of the significant changes SAFE would bring. Other portions of the bill, as discussed ahead, are much more contentious.

Mandatory GMO labeling took a hit in July as the U.S. House of Representatives voted “yes” on H.R. 1599, the Safe and Accurate Food Labeling Act. Largely supported by the food industry, the bill would make it impossible for states to mandate GMO labeling and takes the stance that GMOs are, on the whole, safe.

GMO Labeling Would Be Federal, Voluntary, and Preempt State Law
SAFE would amend the USDA’s Agricultural Marketing Act of 1946 to require the Agricultural Marketing Service to establish a voluntary program to certify non-GMO food. (Read more on page 32.) This voluntary federal program would preempt state and local...
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In other words, if SAFE were to become law following passage by the Senate and a Presidential signature, the law would void all state-level GMO-labeling laws. Notably, this means that the country’s first state-level, mandatory GMO-labeling law passed in Vermont last May would be rendered null. Vermont’s law requires manufacturers to label GMO-containing foods as such and prohibits manufacturers from describing genetically engineered products as “natural.” (Maine and Connecticut have also passed GMO-labeling laws, but a trigger clause means that these won’t become active until other states first pass similar laws.)

The Center for Food Safety (Washington, DC) tallies the number of bills either requiring labeling of GMO foods or prohibiting them outright at 70 to date, introduced across 30-plus states. SAFE would preempt all of these.

**Do We Need a Federal Non-GMO Labeling Law?**

Opinions vary on whether or not there should be a federal non-GMO labeling law, whether that law should be voluntary or mandatory, and whether a federal law should supersede state law.

Vermont’s law has already been challenged by those who don’t believe state-level laws are the answer. In September 2014, the Washington, DC–based Grocery Manufacturers Association (GMA), along with a host of food-chain associations, filed a complaint in U.S. District Court in Vermont challenging the state’s GMO-labeling law (Act 120). Despite this, the law was upheld, as discussed ahead.

According to the GMA’s director of communications Brian Kennedy, “Vermont’s mandatory labeling law is a costly and misguided measure that will set the nation on a path toward a 50-state patchwork of GMO labeling policies that do nothing to advance the health and safety of consumers and exceeds the state’s authority under the U.S. Constitution.”

“That’s a flat-out lie,” asserts Katherine Paul, associate director of the Finland, MN–based Organic Consumers Association (OCA). “Did he not read the 84-page decision of U.S. District Court Judge Christina Reiss?” she asks, referring to the grocery industry’s 2014 challenges to Vermont’s law that were largely dismissed this April. Among those challenges the judge dismissed is the grocery industry’s claim that Vermont’s law, by mandating state GMO labeling, violates the Commerce Clause of the U.S. Constitution, which gives the federal government the power to regulate interstate commerce. The grocery industry’s argument is that GMO labeling in one state interferes with interstate commerce.

While some argue that a federal law would solve the potential patchwork of state-level regulations, others balk at the thought of barring state-level laws. Beth Clay of Maryland-based government relations consultancy Hawk International says: “States and local jurisdictions are the great laboratories of democracy. H.R. 1599 would, if a companion bill is also passed in the Senate, void GMO-labeling laws already on the books and prevent the passage of new GMO-labeling laws.”

Megan Westgate, executive director of the Non-GMO Project (Bellingham, WA), states, “While there’s been concern about a patchwork of laws, state-level efforts are a critical strategy in helping push the need for GMO transparency.”

**Other Concerns, Including Defining Natural**

Another hothed topic nestled within H.R. 1599 is over use of the term natural. H.R. 1599 would prohibit states from holding misbranded any GMO-containing food being marketed as natural. SAFE would also require that FDA finally define and regulate use of the term natural.

Michael McGuffin, president of the American Herbal Products Association (Silver Spring, MD), whose organization opposes federal preemption, points out that SAFE does not offer any specific Congressional view as to whether GMOs will be allowed in any definition of natural.

And then there’s the concern of what will happen to products already verified non-GMO under currently existing, third-party non-GMO certification programs. Will these programs still have a place if a federal GMO standard goes into effect? This also remains to be seen.

**The Wait**

SAFE has endorsers and critics equally fired up. According to David Bronner, cosmic engagement officer for Vista, CA–based brand Dr. Bronner’s, the grocery industry needs to recognize that “consumers have the right to know if their food is engineered to be saturated in toxic herbicides.”

Preemption clause aside, McGuffin says he personally is encouraged by the bill by and large and believes that “every effort should be expended on a Senate version of the bill that is at least as good as the one that passed the House.”

The Senate will return from recess in September, and it remains to be seen if and when a companion bill to SAFE will be introduced and championed—and what the future of GMO labeling is in the United States.

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An award-winning health journalist and consultant, James Gormley has 20 years of experience in the natural products industry. He can be reached at jamesgormley01@gmail.com.
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“Natural” Claims on the Ropes

How long can marketers go on without a definition of natural?

BY JUSTIN J. PROCHNOW, GREENBERG TRAURIG LLP

The atmosphere surrounding “natural” claims in food, beverage, and dietary supplement advertising is still undeniably gray. A Nutritional Outlook article I wrote last year discussing the state of such claims concluded that until FDA formally defines the term natural, this claim—and the lawsuits it inspires—will continue to generate huge expenditures of time, money, and resources for industry companies.

As we take our annual temperature of the regulatory and legal status of “natural” claims, has anything changed? Unfortunately not...for now, at least.

No Definition, No Clarity

“Natural” claims continue to make the headlines of industry magazines, legal websites, and blogs and court dockets for one primary reason: no one knows what natural really means. FDA continues to make it clear that defining natural is not a high-priority agenda item, as reflected in the agency’s actions.

Historically, FDA has taken limited action against companies over the use of natural. When it has taken a public position over the use of natural or variations like all natural or 100% natural, the agency has done so only regarding ingredients that most reasonable people would understand not to be natural.

FDA sent three warning letters on the subject of “natural” claims in late 2014 and one letter in May 2015. The ingredients in question were sodium acid pyrophosphate, calcium sorbate, polysorbate 40, sodium benzoate, and artificial colors such as Yellow 5 and Red 40.

In the case of these four recent warning letters, the ingredients in question were sodium acid pyrophosphate, calcium sorbate, polysorbate 40, sodium benzoate, and various artificial colors such as Yellow 5 and Red 40.

For companies, a good and obvious rule of thumb to follow is that if the word artificial appears in the name of your ingredient, the ingredient is probably not natural. Still, not all cases are as clearly cut. Many “natural” claims are made for products containing ingredients for which it is less distinct as to whether they are by FDA’s standards “artificial,” “synthetic,” or “normally expected to be in a food.”

FDA considers use of the term ‘natural’ on a food label to be truthful and non-misleading when ‘nothing artificial or synthetic...has been included in, or has been added to, a food that would not normally be expected to be in food.” See 58 Federal Register 2302, 2407 (1993)

Fertile Ground for Plaintiff’s Lawyers

Lack of clarity is the arena in which plaintiff’s lawyers like best to play. Without a formal definition, it is difficult for a company to defend its use of natural, all natural, or 100% natural claims—so difficult, in fact, that very few cases, if any, actually proceed to a point that a judge or jury will actually evaluate the reasonableness of a “natural” claim.

Most cases are either dismissed by courts at the class certification stage because the plaintiffs are unable to prove necessary elements like common issues, adequate class representation, or standing, or the cases are settled out. Plaintiff’s lawyers count on the fact that many companies, especially smaller ones without the resources for a prolonged fight, will assess the situation and make a determination that settling early and moving on is better than fighting a case that, while they might eventually win, could end up costing several thousands of dollars...
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in attorney’s fees in the process. The resulting lack of precedent only serves to further uncertainty around the term natural. Until FDA formally defines natural, it will be very hard for companies to know how to properly use the claim.

In the meantime, companies are trying their best to find stable ground. As a general rule, companies are responsible for reasonably interpreting a claim; thus, the more specific a company can be when justifying its “natural” claim, the less opportunity an opposing party has to argue that the company is misrepresenting the claim.

Also consider this: Does 100% natural carry a different standard than simply natural? Is the claim “Made with natural ingredients” different than all natural? Many would answer yes; unfortunately, there is no black-and-white answer. Thanks to these obscurities, even companies trying to advertise responsibly—not just “bad actors”—find themselves vulnerable and are also getting caught up in the net of class action litigation.

An End in Sight?
Should companies consider natural a verboten claim? There has certainly been a slowdown of the rampant use of natural, all natural, and 100% natural. And, for what it’s worth, many marketing pundits suggest that due to oversaturation of “natural” claims and the amount of litigation and headlines over the term, the “natural” claim on a label does not carry the same sway with consumers that it once did.

If a company still decides to call its product “natural,” the company is well-advised to closely evaluate and weigh the benefits from using the claim against the potential risks of litigation.

FDA might not be close to defining natural, but in the near future, the agency may be forced to thanks to a certain GMO-labeling bill on the floor of Congress.

The Safe and Accurate Food Labeling Act of 2015 (H.R. 1599), which would create a voluntary federal certification regime for GMO labeling, passed a U.S. House of Representatives vote in July and pends a vote in the Senate. The bill includes a provision that would require FDA to finally define the terms natural, 100% natural, naturally grown, all natural, and “Made with natural ingredients.” If this bill passes, it could be a game-changer for the “natural” claim. Until then, “natural” claims must tread cautiously.

This article is issued for informational purposes only and is not intended to be construed or used as general legal advice. The opinions expressed are those of the author exclusively.

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Introducing The Coalition for Supplement Sustainability

The group says it will work toward establishing non-GMO standards for dietary supplements.

By Bethany Davis,
Director of Regulatory Affairs,
FoodState and MegaFood

MegaFood has always loved the way real feels. For the past 40 years, we have held ourselves to the highest standard when it comes to the fruits and vegetables in our supplement products. MegaFood is one of the only whole-food supplements companies that controls its production from farm to tablet, working directly with family farms to source only the best non-GMO and often organic produce and botanicals for our whole-food supplements. Because we are so passionate about our quality standards, we started the Non-GMO Dietary Supplement Working Group two years ago. This group was initially founded with a vision to secure a non-GMO ingredient supply chain in the supplements industry. The group consists of like-minded companies collaborating to investigate the questions that non-GMO ingredient sourcing and documentation initiatives pose for the supplements industry.

We’ve made a lot of progress when it comes to figuring out what third-party non-GMO standards should look like for supplements and how companies should comply, but we wanted to take it a step further. We’ve decided to formalize our group, give it a new name, and move towards an industry consensus of what the non-GMO standard should be for dietary supplements. We also want to look beyond GMOs and make sure the group can take on even more issues at large for our industry. As such, our new name, The Coalition for Supplement Sustainability, represents who we are: a new and improved trade association specifically for the supplements industry.

The Coalition for Supplement Sustainability is a member-driven trade association of the dietary supplement industry, established to maintain sustainable, independently verifiable and transparent standards across the entire supplement supply chain. As members, we recognize that we will not agree on all matters and that we often compete for customers, but we are taking this opportunity to raise the bar for our industry and avoid collective risk—something that will only happen through a cooperative effort. We are a vetting mechanism for the industry, and while we do not lobby state or...
federal government, we do inform other associations and retailers on our recommendations and approaches.

One of our biggest initiatives and more near-term goals for the coalition is to collaborate with third-party verifiers to create a credible non-GMO standard specifically for dietary supplements. Our hope is that this will be a toolkit for supplement companies worldwide that are looking to make their products non-GMO verified.

With the existence of the Non-GMO Project Verified seal already on the market, you might wonder why we feel a standard is needed just for dietary supplements. In our opinion, the fact of the matter is that the standard that the Non-GMO Project uses primarily meets the needs of the food industry, whose products differ inherently from supplements. For instance, a bag of corn chips might consist of four or five food ingredients; however, more complex products like dietary supplements, which often comprise dozens of ingredients, demand an industry-tailored solution. We believe that the Non-GMO Verified seal isn’t currently a feasible certification scheme for many dietary supplements and supplement ingredients such as vitamin D3 derived from sheep’s wool. Supplement manufacturers who care deeply about the issues and who are committed to non-GMO would be well served with a certification regime that meets their unique needs.

Beyond GMO issues, our larger goals will also include having members collaborate to review proposed third-party verification standards across all aspects of the supply chain, with the goal of creating a common consensus rooted in the application of international best practices, validated testing, and reliable scientific methods.

We want to hear from everyone. All dietary supplement brands and ingredient manufacturers can become members of the coalition and participate in member meetings to help drive clarity and consensus on these issues. As a coalition, we want to keep the dialogue open and come to an agreement on what the standard for non-GMO verification should be across the supplements industry.

To learn more about The Coalition for Supplement Sustainability, please visit www.supplementsustainability.org.

Bethany Davis is the director of regulatory affairs for FoodState and MegaFood. She is the chief administrative and communications officer for The Coalition for Supplement Sustainability, a group of supplement and ingredient companies that united to support a non-GMO and sustainable supply chain. With a background in pharmaceuticals, Davis was drawn to the natural products industry and is deeply engaged with the non-GMO topic. She holds a master’s degree in regulatory affairs and health policy from Massachusetts College of Pharmacy in Boston and is a voting board member of the Massachusetts General Hospital Partners Institutional Review Board.
In the United States, news headlines are full of the Safe and Accurate Food Labeling Act of 2015 (H.R. 1599), also known as the “Deny Americans the Right to Know” Act, which the U.S. House of Representatives passed this July. The bill would create a federal standard for the voluntary labeling of GMO products, as well as a USDA certification process for a “non-GMO” label. Whether you support or oppose the bill, the House passage forces us to imagine a future with continued, but now permanent, voluntary GMO/non-GMO labeling. Like many along the food and supplement supply chain, ingredient suppliers are wondering how this bill, if passed, may affect the industry. For suppliers, the law’s effect would depend on the standards the USDA sets forth.

For an efficient—and, more importantly, relevant—transition, the USDA should not require verification for all ingredients but only for ingredients that truly are at risk of genetic engineering. If a raw material is inherently non-GMO, then requiring testing and convoluted documentation for the ingredient is unwarranted. The USDA should first determine a list of at-risk ingredients; then, for ingredients determined to be not at risk, create a simple, yet viable, documentation process.

Take, for instance, the vast number of botanicals that are still wildcrafted. There is zero incentive to gene-splice a one-off ingredient only grown deep in the Andes. Involving anything more than a non-GMO statement for such an ingredient would be a waste of testing, effort, and money. For these types of ingredients, manufacturers can already rest assured that the ingredients are inherently non-GMO.

Value can only be found in extensive non-GMO verification for ingredients that are truly at risk of genetic modification, with the label serving as an assurance that manufacturers will consistently be supplied with a non-GMO version of at-risk products.

Unfortunately, as we know, the GMO issue is not as black and white as the above example. There is a lot of gray area. There are products that are not GMO themselves but that utilize at-risk ingredients such as processing aids. For instance, enzymes are standardized with cornstarch, extracts utilize corn-based solvents, yeast grows on sugar beets, animals are fed with genetically modified feed, and so on. If the USDA determines that these processing aids have to be non-GMO–verified in order to bear a USDA “non-GMO” label, then suppliers face the significant challenge of proving that ingredients—through processing and beyond—are non-GMO, stemming from testing at seed level. Would a bromelain...
Compared to an ingredient like corn with a higher likelihood of GMO content, does a low-risk, wildcrafted ingredient like rose hip really require GMO testing?

supplier have to trace back to the seed of the cornstarch used to standardize the ingredient? If so, a complete readjustment of the supply chains of these gray-area ingredients will be needed.

And, in the end, will there be enough availability of acceptable ingredients? Sourcing, validation, testing, and corroboration between supplier and customer would contribute to increased raw-material costs. If this is the case, will there still be demand?

If the Safe and Accurate Food Labeling Act of 2015 passes the Senate and gets signed into law, it will set in motion a direction that the entire industry will have no choice but to follow. There are still many questions to be addressed, questions that only those in the industry can answer. No one understands the nature of our products and our supply chains better than we do. We in the industry, both manufacturer and supplier, need to be the ones setting the standards. Federal voluntary GMO/non-GMO labeling will be a process—a process that the USDA has yet to define and can only achieve with the help of the industry.

George Pontiakos is president and CEO of BI Nutraceuticals (Long Beach, CA).

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Staying Power

Energy drinks are still going strong.

BY INNOVA MARKET INSIGHTS

Scanning the shelves today, it’s hard to imagine that there was once a time when energy drinks were not part of the beverage landscape. But while the energy drinks market gained traction early on in Japan and in other parts of Asia, it was only at the dawn of this century when energy drinks really began commanding the attention of the U.S. mainstream soft drinks market. Heavy promotion and expansion by the pioneering Red Bull brand during the decade that followed brought the concept of energy drinks to Western markets for the first time, initially to Europe and then to North America. Fast-forward, and today energy drinks are firmly established within the food and beverage culture.

In the late 1990s, U.S. energy products were most commonly found in the isotonic/sports drinks market. As this category grew stronger, energy drinks emerged as their own, separate standalone category, driven as much by a trendy image as consumers’ desire to boost their energy levels amidst increasingly busy lifestyles.

Current market-size estimates vary depending on the source and how one defines the category, but generally the global energy drinks market is projected to be worth approximately $10 billion annually. Energy drinks have continued to exhibit good growth rates in recent years, even against the backdrop of an overall relatively static soft drinks market.

As of this March, energy drinks accounted for 6.2% of the total U.S. soft drink launches Innova Market Insights recorded. Energy drinks are now growing at a faster rate than the global soft drinks market as a whole, where annual growth is at just under 4%. Red Bull, Monster, and Rockstar are still the leaders. Most of their products are non-aseptic and primarily canned drinks.

Initially launched as a limited summer edition, Red Bull Yellow Edition became a permanent company SKU in March. “After performing exceptionally well as a limited edition in July and August of 2014, the Red Bull Summer Edition is now permanently joining the Red Bull Editions line as the Red Bull Yellow Edition,” the company announced. Of its new Red Bull Orange and Red Bull Cherry editions, the brand said, “Orange and wild cherry are among the highest-ranked flavors in U.S. flavor-appeal studies and will both provide consumers with great-tasting, zero-calorie, zero-sugar Red Bull options. These new Editions meet the growing consumer demand for zero-calorie flavored energy drink options—which, according to Nielsen data, accounts for 59% of overall energy category growth.”

Chia, meet guayusa: Mamma Chia’s Chia Energy beverage line launched last summer and “combines the powerful nutrients of chia, the clean energy of fair-trade guayusa, and a combination of organic fruit juices for a truly great-tasting beverage that provides an energizing lift to your day,” the company says. Each drink contains 2500 mg of omega-3s, 90 mg of natural caffeine (as much as a cup of coffee), plus green tea antioxidants, fiber, and protein.

New Moves by Market Leaders

Red Bull still leads the energy drinks market both in the U.S. and globally, but critics have questioned the brand’s relatively limited portfolio. With this in mind, Red Bull began expanding its product range in recent years with new launches such as Red Bull Total Zero in 2012, featuring no calories, sugar, or carbohydrates.

Red Bull is also using limited editions to keep consumers engaged. The company introduced Summer Edition Tropical last summer and has since renamed the product Red Bull: The Yellow Edition; in spring 2015, the company made it a permanent brand offering. The drink joined the brand’s already existing Red Bull Red (cranberry) and Red Bull Blue (blueberry). At the same time, Red Bull added Orange and Cherry Editions under the Red Bull Total Zero umbrella.

Red Bull rival Monster Energy launched a Monster Energy Zero edition in the Unit-

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ed States in 2012. Marketed as less sweet, lighter tasting, zero-sugar, and zero-calorie, the drink is sweetened with erythritol, sucralose, and acesulfame-K. It joined other "light" versions of Monster, including Monster Energy Lo Carb and Monster Energy Absolutely Zero.

The Monster brand also moved closer to the sports drinks market in recent years, extending its range with performance lines such as Monster Rehab for refreshment, rehydration, and revitalization, and Muscle Monster Energy Shakes with protein. Monster Rehab is based on tea flavors, and Monster also has a Java Monster range of "coffee plus" drinks.

**Organic Picks Up**

The energy drinks market continues to explore new flavors, formats, and functions, and high levels of competition are resulting in growing segmentation. Marketers are also now focusing on additional benefits such as hydration, endurance, mental focus, immune support, and protein content, bringing the sector more in line with the general health and wellness category.

Marketers should also note ongoing activity in organic energy drinks—most notably by the number-three player in the energy drinks market, Rockstar, which launched the Rockstar Organic Island Fruits drink in 2014 featuring organic sugar and caffeine from organic green coffee beans. More specialized introductions include Mamma Chia’s Chia Vitality energy drinks with chia seeds, guarana, and fruit juices; Natural Motive’s EnerBee with honey, bee pollen, and royal jelly; and Marquis O3 from Marquis Beverages.

**Hybrid Drinks**

We are also seeing hybrid soft drinks in other beverage categories now adding an energy element. Take Celsius's Sparkling carbonated drinks, which include cola, orange, and wild berry. The drinks are marketed not only as "negative-calorie drinks" with ingredients to "increase fat loss, boost energy, and burn more calories," but also as delivering "lasting energy."

There is also activity in caffeinated waters, both plain and flavored. Avitae, for example, extended its original line of unflavored natural caffeine waters made with purified water, caffeine from natural green coffee beans, natural flavors, and citric acid. The brand launched a range of four flavored drinks in its Caffeine + Water range early this year.

Meanwhile, Rockstar launched an horchata line in 2014 as a traditional-style, cinnamon-flavored dairy beverage. Another interesting launch last year was Sunny Day’s SunnyD X range, which leverages the established Sunny D juice drinks brand while positioning the new products as alternative energy drinks for teens. The drink delivers energy from a combination of vitamins and carbohydrates rather than more usual ingredients like caffeine and taurine.

**Market Going Strong**

Increasingly busy lifestyles are boosting demand for products that give consumers either an instant boost or sustained energy. Now firmly entrenched in the mainstream, energy drinks are opening up whole new areas of opportunity as they focus on increasing their spectrum of consumers and usage occasions and offering a variety of innovative, healthier, and convenient options targeted at modern lifestyles.

Avitae calls its Caffeine + Water beverage “healthy hydration with an all-natural energy boost.” Each drink provides 90 mg of caffeine, roughly the same amount provided by a cup of coffee, the firm says. In March, the brand added four flavored-water versions to its lineup. 

Launched in June 2005, Celsius is sold as a “negative-calorie” drink with thermogenic properties that the company says are supported by product-specific, peer-reviewed published studies. According to the brand, “Studies show that Celsius burns calories and provides lasting energy. The science also shows that drinking Celsius 15 minutes prior to exercise reduces body fat, increases endurance, and provides greater resistance to fatigue (increased energy).”

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Non-GMO and Organic

Label Overlap

U.S. shoppers already have a federal non-GMO label in the form of the USDA Organic seal. So why do we need another?

BY JENNIFER GREBOW, EDITOR-IN-CHIEF

In the United States, GMO labeling is on the brink of becoming federal law. The U.S. House of Representatives passed the Safe and Accurate Food Labeling Act (SAFE; H.R. 1599) by a wide margin this July. SAFE, as written, emphasizes inherent safety of genetically modified organisms (GMOs), and instead of a mandatory law requiring GMO labeling, SAFE would establish a voluntary, USDA-led, nationwide non-GMO certification program. SAFE awaited a Senate vote at the time this article published. (Turn to page 16 for more on SAFE and how it will also ban any existing mandatory state-level laws requiring GMO labeling.)

If enacted, SAFE’s federal non-GMO seal would join a handful of non-GMO NGO seals already on the market, most notably the Non-GMO Project’s popular Non-GMO Project Verified seal. Would food marketers flock to a federal seal over independent third-party seals? Time will tell.

Perhaps a better question to ask is whether we need another non-GMO seal at all—and especially at the federal level—considering that the United States already has a nationwide labeling program in place that covers GMO vetting: the USDA National Organic Program (NOP). The NOP prohibits GMO use, and any product labeled USDA Organic should exclude GMOs—a fact many consumers don’t realize.

Do we need SAFE?

GMOs under the NOP

First, understand how USDA’s National Organic Program treats GMOs. GMOs sit alongside other ingredients on the NOP’s list of forbidden substances such as pesticides and most synthetic substances. But the USDA Organic seal does not guarantee that certified-organic products are GMO-free, as discussed later. NOP and third-party auditors also do not routinely test ingredients/products for GMOs unless they suspect GMO contamination.

NOP auditors, rather, inspect and verify that a company’s farming and handling processes are sufficient to protect the ingredient from contracting a GMO. Think of it more as prevention, or processed-based certification, said NOP head Miles McEvoy, deputy administrator, USDA Agricultural Marketing Service (AMS), back in 2011.

“Organic operations implement preventive practices based on site-specific risk factors, such as neighboring conventional farms or shared farm equipment of processing facilities,” McEvoy wrote in a 2013 blog post. “For example, some farmers plant their seeds early or late to avoid organic and GMO crops flowering at the same time (which can cause cross-pollination). Others harvest crops prior to flowering or sign cooperative agreements with neighboring farms to avoid planting...
Would the SAFE Act bring anything new to the already crowded certification market?
Now Another USDA Option: Processed Verified

In addition to the NOP, this year USDA began using its Process Verified Program (PVP) to vet non-GMO operations. PVP’s website describes PVP verification as providing agricultural companies “the opportunity to assure customers of their ability to provide consistent quality products or services.” Essentially, PVP verification assures consumers that a company is meeting any operational standards it sets for itself (or any third-party standards the company chooses), including goals for agricultural sourcing, feeding, raising, or processing. A company seeking PVP verification pays a USDA inspector to audit its practices. USDA’s Agricultural Marketing Service “requires that a company identify its process points and, after approving the system, audits those process points,” a USDA spokesperson explains to Nutritional Outlook. “In addition, AMS provides transparency by listing that particular Processed Verified Program and the standard(s) on which it is based online.”

PVP users vary. Livestock handlers can use PVP verification to testify to how they feed and raise their animals, for instance. This May, ingredient supplier SunOpta (Brampton, ON, Canada) became the first company ever to earn USDA PVP verification validating the company’s non-GMO soybeans and corn.

The USDA representative says SunOpta came to the agency looking for a way to verify its non-GMO claims. “When a producer or industry stakeholder has a standard they want to consistently meet, AMS works with that customer to develop an auditing solution to verify their claim. USDA’s Process Verified Program was a suitable fit in this case,” the spokesperson says.

SunOpta CEO Steve Bromley said in a May 18 press release, “Having USDA verify that we are complying with our standards ensures that our customers can be confident that they are getting the highest-quality non-GMO soybeans and corn.” In the same press release, U.S. Congressman Tim Walz described PVP as “the perfect example of the private sector and the public sector working in tandem to balance the needs of both industry and consumer.” He added, “I applaud the work of both SunOpta and USDA for their innovative approach. The voluntary certification gives certainty to consumers and is flexible enough that it doesn’t put undue burdens on companies that choose to use GMOs in their products.”

But David Carter, CEO of FoodChain ID (Fairfield, IA), points out that the PVP “is not benchmarking one company’s practices against another’s, or against an independent standard. It’s only approving that a company’s process is adequate for meeting its own internal definition of non-GMO.”

Plus, he says, as far as he understands it, the PVP seal is not meant to be an “outward-facing consumer seal” that companies market on retail products. “Rather, it is a business-to-business seal that tells a potential buyer of that ingredient that the ingredient was verified under the USDA program,” he says. “I have not seen anyone in the USDA or elsewhere claim that this program will be used to verify multi-ingredient end-products such as frozen meals, breakfast cereals, soy shakes, etc., as being non-GMO.”

Nevertheless, in a National Public Radio interview, U.S. Secretary of Agriculture Tom Vilsack claimed that other firms are now “lining up” to use PVP for GMO vetting. “Any company that wishes to be verified under the Process Verified Program for a non-GMO/GE process could apply for AMS services by describing the process and standard it plans to use,” USDA’s spokesperson says.

The spokesperson confirms that USDA will continue to offer non-GMO PVP verification alongside the NOP. “It is not duplicative to have two programs, and both programs will continue to coexist,” the spokesperson tells Nutritional Outlook. “The USDA National Organic Program (NOP) regulations prohibit the use of genetic engineering. The organic regulations also address a whole host of standards and requirements that operations must meet to be certified. Some companies may only be interested in non-GMO/GE verification, which makes the USDA Process Verified Program a good fit.”

Firms Still Want Non-GMO Seals

Despite NOP and PVP audits USDA offers to affirm non-GMO practices, for now food marketers who want to capture customers actively looking for non-GMOs labels still prefer certification seals that specifically mention “Non-GMO” front and center.
my curcumin should

my curcumin should **be adulterated**

my curcumin should **be synthetic**

my curcumin should **infringe patents**

my curcumin should **be unnecessarily bioavailable**

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And this has made non-GMO marketing a big business today. Sales of GMO-free food and beverages in the United States alone reached $200 million last year, according to Packaged Facts.6

Corporate giants like General Mills are going their own way, advertising their own-company GMO claims on packaging. More often than not, however, companies are turning to third-party non-GMO certifiers like the Non-GMO Project (Bellingham, WA). To date, the nonprofit group has bestowed its Non-GMO Project Verified seal on more than 27,000 products and “is the fastest-growing label in the natural products industry,” according to the group’s website.7

**Different Seals, Different Standards**

So what does a company get when it chooses to pursue an NGO consumer-facing non-GMO seal instead of—or in addition to—the federal USDA Organic consumer seal? The distinctions are important and go well beyond whether or not a label specifically spells out “Non-GMO.”

**GMO Testing**

USDA NOP auditors, as mentioned, do not routinely test for GMO content unless they suspect GMO contamination. The Non-GMO Project, on the other hand, does require testing of all ingredients deemed “high-risk inputs.” (Testing is done at the ingredient level versus on finished products. According to the group, “Testing finished product is not a reliably accurate measure of GMO presence.”)

Third-party technical administrators perform annual auditing on behalf of the Non-GMO Project and conduct on-site testing of “all major GMO-risk ingredients.” (For ingredients of low risk, auditors conduct a thorough review of ingredient specification sheets to determine absence of GMO risk.) Current technical administrators include FoodChain ID, which cofounded the Non-GMO Project’s product-verification program and was the program’s first technical administrator; NSF International (Ann Arbor, MI); Where Food Comes From (IMI Global; Castle Rock, CO); and SCS Global Services (Emeryville, CA).

To test for GMO content, these auditors use genetics-based testing methods like polymerase chain reaction (PCR). Food-Chain ID’s David Carter offers a glimpse of how this works:

Companies can test unprocessed material such as grain or seed on site with strip tests, which measure whether the protein coded for by the genetically engineered DNA (often herbicide resistance or insecticide) is present. Strip tests play an important role in the production process because they’re rapid, can be performed on site, and provide a clear visual indicator of GMO presence or absence. The disadvantages of strip tests are that they are not as sensitive as tests that quantify GMO at the DNA level and, because protein is sensitive to degradation from processing, they’re only suitable for testing unprocessed material.

PCR tests measure GMO content at the DNA level and are exquisitely specific and sensitive, often having a limit of detection of 0.01% and a limit of quantitation of 0.01%. PCR tests can be used for a wider variety of samples, including some processed materials, and are the industry standard for verifying claims and demonstrating compliance with regulations. They are most often performed by third-party accredited laboratories, as they require specialized equipment. Both strip tests and PCR testing have been used for close to 20 years, and technology advancements have allowed quantitation at lower levels.

**GMO Threshold**

USDA has no officially established threshold for GMO content. “Unlike many pesticides, there aren’t specific tolerance levels in the USDA organic regulations for GMOs,” USDA’s McEvoy wrote in his 2013 blog post. The NOP abides by the Environmental Protection Agency’s 5% tolerance level for pesticides, but “no federal agency, including EPA or USDA, has established tolerance levels for the inadvertent presence of the products of excluded methods (GMOs),” McEvoy wrote in 2011. By contrast, the Non-GMO Project abides by the same 0.9% GMO-content threshold that many global regulators do for human food, ingredients, supplements, and personal care products. The European Union’s mandatory GMO-labeling law, for instance, also uses the 0.9% threshold to denote GMO presence.4

USDA may not have a threshold for GMO contamination, but FoodChain ID’s Carter commends the NOP nonetheless: “With that said, overall, the organic industry does an excellent job in avoiding GM contamination, and buying organic is a very reliable way to avoid GMOs.”

But he also points out, “Not all products can be tested for GMOs if they contained highly processed ingredients in which the DNA has been destroyed during manufacturing. Likewise, organic dairy or meat cannot be tested for GMOs used in feed. Again, while organic producers are very diligent about using verified-organic ingredients, participating in programs like the Non-GMO Project provides another layer of rigorous scrutiny to ensure that best practices are being followed by all suppliers to avoid GMO contamination.”

**The distinctions between certification seals go well beyond whether or not a label specifically spells out “Non-GMO.”**

**No Program Is Perfect**

At the end of the day, no current GMO-testing program can guarantee 100% absence of GMOs. The Non-GMO Project and USDA both acknowledge that trace amounts may slip through the cracks. Again, FoodChain ID’s Carter provides some insight:

“First, the science of testing for GMOs has a limit of detection of .0001, or 1 in 10,000. In other words, the technology available to test for GMOs can never declare anything GM-free, as there could be a level below the limit of detection and the technology would not be able to measure it,” he says. “On a global level, government regulatory authorities as
Jungbunzlauer’s TCC TB: Tricalcium Citrate as an excipient for direct compression

Direct compression has gained popularity in tablet manufacturing in recent years. It is seen as the most economic process in terms of labor, time, equipment, operational energy and space. Additionally, direct compression has the advantage of eliminating problems due to heat and moisture that can occur during granulation. However, it places great demands on the excipients used in the process. Direct compression therefore requires that tablet formulations (active ingredients and excipients) exhibit good compactibility as well as flowability.

When developing low dose formulations, formulators can choose from a wide range of fillers/diluents such as microcrystalline cellulose (MCC), pregelatinized starch (PPS), dicalcium phosphates (DCP), spray-dried lactose monohydrate (SDL) and polyols (e.g., mannitol). When choosing the right excipients, many aspects have to be considered, including mechanical characteristics (e.g., compactibility, compressibility, etc.) and flowability, among others. Additionally, the filler/diluent must be compatible with the active.

Fillers that primarily deform by plastic/viscoelastic mechanisms (e.g., MCC, PPS) typically show better compactibility relative to fillers that exhibit brittle fracture. MCC is the most widely used excipient due to its excellent compactibility. It does, however, have significant drawbacks, including sensitivity to over-lubrication, strain-rate-sensitivity, and incompatibilities (in particular with water-labile actives). Therefore, it cannot be used in some formulations or may require additional efforts to compensate for its disadvantages. Brittle fillers do not exhibit most of the aforementioned drawbacks; however, they lack the excellent compactibility of MCC. Consequently, higher compression forces or the incorporation of additional binders are needed in order to achieve tablets of sufficient hardness.

Jungbunzlauer has recently developed a novel filler/diluent that avoids most of the disadvantages associated with MCC while providing significantly higher compactibility relative to DCP or SDL. Jungbunzlauer’s TCC TB is a tricalcium citrate tetrahydrate that combines exceptional compression characteristics, good flowability and good tolerability. TCC TB is produced by the complete neutralization of non-GMO citric acid with high purity Ca(OH)2. Through Jungbunzlauer’s isolation process, TCC TB forms a unique crystalline structure that is responsible for its excellent powder properties, making it the ideal choice for a direct compression excipient.

When compared to other common excipients that deform primarily by brittle fracture, TCC TB stands out in its ability to produce tablets of sufficient strength, even at relatively low compaction pressures (Figure 1). This reduces the wear on tablet equipment.

Figure 1: Compactibility-Plot (Romaco Kilian Stylo One 105 ML; 8 mm flat; full speed: 900 tablets/h)

Properties of Jungbunzlauer’s TCC TB
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Non-GMO and Organic

well as private industry programs have generally looked at a practical threshold that is attainable given the prevalence of GMOs in many markets and the potential for contamination in storage and processing as well as field drift. For human food, most global authorities set their maximum GMO-content threshold between 0.1%–0.9%, he adds. (And, in the EU, he says, regulators have not set a threshold for animal feed.)

Due to the inability to guarantee 100% GMO-free, USDA will not automatically revoke a company’s USDA Organic seal if a product is found to contain trace GMOs. This means that USDA Organic–labeled products could actually have some GMO content. “National Organic Program policy states that trace amounts of GMOs don’t automatically mean the farm is in violation of the USDA organic regulations,” McEvoy wrote in 2013. “In these cases, the certifying agent will investigate how the inadvertent presence occurred and recommend how it can be better prevented in the future.” But a firm must show that it has taken reasonable steps to avoid GMO contact and that the GMO content is unintentional.

SAFE: More of the Same?

In light of what current non-GMO certifying/verifying programs provide or don’t provide, would the Safe and Accurate Food Labeling Act bring anything different—and better—to the table?

SAFE would provide a federal seal stating the words Non-GMO. For some consumers, organic’s non-GMO assurance isn’t enough, and some consumers may perceive a non-GMO seal from the government as more trustworthy. SAFE proponents also contend that by preempting any state-level GMO-labeling laws, SAFE would help eliminate a nationwide patchwork of labels.

But on a macro scale—at least according to what the bill outlines—what SAFE now proposes and how USDA’s NOP already handles GMO prevention aren’t significantly different. Judging by what’s not in the bill, SAFE would not establish a GMO threshold nor would it implement routine testing; instead it would audit “process controls” much like the NOP does, addressing contact prevention in production and handling.

SAFE’s authors mention how closely the bill aligns itself with USDA’s NOP, stating that it would, “to the greatest extent practicable, establish consistency between the certification programs established under subtitle E of the Agricultural Marketing Act of 1946...the organic certification program established under the Organic Foods Production Act of 1990...and other voluntary labeling programs administered by the Secretary.” One example of crossover? Under SAFE, any product bearing the USDA Organic seal could also bear the new federal non-GMO seal.

It’s still unknown how federal non-GMO certification would work alongside—and in concert with—federal organic certification.

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Would a non-GMO program under SAFE step in to handle the National Organic Program’s GMO vetting?

Would a non-GMO program under SAFE step in to handle the National Organic Program’s GMO vetting? We won’t know this unless SAFE goes into law.

For many, the NOP is a worthwhile role model. After all, most agree that the program, despite any faults, has successfully regulated the organic market now for 15 years, as evidenced by today’s $39 billion U.S. food and non-food organic industry.9 It’s possible that a non-GMO certification program modeled after the NOP could serve the food industry as well as the NOP has all these years.

Michael McGuflin, president, American Herbal Products Association (AHPA; Silver Spring, MD), says, “In AHPA’s view, a voluntary federal labeling program for GMO absence modeled after NOP will provide more consistent information to consumers while minimizing the expense and potential confusion of mandatory labeling laws for GMO presence at either the state or federal level.”

But not all are convinced that we need the changes SAFE proposes, and some believe that the status quo works. (When questioned whether USDA has encountered problems because it does not have a federal non-GMO standard in place now, the agency’s spokesperson tells Nutritional Outlook, “This has not presented challenges.”)

If SAFE were to pass, it’s vital to ensure that the new law doesn’t disturb what’s already working in the NOP, cautions the Organic Trade Association’s Gwendolyn Wyard. “USDA’s NOP regulations prohibit the use of GMOs during the production or handling of any organic product. OTA believes that third-party certification under USDA NOP as ‘100% Organic,’ ‘Organic,’ or ‘Made with Organic (specified ingredients or food groups)’ is sufficient to substantiate a claim that a product is non-GMO.”

“However,” she continues, “OTA also recognizes that each company may need to respond to competitive pressures and consumer needs; therefore, OTA does not oppose the decision to voluntarily seek out additional non-GMO verification. However, any additional standard created by USDA for ‘non-GMO’ should not conflict with the organic standards or set a bar lower than the organic standards...Consistency with the existing USDA organic regulations is critical.”

Megan Westgate, executive director of the Non-GMO Project, supports current
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conditions—namely, how the Non-GMO Project and the NOP work in tandem.

“The National Organic Program has been incredibly successful in providing consumers access to food that is grown in the healthiest way possible. The rigorous requirements of the National Organic Program help prevent GMO contamination of organic foods through a process-based approach, which includes testing when GMO contamination is suspected,” she says. Her group “builds upon the NOP’s measures by ensuring that all major GMO-risk ingredients are tested prior to use in a Verified product, as we believe that ongoing testing is critical to identifying and eliminating GMO contamination.”

“In our experience,” Westgate says, “attributes outside of organic, such as Non-GMO Project Verified, can provide a bridge to the [USDA] certified-organic label. We see organic as very important, and for many of us, our gold standard is both organic and Non-GMO Project Verified.”

More Seals, More Confusion

Both Wyard and Westgate also allude to possible consumer confusion SAFE could introduce if it were to join the USDA Organic seal and numerous other private seals on the market.

“Differing standards set for non-GMO claims could easily increase confusion in the marketplace as to what non-GMO means and dilute the meaning of the organic label,” Wyard says.

In a July 24, 2015, blog post, Westgate plainly acknowledged that SAFE would directly compete with the Non-GMO Project. “While [SAFE’s non-GMO certification program] won’t remove the Non-GMO Project Verified seal from the marketplace, the bill as written would create a competing label that would confuse shoppers and undermine the tremendous progress we’ve made on setting a high standard for GMO avoidance. This is a serious concern for the Non-GMO Project, a nonprofit that has been working since 2007 to successfully establish a consistent and rigorous standard for non-GMO claims,” she wrote.

Commenting for this article, she adds, “In the event that H.R. 1599 were to pass and the USDA created its own non-GMO certification program, it would operate to drastically lower standards than those of the Non-GMO Project.”

Who Wins?

The future of U.S. GMO labeling is now in the hands of lawmakers. “This is the most important fight there will ever be on the GMO issue,” Westgate wrote.

One can only hope that the winner is the consumer searching for clarity and meaning in the non-GMO marketplace.

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When it comes to genetically modified organisms (GMOs), popularity is a relative term. According to a USDA report released last year, American farmers planted about 169 million acres of genetically engineered corn, soybeans, and cotton in 2013 alone, citing increased yields as their primary motivation. These acres represent half of the total land used in America to grow crops. The result? According to the third-party certification program the Non-GMO Project (Bellingham, WA), about 80% of the conventional processed foods currently on American supermarket shelves are genetically engineered.

However, the popularity enjoyed by GMOs among farmers doesn’t quite seem to translate among consumers. Three-quarters of respondents in a 2013 poll by The New York Times expressed concern about genetically modified ingredients, mostly because of potential health risks. And a whopping 93% of respondents wanted GMO products to be labeled.

According to the Non-GMO Project, consumers are also wary of the herbicide tolerance of GMOs (which yield superbugs, superweeds…and super pesticides), as well as the social and economic implications of companies’ ability to sue farmers who grow their patented seeds—either willingly or unwillingly via inevitable drift from neighboring fields.

These shopper concerns are manifesting themselves in sales trends. Packaged Facts reports that sales of U.S. non-GMO food and drinks reached $200 million last year. And if GMO labeling were ever to become mandatory in the United States, non-GMO sales could skyrocket higher.

But many companies aren’t willing to wait for federal or state regulators to develop GMO-labeling laws; instead, they’re taking matters into their own hands and voluntarily acquiring non-GMO certifications to meet consumer demand. Here are the business costs and benefits manufacturers and suppliers need to know before taking the plunge.

Investment
The most obvious cost to businesses considering a non-GMO certification is, of course, monetary. The Non-GMO Project verification program’s costs, for example, vary depending on which testing lab is used, how many products are being verified, and whether those products contain any high-risk ingredients like corn, soy, sugar beets, or canola.

Additional costs may also include facility inspections, if needed. When all is said and done, says Randy Kreienbrink, director of marketing at BI Nutraceuticals (Long Beach, CA), these costs can run upwards of 25%–45% more per kilo of ingredient for suppliers.

For what it’s worth, BI Nutraceuticals also points out that, in theory, not all products need to undergo rigorous testing. In fact, says Kreienbrink, many botanical ingredients are inherently non-GMO, either because of their countries of origin or because farming practices are confirmed to be GMO-free, as is the case with many botanicals in BI’s portfolio.

“We know these ingredients are not genetically modified because, for example, our maca is grown in the high elevations of South America,” he adds. “These growers are just getting into the twentieth century, so forget about twenty-first-century technologies like genetic modification.” (Turn to page 26 for more on why the company believes GMO testing should not be required for all ingredients.)

The Filler Issue
While many botanicals tend to be non-GMO, the story is quite different when it comes to the other ingredients in a capsule or tablet, like binders or fillers.

“These products tend to come from corn-based sources,” says Kreienbrink, although they’re just as often refined or derived from other high-risk sources. “The supply is there, but it is an additional cost to source binders,
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fillers, and excipients that are verified to be GMO-free.” And that can increase costs to suppliers, manufacturers and, ultimately, consumers.

**Marketing Support**

For manufacturers who decide to make the investment in certification, it certainly has its perks—the first of which is being able to offer consumers the peace of mind that comes with third-party verification. But once a product is Non-GMO Project Verified, for example, manufacturers also gain access to the Project’s marketing team to collaborate on messaging, campaigns, social media promotions, and sales materials. And a specialized Participants’ Toolkit is provided to help companies come up with their own messaging about their verified products.

Verified products are also featured in the Project’s online product directories and mobile shopping apps, and UPC data is shared with its registered retailers and distributors. The Project also announces newly verified products in a press release posted to its website.

**Network and Resources**

The Non-GMO Project also provides manufacturers of verified products with access to its trademarked campaigns, materials, hashtags, and targeted audience messaging. Plus, companies have access to all of the Non-GMO Project’s retailer and consumer channels, which are only available to brands with verified products. In that way, businesses can join a network of companies and brands committed to accurate labeling on the shelf and increasing consumer access to non-GMO foods and supplements. \[N\]

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

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Going Non-GMO:
Be Realistic—and Start Early

Food and supplement manufacturers seeking non-GMO supply chains and programs must have a realistic understanding of the time frames and effort involved.

BY MAUREEN KINGSLEY

With strong demand for non-GMO dietary supplements and health-food ingredients showing no sign of lessening, now is a good time for food and supplement manufacturers interested in removing GMOs from their products to take action. But where to start? Nutritional Outlook got some tips from Kelly Mae Heroux, marketing manager for FoodChain ID, part of Global ID Group (Fairfield, IA), a provider of testing, third-party consultation, and certification regarding genetic modification (GM) in food and agricultural products.

Pressure from both consumers and industry has already resulted in the development of more-established, more-global non-GMO–ingredient supply chains, Heroux says. For example, FoodChain ID, which provides Non-GMO Project verification services, now works with non-GMO–ingredient suppliers in 96 countries and counting. “We also co-initiated the Non-GMO Working Group along with supplement industry leader MegaFood,” Heroux adds, to unite supplement manufacturers in demanding access to and full disclosure from ingredient partners. (Read more about this group, now called The Coalition for Supplement Sustainability, on page 24.)

Food and supplement manufacturers might be keen to take advantage of these new supply chains and programs, but they need to arm themselves very early on with the knowledge of what will be required in terms of timing, resources, and information.

Where and How to Begin?

“It’s critical that food processors new to non-GMO sourcing start early and use an organized framework,” Heroux advises. “They should inform existing suppliers or locate new suppliers very early in the process and well in advance of their anticipated timing needs.”

Heroux also recommends using a “respected” system to track all relevant information and data, such as Global ID’s SupplyTrak supply-chain compliance software, because Non-GMO Project verification, for instance, requires “extensive mapping” not only of products and ingredients but also of all suppliers and their manufacturing facilities.

“Too often,” Heroux says, “these all-important details are tracked by pencil and paper and aren’t as audit-ready as they should be.”

First Steps to Non-GMO Verification

Before officially beginning down a path to non-GMO verification, manufacturers should consult with a technical administrator or verifying body to “identify risks and uncover potential obstacles” that lie ahead, offers Heroux. This pre-planning and initial consultation can help to improve efficiencies and reduce costs once the manufacturer is enrolled in a program.

Data collection is another important pre-enrollment step. Manufacturers are advised to use a standardized data-collection tool, such as the forms used by the technical administrator. Relevant data to capture will include disclosures of additives, carriers, enzymes, microorganisms, fermentation media, raw-material sources, and non-GMO manufacturing systems, Heroux explains.

Next, enrollment of products should be ordered beginning with bestsellers or product formulas that include various high-GMO–risk ingredients. (Aspartame, citric acid, high-fructose corn syrup, sucrose, xanthan gum, and lactic acid are examples of ingredients commonly derived from
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GMO-risk crops or “produced with genetically modified inputs,” Heroux warns.) This approach also helps familiarize staff with what will be required of ingredient suppliers, eases the severity of the learning curve, and lessens the workload of the quality department, she adds.

What Not to Do
Manufacturers are urged not to assume, upon enrollment in a non-GMO verification program, that inputs are non-GMO.

“We commonly see overconfidence due to lack of understanding of the depth to which GMOs have penetrated the ingredient-manufacturing supply chains,” Heroux says. GMOs are not a static issue; they make up an “evolving landscape,” with new GM technologies on the horizon and evolving standards. “It must be understood that non-GMO standing is an ongoing effort and investment,” she stresses.

For food and supplement manufacturers who are serious about pursuing and maintaining non-GMO verification, understanding the growth and trends of non-GMO production is important, as is continually tracking where and how GM production is occurring. Contamination is a legitimate threat, Heroux warns.

“Choosing suppliers who grow non-GMO foods that are not in close proximity to GM crops, or who otherwise have strong traceability and segregation practices in place,” will be a non-GMO–product marketer’s path forward, she says.

Non-GMO Verification: Better for Business?
According to SPINS, which provides analytics and consulting for the natural, organic, and specialty products industries, displaying the Non-GMO Project Verified seal on a retail product can lead to sales increases of 5%–10%.

“The upticks of interest” from consumers and industry, as well as the sales-growth data, each “represent objective measures suggesting that, despite all that is involved in sourcing non-GMO ingredients, companies are increasingly finding the process to be worthwhile,” Heroux says.

She adds that the “degree of challenge” involved in going GMO-free today is considerably less than what it was just five years ago. Shortages of some non-GMO ingredients remain, but FoodChain ID says it has verified an “impressive” number of ingredient manufacturers that are “making ingredient sourcing less difficult for other companies that wish to formulate non-GMO products,” Heroux says.

Maureen Kingsley is a freelance writer, editor, and proofreader based in Los Angeles. She covers a variety of industries, including medical technology, food-ingredient manufacturing, and cinematography.
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Omega-3 fatty acids, in particular the long-chain fats eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA) found abundantly in oily fish, continue to shine as nutrients that promote health and wellbeing. In addition to well-known benefits to the heart and vascular system, researchers investigating omega-3s are uncovering new arenas for their broad spectrum of health effects, including some not previously explored.

The importance of omega-3s supplementation stems from several factors; firstly, modern diets are woefully inadequate in terms of their omega-3 content, whereas traditional diets were much higher in omega-3s. Additionally, anti-inflammatory omega-3s counteract the effects of the more ubiquitous omega-6 fats (from various vegetable oils), which are pro-inflammatory by nature and are over-abundant in modern diets. Restoring this imbalance and shifting the omega-3:omega-6 intake ratio to include more omega-3s should be a goal for anyone who is looking to stay healthy.

Studies show that adults in the United States are falling short of even modest intake goals for omega-3 fats. American Heart Association recommendations include an emphasis on the intake of two 3.5-oz servings per week of oily fish in order to increase EPA and DHA intake, while the 2010 Dietary Guidelines for Americans recommended the consumption of two 4-oz servings of seafood per week to provide an average amount of 250 mg/day of long-chain omega-3 fatty acids. A study using observational data from the National Health and Nutrition Examination Survey (NHANES) from 2003–2008 revealed that average daily intakes of EPA and DHA were only 23 mg/day and 63 mg/day, respectively. It is clear that a greater emphasis on diet and supplementary measures is needed to enhance individual intakes of these critical health-promoting fats.

Emerging data has opened the door to research into significant benefits of omega-3s for unique indications. Recent studies have explored the effects of omega-3s in aging adults and in several chronic illnesses. Also, further investigations have been conducted to explore the association between fish oil omega-3 intake and prostate cancer in light of a 2013 study that speculated that increased intake of certain omega-3 fatty acids adversely raises the risk for prostate cancer. Ahead, we review current studies in these diverse and fascinating areas of interest.

**Aging Adults: Muscle Mass, Healthy Bones, Brain Structure, and Cognitive Function**

Sarcopenia is a condition affecting the elderly that is characterized by a loss of muscle mass. Gordon Smith and colleagues from the Washington University School of Medicine in St. Louis conducted a study assessing the ability of omega-3 fats from fish oil to slow the loss of muscle mass and function in the elderly. In the study, 60 healthy men and women aged 60–85 received a daily omega-3 supplement (four 1-g pills of ethyl ester fish oil providing 1.86 g EPA and 1.50 g DHA per day) or placebo (corn oil) for six months. Fish oil supplementation was shown to reduce the normal decline in muscle mass and function in older adults by increasing thigh muscle volume, hand grip strength, and one-repetition maximum upper and lower body strength. As such, omega-3s offer a therapeutically approach for preventing sarcopenia in older adults.

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Tamara Harris and colleagues from the National Institute on Aging in Bethesda, MD, aimed to look at the association between fish oil consumption and the risk of osteoporotic fracture in later life. The authors analyzed data from medical records over 5–9 years of follow-up in 1,438 men and women aged 66–96. Fish oil consumption was assessed using a validated questionnaire, and individuals were classified into using fish oil “never,” “less than daily,” or “daily.” Plasma measures of phospholipid fatty acid content were also taken by gas chromatography.

The analysis showed that, in men, the group in the highest third of fish oil consumption and also with higher EPA intake had a decreased risk of fractures. In women, overall intake of omega-3 fatty acids also trended towards a protective effect against fractures, although this did not reach the level of statistical significance. The authors further found that daily consumption of fish oil in late life was associated with lower fracture risk in men, whereas daily consumption of fish oil in mid-life was most associated with lower fracture risk in women. Thus, regular consumption of omega-3 fatty acids from fish may be an important addition to an overall nutritional strategy for enhancing and maintaining bone health.

Looking into a groundbreaking new area of research, Veronica Witte and colleagues from the Department of Neurology at Charité-Universitätsmedizin Berlin investigated the impact of high intake of omega-3 fatty acids from fish on the aging brain. The prospective intervention study included 65 healthy men and women between the ages of 50 and 75 and aimed to assess whether supplementation with fish-based omega-3 fats could improve cognition and brain structure. The participants consumed fish oil containing 2,200 mg total omega-3 fats (1,320 mg EPA and 880 mg DHA), or a sunflower oil placebo, daily for 26 weeks. The results showed that the fish oil intervention improved cognitive executive functioning by 26% from baseline, whereas the placebo group showed no improvement.

What was even more fascinating about the study were the beneficial effects attributed to fish oil in supporting the microstructural integrity of white matter, as well as supporting gray matter volume in the frontal, temporal, parietal, and limbic areas of the left hemisphere of the brain. These findings are important in that brain atrophy is a characteristic of dementia and other brain diseases, and the improvement in structural integrity with fish oil supplementation indicates its benefit in supporting cognitive function and brain structure with increasing age.

Several studies also indicate that essential omega-3 fatty acids can help support various aspects of memory function in adults. In a recently published meta-analysis, Karin Yurko-Mauro and colleagues conducted a review of clinical trials and observational studies assessing the role of omega-3 fatty acids on memory function in healthy adults. Fifteen intervention trials and 13 observational studies were included in the review and comprised participants—who were free...
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In groundbreaking research, scientists discovered that fish oil improved brain structure in seniors.

UK researchers are investigating the effects of fish oil on the aging brain.

of neurologic disease at the time of inclusion—either with or without mild memory complaints at baseline.

The final analysis revealed that supplementation of 1 g or more per day of DHA and/or EPA improved episodic memory function in adults with mild memory complaints, while changes in semantic and working memory were also significant with DHA supplementation compared to baseline measures.

Chronic Conditions: Fatty Liver, Epilepsy, Rheumatoid Arthritis
Non-alcoholic fatty liver disease (NAFLD) is a condition associated with the onset of metabolic syndrome and dysregulation characterized by excess fat accumulating within liver cells. NAFLD increases the risk of chronic liver conditions, liver cancer, diabetes, and heart disease. Apart from lifestyle changes, there are few other proven interventions for effectively addressing this condition.

In a recent study, Eleonora Scorletti and colleagues from the University of Southampton in the UK sought to assess the effects of supplementation with DHA and EPA on liver fat content in individuals with NAFLD. This double-blind, placebo-controlled study included 103 participants with histological confirmation of NAFLD, imaging evidence of liver fat accumulation, or presenting with features of metabolic syndrome. Individuals

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were randomized into two groups: the first supplemented with 4 g/day of the ethyl ester form of fish oil (providing 460 mg of EPA and 380 mg of DHA per gram) or 4 g/day of an olive oil placebo for a period of 15–18 months. Liver fat was measured by magnetic resonance spectroscopy, and red blood cells EPA and DHA levels were also assessed.

While in the overall group of participants no significant changes were noted in liver fat percentage, in those participants in which red blood cell enrichment was achieved via supplementation with DHA and EPA, levels of red blood cell DHA were linearly associated with decreased liver fat percentage. In other words, the results indicate that in those with increased uptake of DHA into red blood cells, substantial reductions in liver fat accumulation can be achieved.

Drug-resistant epilepsy is a condition defined as the failure of an individual with epilepsy to respond to two or more antiepileptic drugs. Also accompanying this serious condition is an increased risk of death from myocardial infarction. Previous animal studies have shown that the administration of omega-3 fats reduces seizures; however, two human clinical trials using relatively high doses of fish oil showed inconclusive results.

Christopher DeGiorgio and colleagues from the UCLA School of Medicine conducted a placebo-controlled crossover study of fish oil in drug-resistant epilepsy to test the efficacy of high-dose versus low-dose supplementation. Twenty-four individuals with an average age of 33 and a history of drug-resistant epilepsy were included in this triple-crossover trial in which the three groups alternated between low-dose fish oil (total omega-3 intake 1,080 mg/day), high-dose fish oil (2,160 mg omega-3/day), or a corn oil placebo for 10 weeks each, with two six-week washout periods between treatments. The researchers found that low-dose fish oil was effective at reducing the incidence of seizures compared to placebo on a similar magnitude as that seen in antiepileptic drug trials. In addition, the low-dose fish oil moderately reduced blood pressure levels, reducing overall heart risk.
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The high-dose fish oil, on the other hand, showed no difference versus placebo in reducing seizures or in improving cardiac risk factors. The authors speculate that the reason for the ineffectiveness of the high dose of fish oil may have to do with differences in lipid processing, such as causing excessive reductions of arachidonic acid and other non-esterified fatty acids in individuals with drug-resistant epilepsy compared to healthy individuals. This has been shown previously in animal models. The efficacy of fish oil in this condition likely derives from the ability of omega-3 fats to cross the blood–brain barrier, incorporate themselves into neuron membranes, modify calcium and sodium channels, and reduce membrane excitability of both neurons and heart cells.

Due to the anti-inflammatory effects of omega-3 fats, researchers have often explored their benefits for joint health. Susanna Proudman and colleagues from the University of Adelaide in Australia recently conducted a trial using fish oil in patients with recent-onset rheumatoid arthritis (RA). As omega-3 fatty acids are well known for their suppressive effect on the synthesis of omega-6–derived pro-inflammatory eicosanoids, including prostaglandin E2 and leukotriene B4, the researchers chose to examine the benefits of a high-dose fish oil (5.5 g/day of the omega-3s DHA and EPA) versus a low-dose fish oil (designated as the control group and administered 0.4 g/day of DHA plus EPA) in individuals with early-onset RA also taking a combination of anti-rheumatic drugs. The triple anti-rheumatic drug protocol included methotrexate, sulfasalazine, and hydroxychloroquine, and doses were modified throughout the trial period based on symptom presentation. A total of 139 individuals with diagnosed RA of less than 12 months in duration were included in the year-long study (86 in the fish oil group and 53 in the control group).

After one year, only 10.5% of the subjects in the fish oil group progressed to failure of the drug therapy, while 32.1% of those in the control group progressed to failure, indicating significant benefits for the high-dose fish oil in patients with early-onset RA. Individuals in the fish oil group also experienced a higher rate of remission of disease activity compared to the control.

**Prostate Cancer Risk**

There has been increased media coverage recently related to earlier data showing a potential association between the intake of omega-3 fats and prostate cancer in men. In order to explore this connection further, Francesca Crowe from the Cancer Epidemiology Unit of the University of Oxford and co-researchers from around the world contributed to a collaborative meta-analysis to investigate the role circulating fatty acids play in prostate cancer risk. The analysis included 5,891 individuals who had developed prostate cancer and 6,649 control cases from seven studies with an average follow-up of 5.1 years. Studies were eligible for inclusion if blood levels of circulating fatty acids had been analyzed prior to a diagnosis of prostate cancer.

The results of the analysis revealed significant differences between studies in terms of the association between levels of circulating fatty acids and prostate cancer risk. The collaboration of researchers ultimately concluded that it is unclear if the modest associations of the fatty acids EPA and docosapentaenoic acid (DPA)—another omega-3 fatty acid—with cancer seen in some studies are causal factors. Overall, the researchers concluded that there is no strong evidence that circulating fatty acids are important predictors of prostate cancer risk.

Interestingly, this conclusion contrasts with the conclusions of a 2013 SELECT trial coauthored by Theodore Brasky and Alan Kristal, among others, who are also coauthors of the meta-analysis led by Francesca Crowe. The strongly worded conclusion of the initial Brasky et al. analysis of the SELECT trial stated that “this study confirms previous reports of increased prostate cancer risk among men with high blood concentrations of long-chain omega-3 polyunsaturated fatty acids. The consistency of these findings suggests that these fatty acids are involved in prostate tumorigenesis.” Apparently, after a more comprehensive review of published data in the current meta-analysis led by Francesca Crowe, the coauthors of the 2013 paper felt less strongly about the link between circulating omega-3 levels and the risk of prostate cancer.

A further meta-analysis led by Dominik Alexander of theEPidStat Institute in Ann
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Arbor, MI, and supported by omega-3 industry association GOED (Global Organization for EPA and DHA Omega-3s) also downplays any association between omega-3 levels and prostate cancer. In their comprehensive and systematic review, the authors included prospective studies that reported omega-3 levels quantitatively either through supplemental or dietary intake or via biomarker status. The primary outcome analyzed was incidence of prostate cancer. A total of 21 prospective cohort studies comprising 461,050 participants were included in the analysis.

Based on their findings, the researchers concluded that the meta-analysis failed to support an association between the intake of omega-3 fatty acids and the risk of prostate cancer. Taking the findings from this meta-analysis together with the one conducted by Francesca Crowe, it is clear that the association between omega-3 intake and prostate cancer is tenuous at best.

The Field Is Wide Open
Research keeps reinforcing the broad benefits of the fatty acids DHA and EPA for a variety of conditions. Despite recent negative reports in the mainstream media concerning the intake of these healthy fats, it is clear that their health benefits extend to multiple areas.

In view of the fact that most adults in the United States have inadequate intakes of these nutrients, it is important that public health policymakers continue to pursue efforts to increase omega-3 consumption through diet and also emphasize supplementation as a means to bridge the gap.

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

References
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Market Update: Are U.S. Shoppers Back to Loving Omega-3s?

Did an industry-led national advertising campaign move the needle on U.S. omega-3 sales?

BY ELLEN SCHUTT, GLOBAL ORGANIZATION FOR EPA AND DHA OMEGA-3S

ow that the “Omega-3s: Always a Good Idea” national advertising campaign is complete, what can we learn from the results?

To recap: In 2014, a coalition of omega-3 companies concerned about recent sales declines in the omega-3 category began working with the Global Organization for EPA and DHA Omega-3s (GOED; Salt Lake City, UT) on the advertising campaign to stimulate sales. The campaign first test-marketed in Charlotte, NC, last fall. Based on those learnings, the coalition moved forward with a national campaign that ran from mid-March to May of this year.

The campaign included television and digital advertising, the latter run through a partnership with Google. It also featured retail activation with in-store signage and an online retailer center, as well as integrated public relations and social media outreach.

The result? Final data show that year-over-year monthly unit food/drug/mass (FDM) sales increased more than 5% during the national campaign time frame.

What We Did

“The national campaign was different than what we did in Charlotte, based on what we learned during the test market,” explains Adam Ismail, GOED’s executive director. “We emphasized digital advertising much more heavily, and working with Google allowed us to draw on their data expertise to adjust the campaign on the fly and optimize ads based on real-time data.”

The national campaign also leveraged a network cable television purchase, giving the campaign visibility on stations including HGTV, The History Channel, Discovery, ESPN, and TBS.

Additionally, in-store signage appeared on shelves in CVS, Walgreens, Duane Reade, and a host of smaller, independent pharmacies, and was also promoted to 1300 natural retailers.

Campaign Analysis

While it was easy to see the effect of the campaign in Charlotte, analyzing the national campaign outcome was more complex.

“The Charlotte campaign was pretty straightforward, and we were able to easily show the increase in sales,” says Ismail. “With the national campaign, there were a few factors that added ‘noise’ to the data.”

A big factor was the unfortunate timing of an article, titled “Fish Oil Claims Not Supported by Research,” published at the end of March in The New York Times and just a few weeks into the campaign.

“While this—and the resulting national media coverage—did hurt the [campaign’s] results,” Ismail says, “the impact was short-
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Results Paint a Positive Picture

When analyzing the campaign results, “the challenge was digging into the data to understand what the market had done prior to the campaign launch,” Ismail says. Right before the campaign, for instance, the market experienced an unusual and notable 7.68% sales dip. The campaign’s results are positive, considering the fact that the campaign thus “had to climb up even more than expected” to overcome that initial deficit, Ismail says.

The campaign’s effect also rippled through the natural channel. At the time this article was published, GOED was still waiting for natural-channel results for the final weeks of the campaign. What we do know is that in this channel, retail activation made a difference, and according to the coalition’s Market Research Committee, retail brands that used retail activation assets fared best. Ismail confirms, “We saw the same thing in the Charlotte test market. Having signage or a flyer at the point of purchase was definitely a driver of sales. This makes sense, as we believe that seeing a reminder is sometimes what people need to keep purchasing—and using—omega-3s.”

Despite some good news, the campaign did not return the market to growth. “Simply, the campaign was underfunded,” says GOED’s Ismail.

While this is all good news, it’s important to note that the campaign did not return the market to growth. Ismail discusses the reasoning behind that, too. “Simply, the campaign was underfunded,” he says. “To make an impression on consumers is extremely difficult in today’s media-saturated marketplace, and with a budget of less than $5 million, it was hard to move the needle. Having said that, we are happy with what was achieved and believe we did well with the budget we had.”

The Market Research Committee also estimated where the market would have gone in a normal cycle, without the effect of the campaign, using a regression model starting in December 2014. Comparing actual sales to the forecast indicates a possible sales increase of 7% as a result of the campaign.

Science Driving Future Initiatives

Now that the national advertising campaign is over, the coalition continues to work on public relation initiatives that reinforce the
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science-supported benefits of omega-3s. To further this goal, a Science Advisory Council comprising a team of cardiovascular experts, researchers, and nutritionists was formed to complement the coalition’s efforts to educate consumers about the benefits, efficacy, and safety of omega-3s.

Specifically, the council will work to provide independent scientific insights and perspectives regarding omega-3 claims for cardiovascular health. It will also help guide research on the connection between omega-3s and cardiovascular health and broadly serve as advocates to peers and consumers for incorporating more EPA and DHA in the diet.

Members of the Omega-3 Science Advisory Council include:

- Bill Harris, PhD, FAHA, FNLA, an internationally known expert on omega-3 fatty acids and how they benefit patients with heart disease
- Daniel Soffer, MD, FNLA, an internist and lipidologist with Penn Medicine of the University of Pennsylvania. He lectures regularly on lipid and lipoprotein metabolism and clinical management of lipid disorders and atherosclerosis.
- Marie Spano, MS, RD, CSCS, CSSD, a food and nutrition journalist, spokesperson, and frequent guest on national and regional TV stations
- In addition, Dariush Mozaffarian, MD, PhD, Dean of the Tufts University Friedman School of Nutrition Science and Policy and a board-certified cardiologist and epidemiologist, will serve as scientific consultant to the Omega-3 Coalition and GOED.

*Ellen Schutt is communications director for the Global Organization for EPA and DHA Omega-3s (GOED; Salt Lake City, UT).*
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High Times for High Concentrates

In both the drug and dietary supplement markets, high concentrates are taking a slice of the omega-3 pie.

BY MAUREEN KINGSLEY

The market for highly concentrated omega-3 fatty-acid fish oils for both pharmaceuticals and supplements is strong and growing, according to suppliers and industry experts.

Adam Ismail, executive director, Global Organization for EPA and DHA Omega-3s (GOED; Salt Lake City, UT), characterizes the omega-3 pharmaceuticals market in particular as “growing overall,” pointing out that omega-3 pharmaceuticals are “extremely effective,” with a good safety profile.

As physicians learn more about these products, Ismail asserts, the drugs’ efficacy and safety provide a strong incentive for practitioners to prescribe them to their patients. He points to GlaxoSmithKline’s Lovaza, Amarin Pharma’s Vascepa, and Trygg Pharma’s OmTryg as leading examples of omega-3 pharmaceuticals marketed and prescribed for treating hypertriglyceridemia, and says that additional high-concentrate omega-3 pharmaceuticals will continue coming to market.

“There are more than 50 R&D projects in the pipeline containing high-EPA and -DHA concentrates,” he says.

He predicts the demand for omega-3 pharmaceuticals will grow and grow—even if none of those current 50-plus R&D targets reaches the market.”

Likewise, high-concentrate fish oils and high-purity krill oils will continue to increase in popularity with supplement manufacturers, predict the GOED leadership and those who supply the oils, as supplement consumers learn more about high concentrates and demand increased convenience and higher omega-3 dosages.

“The drive toward convenience means we are seeing many more supplement products utilizing high concentrates to deliver smaller pill sizes, and there are also a number of loyal consumers who want to upgrade their usage and start to see and feel differences they attribute to the omega-3s, or learn more about the science,” Ismail explains. Those consumers who are just beginning supplementation with omega-3s, the “entry-level consumers,” don’t typically purchase high-concentrate omega-3 products, he adds, so the potential for the high-concentrate omega-3 supplement market to grow is dependent on existing omega-3 consumers becoming more educated and sophisticated regarding omega-3s and their benefits.
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First Things First: Defining High-Concentrate Omega-3 Fish Oil

The generally agreed-on definition of a high-concentrate omega-3 fish oil is also supported by the Codex Alimentarius Commission’s current draft fish-oil standard: Highly concentrated fish oils contain greater than 50% w/w fatty acids as a sum of EPA and DHA. Additionally, highly concentrated fish-oil ethyl esters (the result of processing and refining raw fish oils) are defined by the draft standard as greater than 60% w/w fatty acids as a sum of EPA and DHA.

Commercially available examples of high-concentrate omega-3 oil include products in Organic Technologies’ (Coshen, OH) AlaskOmega line, which AlaskOmega Ingredients’ global director, Steve Dillingham, says are up to 80%–85% omega-3. “At the highest end of our omega-3 concentrate spectrum,” Dillingham explains, “we produce an 800 mg/g EPA concentrate, a 600 mg/g EPA and 200 mg/g DHA concentrate, and a 570 mg/g EPA and 230 mg/g DHA concentrate.” These concentrated oils are all in ethyl ester form, he adds. In triglyceride form, AlaskOmega offers a 530 mg/g EPA and 200 mg/g DHA concentrate, “with other high-triglyceride concentrates currently in the pipeline,” Dillingham says.

KRILL-OIL SUPPLIERS HAVE THEIR SAY

The oil contained in krill, an ocean-dwelling crustacean, provides another source of omega-3 fatty acids, and it has recently been touted by those marketing it within the supplements industry as a more bioavailable source of these acids. (According to a 2014 editorial in the journal Lipids in Health and Disease, this bioavailability claim has yet to be fully substantiated.)

Tina Sampalis, medical science liaison for Neptune Technologies & Bioresources (Laval, QC, Canada), a supplier of krill oil, describes the advantages of the product this way: “Krill oil is concentrated by increasing its purity by removing triglycerides and other less beneficial elements from the crude oil, leaving the bioactive ingredients unaltered in their natural state. High-concentrate krill oil is composed of natural and highly bioavailable omega-3 phospholipids.” Sampalis’s opinion is that fish oil–derived omega-3 ethyl esters “have reached their plateau,” and that the market is “now ready for more innovative, dose-friendly, and better-absorbed products” derived from krill oil. “The future looks bright for concentrated krill oils that offer the combined benefits of highly absorbed omega-3 phospholipids and antioxidants,” she concludes.

Similarly, Enzymotec’s (Migdal HaEmeq, Israel) Volkan Eren asserts his company’s K-REAL high-potency krill-oil products consist of a “unique and sophisticated profile that reaches higher levels of phospholipids, EPA, DHA, and astaxanthin” than standard krill oil, “all in an easy-to-consume small softgel size.”

Krill oil–based prescription-drug update: Pharmaceutical firm Acasti, which has an exclusive license from Neptune Technologies & Bioresources to develop pharmaceutical products customized to manage cardiovascular disease, continues to develop drug candidate CaPre for the prevention and treatment of cardiometabolic disorders, including hypertriglyceridemia. According to documents published on Acasti’s website, Acasti has successfully completed two Phase II clinical trials designed to evaluate the safety and efficacy of its drug candidate for the management of hypertriglyceridemia, and it has also successfully completed a pharmacokinetic trial evaluating the bioavailability and safety of CaPre on healthy individuals taking single and multiple daily oral doses of the product.

Epax Omega-3, a division of FMC Health and Nutrition (Sandvika, Norway), offers a Core Concentrates high-concentrate omega-3 line, which consists of products containing a minimum of 300 mg/g and a maximum 699 mg/g combined EPA and DHA, and an Ultra Concentrates line whose products contain a minimum of 700 mg/g combined EPA and DHA.

“We do not consider anything less than 500 mg/g EPA and DHA high concentrate,” states Epax Omega-3 associate products manager, FMC Health and Nutrition, Sarah Christianslund.

Safe, Effective, and Gaining in Popularity: High-Concentrate Omega-3s in Pharmaceuticals

Drugs containing therapeutic levels of high-concentrate omega-3 fatty acids have been commercially available in the United States for about a decade. Lovaza, a high-concentrate omega-3 drug for which BASF (Florham Park, NJ) supplies the active ingredient, came to market in the United States in 2005 for treatment of hypertriglyceridemia. BASF is “clearly focused on the high-concentrate omega-3 market in both pharmaceuticals and dietary supplements,” says the company’s Andres-Christian Orthofer, global communications, nutrition & health products manager, & Biologics, global communications, nutrition & health products manager, FMC Health and Nutrition, Sarah Christianslund. “The usual pharmaceutical market dynamics [including competition from generics] impacted Lovaza, but at a lower pace than normally experienced on the market,” Orthofer says. “Nevertheless, driven by generics, we expect the total U.S. market for omega-3 pharmaceuticals to further expand. Currently we see a strong interest in the market, especially from generic players and originators, with a need for next-generation products. This will further drive awareness of the health benefits of omega-3 fatty acids among consumers.”

Demand for high-concentrate fish oils and high-purity krill oils will continue to grow as consumers learn about the added convenience that comes with higher dosages.
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He adds, "BASF will continue to further shape the global and U.S. markets with our unique knowledge, expertise, and capabilities as a pioneer and leader in pharmaceutical application of omega-3s."

AlaskOmega’s Dillingham takes a similar view to Orthofer, pointing out that the "major success of Lovaza and Omacor [Lovaza’s brand name outside of the United States] shows the significant market potential for these types of products."

Dillingham believes that further differentiation in the omega-3 drug space will bode well for further market expansion. "As more and more omega-3 drug candidates come on line," he says, "the general population will become increasingly aware of the science supporting higher omega-3 dosing for certain health benefits," which will, presumably, drive demand.

BASF’s Orthofer predicts that differentiation in this market will focus on the "purity" of the omega-3s (i.e., the absence of environmental pollutants).

**Not Just for Pharma: High-Concentrate Omega-3s in Supplements**

GOED’s Ismail describes the supplement market for high-concentrate omega-3s as having "lots of potential," in part because "the drive toward convenience means we are seeing many more products utilizing high concentrates to deliver smaller pill sizes," he says. Likewise, FMC’s Christianslund agrees that high concentrates are "definitely not limited to pharmaceuticals." She asserts her company’s Epax oils were first to market with high concentrates intended for dietary and food supplements back in the late 1980s, "enabling brand owners to promote omega-3 as a condition-specific supplement through a range of various scientifically proven EPA/DHA ratios and concentrations," and this application remains relevant.

"As more and more omega-3 drug candidates come on line, the general population will become increasingly aware of the science supporting higher omega-3 dosing," Dillingham says.

BASF’s Orthofer points to a "strong underlying trend" toward using higher concentrates in the nutritional supplements market, particularly in North America, as consumers stepwise become more educated about the benefits of these oils. He lists "the convenience needs of consumers, an increasing need for solutions to health-specific conditions, and innovative health concepts to
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differentiate from competition” as the main drivers of this trend.

Supplement manufacturers who purchase AlaskOmega’s high omega-3 concentrates, for instance, are typically looking to stand out in the market through innovation and product differentiation by “delivering a clinically relevant dosage of omega-3 in a smaller capsule size,” Dillingham says. The supplier’s supplement-manufacturer customers are also, in some cases, looking to formulate multiple-ingredient combination products without sacrificing omega-3 potency. “These manufacturers, in turn, are serving an omega-3 consumer base which values ease of use and being able to reduce overall capsule count in their daily supplement regime.” Dillingham says, echoing comments from his industry peers about consumer convenience.

Onward and Upward for High-Concentrate Omega-3s

Industry consensus is that highly concentrated omega-3 oils will continue to grow in demand for both the pharmaceutical and supplement markets.

“As a drug,” BASF’s Orthofer points out, “omega-3 is a well-established treatment for hypertriglyceridemia. Furthermore,” he adds, “the strong growth of lifestyle-related diseases also increases the need for new and affordable treatments with products like omega-3 in all life stages. There is strong clinical evidence for the benefits of omega-3 fats on the cardiovascular system. However, studies indicate that omega-3s have additional beneficial health effects on the brain, the eyes, and the nervous system.” Indeed, in Europe, the EU Register on Nutrition and Health Claims permits food and supplement labeling related to omega-3 fatty acids’ contributions to the maintenance of normal blood pressure, brain function, vision, and heart function, among others. (Turn to page 52 for a look at emerging research frontiers for omega-3s.)

BASF, for one, is “significantly investing” in research to further explore and prove the benefits of omega-3 for the human body,” Orthofer concludes, and it appears likely that others will follow its lead.

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Finding a Home for Hemp

Will hemp CBD be a drug or a dietary supplement ingredient?

BY MICHAEL CRANE, ASSOCIATE EDITOR

For an ingredient that isn't officially approved for use in the United States, hemp CBD is quickly gaining ground in the dietary supplement market. Health food retailers across the country have begun carrying CBD supplements in recent years, even if FDA hasn't actually recognized hemp CBD as a legal ingredient.

Hemp CBD, short for cannabidiol, occupies something of a legal grey area, due in large part to its associations with marijuana and CBD's chemical cousin, tetrahydrocannabinol (THC). Both marijuana and industrial hemp are varieties of the Cannabis sativa plant, but the industrial hemp most CBD is derived from contains only minute amounts of THC and is therefore not psychoactive.

As public perception has warmed to the broader hemp category in the last few years, FDA has taken a relatively hands-off approach to CBD supplements. However, those days may be coming to an end. FDA is currently considering an investigational new drug (IND) application for hemp CBD, which has already prompted the agency to speak out against CBD in dietary supplements. And if the IND is accepted, some industry experts fear the door could close on CBD ever reaching legal acceptance as a food or dietary supplement ingredient.

The Current Grey Area

CBD's rise to prominence has come at a time when the hemp category as a whole is experiencing strong and steady growth. According to the Hemp Industries Association (HIA, Summerland, CA), U.S. sales of hemp food and body care products grew by 21.2% in 2014 to reach $200 million. Hemp seed products are stealing the spotlight, but there's a lot to love about CBD as well.

Recent research has shown CBD's potential benefits on anxiety, sleep regulation, heart health, and more.

It may then be surprising that CBD dietary supplements have been able to reach U.S. consumers without being deemed generally recognized as safe (GRAS) by FDA, without being established under a new dietary ingredient (NDI) provision, and, depending on interpretation, while still being considered a Schedule 1 drug on the same list as marijuana and LSD. Many U.S. states have legalized the growing of hemp for research purposes, and there are several proposed bills in Congress to legalize cultivation of industrial hemp nationwide. As of now, however, hemp CBD is an ingredient without legal standing.

And yet, FDA has mostly steered clear of taking action against hemp CBD supplements, says Eric Steenstra, executive
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director, HIA. Even earlier this year, when FDA sent warning letters to a slew of firms that market CBD products, it was on the basis of problematic disease claims, not CBD’s shaky legal status.

“The only indication we have from FDA on [CBD] is that they did send out a handful of letters to some companies that made specific health claims, but they could do that to any food or dietary supplement product based on the regulations about health claims,” says Steenstra. “It didn’t have anything to do with them objecting to CBD; they just objected to the health claims.”

Meanwhile, the CBD industry has been marching forward. While much of the CBD-rich oil in U.S. products is imported from Europe or China, companies like CannaVest (San Diego) have begun growing hemp in Kentucky or Colorado for research purposes—research that can even extend to sales and marketing of hemp, according to Chris Boucher, vice president of product development, CannaVest. With much of the infrastructure and supply chain in place, Boucher says the CBD industry is ready to explode.

“I think if it does become legal, we’re talking, potentially, a billion-dollar industry, without a doubt,” says Boucher.

**FDA Draws Line**

In May, FDA did finally offer some clarification on the status of CBD as an ingredient. Unfortunately for firms that produce hemp CBD dietary supplements, it’s not what they might have hoped for.

“Based on the available evidence, FDA has concluded that cannabidiol products are excluded from the dietary supplement definition under section 201(ff)(3)(B)(ii) of the [Federal Food, Drug, and Cosmetic Act],” says the statement from FDA published in an online Q&A about the agency’s treatment of marijuana. The reasoning? Companies have already filed IND applications to make CBD a drug ingredient, such as those submitted by GW Pharmaceuticals for its Sativex and Epidiolex products.

FDA’s statement continues, “under that provision, if a substance (such as cannabidiol) has been authorized for investigation as a new drug for which substantial clinical investigations have been instituted and for which the existence of such investigations has been made public, then products containing that substance are outside the definition of a dietary supplement.”

Essentially, because CBD is under consideration as a drug ingredient, it cannot be considered a dietary supplement ingredient. Even more troubling, if FDA is already speaking out against CBD supplements now, while the drug application has yet to be approved, what happens if GW Pharmaceuticals is successful and CBD becomes accepted as a drug ingredient?

“If they [GW Pharmaceuticals] do get [the IND application] first, and it’s not on the market as a dietary supplement, it could preclude it ever being a dietary supplement, based on DSHEA [the Dietary Supplement Health and Education Act of 1994],” says Mark Blumenthal, founder and executive director, American Botanical Council (Austin, TX).

Still, the battle isn’t over yet. There’s an argument to be made for CBD being recognized as a supplement ingredient and not a drug ingredient, and it all comes down to timing.

**Which Came First?**

Under DSHEA, the law would allow CBD to be sold as a dietary supplement ingredient—based on grandfathered status and without NDI notification—so long as a company could prove that CBD was sold on the market as a dietary supplement ingredient prior to 1994.

Similarly, FDA’s May statement actually does leave some room for the possibility of CBD supplements—if the industry can show CBD supplements were on the market before GW Pharmaceuticals began its investigation into CBD for drugs.

“There is an exception if the substance was ‘marketed as’ a dietary supplement or as a conventional food before the new drug investigations were authorized,” says FDA in the same marijuana Q&A. Although the statement goes on to say FDA is not currently aware of any such evidence for CBD, it also invites interested parties to submit any information that might call into question that conclusion.

FDA has not specified the exact date when the drug ingredient process began, but it was likely between 2006 and 2008, says CannaVest’s Boucher. Michael McGuffin, president of the American Herbal Products Association (AHPA; Silver Spring, MD), says it is AHPA’s understanding that the earliest IND for CBD was filed in November 2007, the time when GW Pharmaceuticals announced a clinical trial of a drug containing CBD.

CannaVest is confident there is enough evidence to show CBD was marketed as a supplement ingredient first.

“It is our opinion, which is broadly shared by the marketplace, that CBD has been marketed as a dietary supplement prior to commencement and public notice of any substantial clinical investigations instituted on CBD,” says Stuart Tomc, vice president of human nutrition, CannaVest.

Tomc also questions the “substantial” nature of the drug investigations on CBD that did exist at the time—namely, stating that those investigations that were publicized were not substantial, were limited in number, and were preliminary in nature, “thereby rendering the IND preclusion inapplicable,” he says.

But even if there is proof that CBD-containing supplements were on the market prior to what FDA would consider the critical date in drug development, FDA might still dismiss the idea of an exception to the drug application because CBD did not have regulatory approval for supplements.

“I think if it does become legal, we’re talking, potentially, a billion-dollar industry, without a doubt,” says Boucher.
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"I suppose FDA could come back, or the pharmaceutical company could come back, and say, 'Yes, but you were selling [CBD in supplements] illegally. You didn't have regulatory status,'" says John R. Endres, ND, chief science officer for GRAS and NDI regulatory consultant AIBMR Life Sciences Inc. (Puyallup, WA).

Additionally, CannaVest’s Tomc thinks the conversation about CBD’s future is bigger than this issue of timing and should also include a discussion of dietary supplements and drugs both using CBD legally.

"I think that an exception has to be made that we can coexist in the same space, because of the fact that government can’t and shouldn’t stop people from growing and creating their own medicine," says Tomc.

CBD products currently on the market. HIA’s Steenstra expects CBD supplements would not be high on FDA’s list of priorities.

"They have limited resources, as with any federal agency, and they have to weigh what things are important and what aren’t," says Steenstra. He adds, "I would like to continue to believe that FDA has more important things to do than to try to stop companies from marketing CBD as a dietary supplement when, not only is it not harming anybody, it’s actually quite helpful."

One clue of what to expect might lie in the 1997 case of a red yeast rice supplement ingredient and the regulatory tension between supplement firm Pharmanex (Provo, UT) and pharmaceutical firm Merck (Kenilworth, NJ).

"The Pharmanex case provides some context for what could happen," says AHPA’s McGuffin. "FDA acted against Pharmanex in 1997 for that company’s marketing of its red yeast rice dietary supplement product, Cholestin, which was manufactured to contain a controlled level of lovastatin. FDA had authorized Merck’s lovastatin drug (Mevicor) several years prior to the introduction of the Pharmanex product."

McGuffin continues, "Although FDA acted forcefully to removed Cholestin, red yeast rice products standardized to lovastatin have continued to be available since the removal of this one brand. FDA issues occasional warning letters to marketers of these products, including at least two such letters in 2014."

But even if FDA takes minimal enforcement actions against CBD supplements, the drug application could still have an impact on the market. In fact, it already has.

**Trade Show Turns Away CBD Supplements**

The first big ripple to come as a result of FDA’s statement on CBD may be the July announcement from New Hope Natural Media (Boulder, CO), organizer of the Natural Products Expo trade shows, that it will ban dietary supplements containing CBD from its show floors.

"The Expo standards department is requesting that exhibitors not display, sample, or promote CBD products packaged or labeled as dietary supplements, based on U.S. FDA’s May 13, 2015, statement that the agency considers CBD products to be excluded from the definition of ‘dietary supplements,’" said New Hope.

CBD-rich foods, cosmetics, and bulk CBD will still be allowed for display at the New Hope shows, however. Although CBD foods and CBD supplements may both lack official regulatory status, New Hope seems to be following FDA’s explicit mention of CBD supplements in making its decision to ban CBD supplements, but still allow foods.

"It kind of makes me wonder whether Expo does really want to support CBD, but feels like they can’t for that one thing that got knocked off the list because of what FDA said," says AIBMR’s Endres.

CannaVest’s Tomc says he was surprised by the announcement from New Hope and disappointed to see CBD on the same list as the show’s other prohibited supplement
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ingredients, such as artificial sweeteners and artificial colors. However, he says he hasn’t seen any other signs of anxiety in the industry as a result of FDA’s statement on CBD. Actually, he’s seen the opposite.

“The more I tell people about this, the more they want to carry the product. It’s having the exact opposite of the intended effect,” says Tomc. He adds, “If anything, this has increased awareness and will continue to increase awareness of this ingredient that we’re being told can be controlled by a pharmaceutical company for one narrow indication.”

What’s Next?
The consensus seems to be that, justifiably or not, the approval of CBD as a drug ingredient would be detrimental to the prospects of CBD as a supplement ingredient. But what happens if the drug ingredient application fails, or FDA decides CBD was legally used in supplements before 2007? Well, there are still a few obstacles to legal acceptance.

Perhaps the most likely first step is to definitively reschedule CBD so it is no longer a Schedule 1 substance. Although some, such as HIA’s Steenstra, do not believe CBD is currently Schedule 1 anyway because it is not specifically mentioned in the Controlled Substances Act, it’s a step that may still be necessary to clear up any lingering taboo around industrial hemp. There are already bills being considered in the U.S. legislature that would decisively extricate CBD from the definition of marijuana.

A GRAS application would likely soon follow, and CannaVest’s Boucher says the industry is currently amassing the toxicology studies and other research necessary for GRAS review. And once that happens, CBD could really take off in foods and supplements.

“A GRAS recognition for CBD would be a huge step, says Boucher.

“If it gets GRAS, I think that’s when you’re going to see it really take off. Then your big players in the field will start using it,” says Boucher. He adds, “The legal technicality is keeping some of these multibillion-dollar corporations from entering it—the whole grocery chain, some of the big vitamin chain stores, the health food stores. Your big corporate chains are just on the sidelines, and I think it would open the doors to companies of that size to say ‘Okay, we’re jumping in.’”

But if FDA chooses to accept CBD as a drug ingredient and remains inflexible to CBD supplements, mass-market retailers may continue to stay on the sidelines when it comes to CBD supplements. Boucher says the move would certainly pose challenges, but that CannaVest will continue to look for ways to navigate the legal options and get CBD supplements to consumers.

“It will bring us into a different category,” says Boucher. “We’re working on different business models if that does happen. We’ll still be here. We’ll still be in the supply chain. We’ll just have to go in a different direction.”

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Just What the Doctor Ordered?

We need clarity on medical foods—stat!

BY KIMBERLY J. DECKER

The saying goes that success has many fathers, but failure is an orphan. For sufferers of rare diseases like phenylketonuria, methylmalonic acidemia, and T-cell lymphoma, however, the U.S. Orphan Drug Act (ODA) of 1983 was anything but a failure. That’s because the ODA gave FDA the green light to encourage research and development into drugs and medical foods—the act’s poignantly named “orphans”—which, though necessary to manage such rare conditions, were often missing from the marketplace simply because their profit potential fell short of the expense of bringing them to market.

It’s hard to find a more altruistic example of our legislative process at work. Yet fully a generation after the ODA’s passage, companies charged with actually developing the act’s “orphans” are still trying to figure out what kinds of products, exactly, the law encourages them to develop. This is especially the case with medical foods, which, says Brian Carroll, PhD, scientific and regulatory affairs manager, Primus Pharmaceuticals (Scottsdale, AZ), “have been somewhat poorly defined from a regulatory and FDA point of view. The industry has been working it out in real time.”


Looking for a Home

Congress passed the ODA to help patients dealing with health conditions so rare that, absent incentives like temporary market exclusivity or R&D tax credits, pharmaceutical manufacturers would have little to gain in addressing them. “With nobody wanting to take on these particular patient types or rare diseases,” Carroll recalls, “they were looking for a home.”

And because nutrition plays such a critical role in managing many such conditions, Congress extended the law’s “orphan” umbrella to cover not only traditional drugs but medical foods, too, which the statute defined as a food “formulated to be consumed or administered enterally under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation.”

There’s a lot to unpack there—and it’s only the start, too. For while “the statute is what Congress gives to FDA,” says Jessica P. O’Connell, special counsel, Covington & Burling LLP (Washington, DC), “FDA then makes rules interpreting it.” In other words,
what Congress legislates, FDA implements using rulemaking, guidance, and ground-level regulatory enforcement. And that’s where medical foods get complicated.

A Matter of Interpretation

The reason for this complication is that though the letter of the ODA says one thing, FDA has read it to say...well, not necessarily something different, but something narrower, perhaps. Specifically, the agency’s 2013 draft guidance on medical foods states that it “considers the statutory definition of medical foods to narrowly constrain the types of products that fit within this category of food.” Thus FDA established the following criteria, found in 21 CFR 101.9(j)(8), to “clarify” the statutory definition:

1. A medical food is a “specially formulated and processed product (as opposed to a naturally occurring foodstuff used in its natural state) for the partial or exclusive feeding of a patient by means of oral intake or enteral feeding by tube.”
2. It is “intended for the dietary management of a patient who, because of therapeutic or chronic medical needs, has limited or impaired capacity to ingest, digest, absorb, or metabolize ordinary foodstuffs or certain nutrients, or who has other special medically determined nutrient requirements, the dietary management of which cannot be achieved by the modification of the normal diet alone.”
3. “It provides nutritional support specifically modified for the management of the unique nutrient needs that result from the specific disease or condition, as determined by medical evaluation.”
4. It is “intended to be used under medical supervision.”
5. It is “intended only for a patient receiving active and ongoing medical supervision wherein the patient requires medical care on a recurring basis for, among other things, instructions on the use of the medical food.”

And that, ladies and gentlemen, is what FDA calls a “clarification.” Says Laurie C. Dolan, PhD, senior toxicologist, Burdock Group (Orlando, FL), FDA has “melded the definition of medical food as defined in section 5(b)(3) of the Orphan Drug Act (21 U.S.C. 360ee(b)(3)) with the definition as defined in 21 CFR 101.9(j)(8)” for food labeling. So you can see why companies are calling their lawyers.

Straight and Narrow

As it happens, Covington & Burling’s O’Connell was an attorney in FDA’s Office of Chief Counsel as the guidance was being drafted, and she participated in the process. To her mind, among the document’s more notable features is its treatment of the ODAs’ “distinctive nutritional requirement” language, which she believes FDA has construed...
"really narrowly" to mean "a need that can’t be met through dietary modification alone," as noted in bullet 2 above. That narrow reading has led some to question whether it’s "an appropriate interpretation of the statute," O’Connell adds, and even to charges that FDA is overstepping its authority.

Dolan might sympathize with that sentiment. "This new guidance is an attempt by FDA to turn back the clock to before 1972, when medical foods were regulated as drugs," she says. Taking issue with the document’s "modification of the normal diet alone" language, and with its requirement that medical foods be administered under physician supervision, Dolan claims that it "provides little guidance about the conditions that can be served by medical foods" and "seems to ignore medical-food use for people who cannot swallow or ingest foods normally, but instead stresses the inborn-errors-of-metabolism issue."

Inborn errors of metabolism (IEMs), as the guidance states, are "inherited biochemical disorders in which a specific enzyme defect interferes with the normal metabolism of protein, fat, or carbohydrate." Perhaps the best known is phenylketonuria (PKU), in which a deficiency in the enzyme phenylalanine hydroxylase allows toxic levels of phenylalanine to accumulate in the blood and tissues, causing neurological damage and more as a result.

And while the guidance acknowledges medical foods’ centrality in helping phenylketonurics and other IEM patients "obtain adequate levels of essential nutrients which can be served by medical foods," says Richard L. Eichholz, PhD, partner, bio-Strategies Group (Chicago). For despite the fact that rates of type 2 diabetes and related metabolic diseases are approaching epidemic status—with costs to society, the healthcare system, and individual quality of life—"the guidance just said medical foods can’t be used in diabetes or obesity," Eichholz says.

He can only speculate as to why, but Eichholz figures FDA’s reasoning may rest on a view that type 2 diabetes is "pretty far-removed from an inborn error of metabolism," he says. Nevertheless, "We still have a huge diabetes problem, and the obesity problem is not going away. So I would honestly say that it makes sense to encourage somebody to develop a medical food for type 2 diabetes and obesity. That’s where I’d like to see this go."

FDA’s conclusion, then: "Diet therapy is the mainstay of diabetes management," and the agency thus would not generally consider a product marketed for type 1 or 2 diabetes to meet the regulatory criteria for a medical food. That, however, is the real dilemma for me," says, "as they could be considered supplements, medical foods, or foods for special dietary use, depending on the user."

Resource Allocation
Which, again, leaves manufacturers wondering how to proceed. In light of the continuing regulatory uncertainty hanging—the guidance is still in draft form and contains non-binding recommendations—one suggestion may be: with prudence and caution. After all, Carroll says, the agency "is clearly intent on narrowing the medical-food definition." And though getting inside the head of the FDA "mega-bureaucracy," as he calls it, may always be a crapshoot, he suspects the motivation for their narrowing may be resource allocation.

To be fair, whether it’s recalling faulty hip implants or revoking trans fats’ GRAS status, FDA has a lot on its plate; monitoring activity in the medical-foods sector adds yet another task to its docket. So “given the resources FDA has to oversee the category compared to the more traditional categories of pharmaceuticals, foods, and dietary supplements,” Carroll says, “the desire to narrow the category, or at least maintain its current narrowness, makes sense, certainly from their point of view. They probably want to make sure they’re ahead of the wave.”

**FDA’s latest draft guidance for medical foods leaves many in industry wondering where these products now fit into the health-and-wellness landscape.**

**Diabetes Nation**

Another good example of FDA’s restricted view, as O’Connell calls it, is the guidance’s stance on diabetes. Both type 1 and type 2 diabetes are metabolic disorders, yet the document makes clear that patients with type 1 diabetes can follow a carbohydrate-counting or -exchange system to match insulin replacement to carbohydrate intake, while those with type 2 “should restrict calories, eat regularly, increase fiber intake, and limit intake of refined carbohydrates and saturated fats” to manage their conditions.

**Off Limits, and On**

Alas, he won’t likely see it happen should FDA’s current thinking become legally enforceable. So if the medical-food marketplace is off limits to diabetes products—and, by the way, to products targeting pregnancy, scurvy, and pellagra, all of which the guidance also shoots down—what products can we label and market as medical foods?

According to Dolan, “complete nutritional products for tube feeding, or foods specifically designed for people with inborn errors of metabolism” are fair game, such as Phenylade for phenylketonuria and UCD Anamix for urea cycle disorder. Additionally, protein substitutes such as Vitaflō’s PKU gel and TYR gel for tyrosinemia, which “can be mixed with low volumes of water or beverages to form gels to be eaten with a spoon, or with larger volumes of water or beverages to make drinks,” she explains, get the go-ahead.

But as for popular electrolyte-replacement beverages like Pedialyte and nutrition drinks like Ensure—both from Abbott Nutrition, an active player in the medical-foods field—it’s unclear where they fit, Dolan says, “as they could be considered supplements, medical foods, or foods for special dietary use, depending on the user.”
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Riding the Wave
And the wave is cresting. Market research firm Frost & Sullivan predicts the global medical-foods category will reach $13.34 billion by 2018. Already, Nestlé has moved from the consumer space into medical foods with its purchase of several medical-foods makers, and Abbott has made its own shift from pharmaceuticals into medical foods. ‘And then,’ bioStrategies’ Eichholz adds, ‘you have a whole bunch of startups that started as medical-food companies but got there from different places.’

Ergo the possibility that a slew of products hoping to ride that rising tide will surface. Just consider diabetes. O’Connell wagers that the draft guidance focused so much on the condition “because there was concern that there were a lot of convenience-type products making it easier to eat a low-sugar diet being marketed as medical foods, but that FDA didn’t consider medical foods,” she says. Heading off that flood at the pass “was the only way FDA could communicate its current thinking to industry aside from going through rulemaking, which would have been a lot more time-intensive for FDA to do.”

Appealing Targets
Far less time-intensive is issuing warning letters to companies whose products FDA believes violate current medical-foods regulations. And since 2004, O’Connell says, the agency has sent warning letters to a number of companies charging that the products under question address diseases or conditions for which no “distinctive nutritional requirement” exists; since 2009, many letters have zeroed in even further on the charge that the products lack any “distinctive nutritional requirement” that cannot be met through “modification of the normal diet alone.”

“FDA was concerned that they didn’t even know what was out there,” O’Connell says. “And they were concerned that consumers, either seeing the words medical food or seeing a certain disease identified on the label, would assume that the product had undergone some sort of review, or was at least subject to some sort of evidentiary limitations. And that really isn’t the case for that category.”

Indeed, while supplements must follow Nutritional Labeling and Education Act (NLEA) restrictions “on what, where, how, and why food or supplement manufacturers can make health and nutrient-content claims,” O’Connell explains, that same act specifically exempted medical foods from those claim requirements, allowing the products to “explicitly state that they’re for the dietary management of named diseases.” So it’s no surprise, she says, that “companies see the medical-foods category as more appealing; there are fewer labeling requirements than for other products.”

Another possible reason manufacturers are exploring the category might be the financial incentive that comes with marketing medical foods to physicians and healthcare providers charged with supervising their use. As Carroll notes, “the medicines physicians prescribe are subsidized, for the most part. So if you can tap into the subsidy—that is, the insurance reimbursement—that gives you pricing power and enables your margins to be robust and to sustain more development and investment in your business.” Being able to “capture some of this insurance reimbursement,” he says, is the “holy grail” for the medical-foods industry.

All about the Patients
But those who know the sector both inside and out insist: Nobody’s building commercial empires on the back of medical foods alone. Remember, Congress originally wrote the ODA to convince manufacturers to give these products a shot despite their pool of potential consumers being so paltry. Sure, an aging population and an increasingly sophisticated grasp of nutrition’s role in disease management will expand that pool, but the aggregate of those little niches pales in comparison to the current market size of dietary supplements and functional foods in retail, Carroll says.

Perhaps that’s why he’s “very optimistic about consumer trends toward healthier alternatives to disease management,” he says. “Medical foods are well positioned to meet a growing need for both traditionally minded and nutrition-focused physicians, their practices, and, most importantly, their patients.”

And bringing these products to market isn’t all about the money anyway. “I have to tell you that the people I’m familiar with in the medical-foods area are highly ethical, highly dedicated, and they don’t generally get in this area just to make a profit,” Eichholz says. “Usually there’s something else that’s driving them. They’re all about the patients.”

Given the direction of FDA’s latest guidance, that’s probably just how the agency likes it. Interestingly, though, Eichholz has noticed a possible unintended consequence of the guidance—namely, that it’s “helped a couple of our clients or would-be clients decide not to be medical foods,” choosing the pharmaceutical route instead. Why? “The bar got a little higher,” he figures, “so if you’re going to raise the bar that much, you might as well go all the way to being a drug.”

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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The study also showed a normalizing of saliva pH levels which is often indicative of a reduction in inflammation.

Conclusion: The study results showed that TendoGuard™ when taken at a dosage of 375mg – 500mg twice per day appears to benefit joint inflammation, secondary mobility and other tertiary effects. The study shows that TendoGuard™ may be a viable treatment option for the management of joint and connective tissue disorders.

Pain Scale Reduction Chart Recorded During Trial

* These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.

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Beauty Besties

Topical and ingestible cosmetics unite!

BY MICHAEL CRANE, ASSOCIATE EDITOR

Whether the description is “beauty from within,” “long-term beauty,” or “beauty from the inside out,” nutricosmetics are frequently billed as a lasting and genuine way to enhance skin health. Contrast that with the perception of some topical-cosmeceutical effects as short-term and superficial, and it’s easy to see why a growing number of cosmeceutical firms have begun to pair their topical products with a nutricosmetic supplement. Some, even, are looking into combinations of ingestibles, serums, medical devices, and masks to offer a comprehensive package for all beauty needs, long-term and short-term.

But what’s the appeal of these combinations, and which ingredients are best suited to the pairings?

Separate Industries Converge

Dubbed “bi-directional beauty” or “twincosmetics,” nutricosmetics and cosmeceuticals may seem like an obvious combination. But actually, it’s only been a short time since these two markets have started to come together.

“Until recently, nutricosmetics has been a niche market mostly served by food supplement companies, not cosmetics,” says Fernando Cartagena, marketing manager, Monteloeder (Alicante, Spain). However, the tide is changing.

Some see topical cosmetics as a short-term, surface-level fix.

“More and more cosmetic companies have seen the value of leveraging their brand, expertise, and consumer base to launch a nutritional line,” says Cartagena. “Similarly, food supplement companies specializing in skin health are also adding topical products, trying to cover the whole skin-health spectrum.”

Lauren Clardy, president of NutriMarketing (Santa Rosa, CA), says the pairings of cosmeceuticals and nutricosmetics is a new phenomenon that is starting to make its way into mass markets.

“It’s just starting right now,” says Clardy. “We’re really still in the infancy stage, and it’s going to grow.”

The shift may actually be driven by interest from consumers and retailers, according to Tim Mount, director of education at NeoCell (Irvine, CA).

“We’ve received a lot of interest from large retail chains for these types of pairings recently,” says Mount. “The beauty category has been exploding over the past few years, and retailers want to capture the trend by offering a comprehensive beauty routine with supplements and topicals. Often, we organize premium placement at the store level to ensure we have space to educate on this trending approach to beauty.”

The Dual Approach

For two categories that have historically been fragmented, both nutricosmetics and cosmeceuticals seem to benefit from this new combination.

From the cosmeceutical perspective, the marriage may offer the opportunity to go beyond perceptions of a short-term, surface-level fix.

“I think it goes back to, basically, you are what you eat. You can put the most expensive,
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$500 creams on your face, but if you’re smoking cigarettes, in the sun all day, or eating McDonalds all day long, it’s going to affect your skin,” says Clardy. “I think definitely people understand that you can’t just put creams or topicals on and think that it’s going to reverse the signs of aging.”

And for nutricosmetics, partnering with topical cosmeceuticals may allow consumers to see an immediate improvement in skin health until the ingestible supplement begins to take effect—possibly encouraging them to continue use of the product.

“While you can’t get the same absorption topically as you can internally with nutricosmetics, you can feel that instant moisture your skin needs,” says NeoCell’s Mount. “Consumers so often want an instant fix, so the topical solution is great for adding dewiness or moisture while the nutricosmetic is working at a deeper level for the longer-term benefits reported.”

For instance, collagen, one of the most popular ingredients in nutricosmetics, may take a few weeks to have any sort of noticeable effect on the skin, according to Mount.

“Some consumers expecting instantaneous results may grow impatient, so coupling collagen with a serum may help to provide a quick benefit while they wait for the collagen to kick in,” says Mount.

So what are some of the products taking off in the new bi-directional beauty space?

**ZSS Skincare**

First hitting shelves in late 2014, ZSS Skincare (Chesterfield, MO) pairs a topical serum made from zeaxanthin, chlorella extract, and many other ingredients with two different ingestible dietary supplement options—Method 1 Radiant Skin or Method 2 Clear Skin. The Clear Skin supplement is made primarily with zeaxanthin, probiotics, and fish oil–derived omega-3s, while the Radiant Skin supplement contains key ingredients like zeaxanthin, alpha-lipoic acid, seabuckthorn fruit oil, and gotu kola seed.

Paula Simpson, cofounder of ZSS Skincare, says zeaxanthin was the ideal ingredient because it is “effectively absorbed in skin tissue where it can work as a primary antioxidant against oxidative stress.”

“Although we hear about the benefits of antioxidants for skin health, when taken orally, many are neutralized in the gut before they can reach skin tissue,” says Simpson. “When consumed in supplement form, zeaxanthin can bypass the digestive system and reach skin tissue where it works effectively as an antioxidant and improves overall skin radiance.”

The addition of probiotics *Lactobacillus acidophilus, Bifidobacterium breve,* and *Lactobacillus salivarius* to the Clear Skin supplement stemmed from building evidence behind a gut/skin health axis. Simpson says the combination of the probiotics and zeaxanthin may “rebalance gut and skin microflora to calm and clear skin.”

Research is still underway into the combination of serum and supplements for skin health, but an unpublished study presented at the American Academy of Dermatology in March explored the effects of combining probiotics and zeaxanthin in supplement form. Twenty-one female subjects aged 35-65 were randomized to receive either the ZSS probiotic/zeaxanthin capsules or a placebo daily for 12 weeks. At four-week intervals, the participants were evaluated for skin redness, redness variation, radiance/luminosity, and inflamed lesions. The study was placebo controlled and double blind.

At the conclusion of the study, researchers observed significant improvements in skin radiance/luminosity, a reduction of redness and redness variability, and improved cumulative erythema scores in the experimental group compared to the placebo group. Also, the percentage of inflamed pores in the experimental group was reduced by 29.9% over the course of the study, compared to just 4.2% in the control group.

“These data add to the evidence that probiotics combined with zeaxanthin may be considered for future research in the target population to reduce inflammation and the signs of photo damage, and to reduce facial redness and improve skin’s glow,” concluded the researchers.

The ZSS Radiant Skin is designed to support skin as it ages, reduce redness, and promote skin hydration, while the Clear Skin is meant to manage skin breakouts, even skin
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*Synergy protein research has been in collaboration with its parent company, Carbery, a leading manufacturer of whey protein.
tone, and support pore health. Both product packages combine the topical Nutri-Serum with a combination of soft gel and capsule dietary supplements intended for daily use.

**NutroxSun**

Monteloeder is another ingredient supplier exploring the “twincosmetic” space with its NutroxSun ingredient, a Mediterranean blend of natural grapefruit and rosemary extracts. The ingredient is designed to defend against the effects of sunburn and photoaging without interfering with the skin’s tanning system.

“The benefits of sun protection from ‘within’ products, as opposed to creams and sprays, are becoming more widely appreciated. Topical sunscreens alone often fail to provide reliable all-day defense for the skin,” says supplier Monteloeder.

“Sun protection ingredients for oral consumption are also growing in popularity worldwide, with more and more people becoming aware that 80% of lifetime sun exposure happens in daily life and not on holidays, therefore needing a solution that is more convenient than applying a sunscreen cream,” says Cartagena.

A soon-to-be-published study followed 105 subjects aged 18 and older who were exposed to ultraviolet light on their backs and then given either a placebo or NutroxSun dietary supplement to ingest daily. Researchers found that in the NutroxSun group, skin elasticity was increased, wrinkle depth was decreased, oxidation of skin cells was diminished, and the onset of sunburn was delayed, according to a press release from Monteloeder.

“Topical sunscreens alone often fail to provide reliable all-day defense for the skin,” says supplier Monteloeder.

Even More Combinations

Even with the relative novelty of cosmeceuticals and nutricosmetics coming together, Clardy says she is beginning to see even more than just the combination of these two.

“There are companies coming out with systems now that really cover the gamut,” says Clardy. “For example, let’s say it’s an age-delay system, and it will have a serum or a cream. But then it will also include a mask, and then it will include a medical device, and then it will include one or two ingestibles.”

Clardy expects the home use of low-potency medical devices to continue to grow, suggesting an all-in-one beauty support system of nutricosmetics, cosmeceuticals, and medical devices could be the next big combination to come out of the beauty world.

**Collagen Combinations**

Collagen, one of the most popular ingredients in nutricosmetics, definitely isn’t missing out on the action of bi-directional beauty pairings.

This summer, supplements brand NeoCell partnered its Super Collagen peptide supplements with topical creams from MyChelle Dermaceuticals, like its Supreme Polypeptide Cream and Peptide+ Anti-Wrinkle Serum. The pairing was commercialized together at Whole Foods stores in the northeastern United States.

“We have found that the long-term beauty benefits from taking our NeoCell Collagen beauty-from-within supplements pair well with external lotions and serums, which provide more immediate results, but are often not long lasting,” says NeoCell’s Tim Mount.

NutriMarketing’s Clardy says Nippi Collagen (Tokyo) is also looking into marrying its nutricosmetic collagen ingredients to cosmeceutical products.

“I am aware that Nippi Collagen is currently working with a number of partners in various channels for a nutricosmetic/cosmeceutical pairing,” says Clardy. “Most involve a drink, either a shot format or a [ready-to-drink], and a serum or cream. However, I have seen drinks and masks also, jellies, and both day and night creams.”

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Still Some Resistance

Not everyone in the nutricosmetic world, however, is ready to embrace a pairing with a cosmeceutical. Dietary supplement firm Reserveage Nutrition (Boca Raton, FL), for instance, continues to market its nutricosmetic supplements independently as a more genuine, foundational way to promote skin health than cosmeceuticals.

“We believe that the best approach to beautifying from within is accomplished by using high-quality oral supplements that provide the building blocks to help enhance and maintain a youthful appearance,” says Dorothy MacDiarmid, public relations and communications, Reserveage Nutrition. “Cosmeceuticals, unlike nutricosmetics, are not designed to support, but rather conceal, the signs of aging.”

Combining nutricosmetics with cosmeceuticals could open up new markets for both product types, but will consumers buy into “twincosmetics”? With a trend this young, only time will tell.
Weight Management Gets a Helping Hand

New evidence backs fiber and protein strategies for kids.

BY MAUREEN KINGSLEY

Seeking strategies for preventing continued overweight and obesity in children is among the chief concerns of U.S. dieticians and pediatricians. According to Centers for Disease Control statistics, approximately 17% (12.7 million) of U.S. children and adolescents aged 2–19 years are obese. In children, obesity is defined as having a BMI at or above the 95th percentile for children and teens of the same age and sex. Two recent studies of nutritional supplementation for weight management in children center on chicory-root fiber and soy protein, respectively.

The first, whose results were announced in May of this year, looked at the effects of chicory root–derived prebiotics supplementation on the rate of weight gain in overweight and obese children. A research group led by Raylene Reimer, PhD, RD, of University of Calgary in Canada concluded that supplementing the children’s diets with the probiotic chicory root–fiber product Orafti Synergy1, marketed by Beneo (Manheim, Germany), improved appetite regulation and decreased food intake in overweight and obese children.

The second study, a collaboration between the University of Missouri and DuPont Nutrition & Health (Copenhagen) and led by assistant professor Heather Leidy, PhD, found that teenagers' consumption of a soy protein–rich afternoon snack resulted in reduced appetite, delayed subsequent eating, and improved diet quality when compared to other snack options.

Focus on Fiber

For the study that supplemented children’s diets with chicory-root prebiotic fiber, 42 overweight and obese children between the ages of 7 and 12 years of age were given 8 g each of the Orafti Synergy1 prebiotic powder, dissolved in a bottle of water, daily for four months. The subjects consumed the dissolved prebiotic powder before their evening meal each day.

Results, presented at the American Society for Nutrition’s Scientific Sessions at Experimental Biology 2015 in Boston, illustrated that the children who consumed the daily prebiotic supplement had "significantly higher ratings in their feeling of fullness and satisfaction and a lower prospective food..."
“Snacks and breakfast are the top day parts where parents are seeking healthier solutions,” Heggie says.

consumption” than the control subjects did, according to lead researcher Reimer. Her team also reported that satiety was found to be significantly higher in those given the fiber supplementation.

Reimer points to two previous studies, one published in 2009 on the benefits to overweight and obese adults of consuming prebiotic fiber and one from 2007 on the effects of prebiotics consumption and calcium intake on bone mineral density in children, as “driving factors” for the current study. A third factor, Reimer says, is the recent discovery of the importance of gut bacteria to the obesity field.

“We’ve learned over the past 10 years that there can be negative changes that occur in the gut-bacteria profile” in obese persons, and that these individuals have a “different gut-bacteria profile than their lean-body weight peers. So what we are looking to do now is see if there are ways to manipulate those bacteria to resemble more of a healthy profile,” Reimer explains. “For those of us who are registerd dieticians and nutrition scientists, we are really interested in knowing if that can be done via diet. Of the various nutrients in foods that could positively impact the gut microbiota,” she continues, “the prebiotics are really an excellent option for doing that.”

The Significance of Chicory Root
Not all plant fibers are created equal. What makes chicory-root fiber unique, Reimer says, is its status as a prebiotic.

“Prebiotics are a bit different from other dietary fibers in that they will specifically alter the number and the function of the bacteria in the intestine. And by altering the bacteria, prebiotics give a health benefit to the person who is consuming them,” she explains.

The difference between prebiotics and probiotics—a trendy added ingredient in many processed foods and nutrition supplements now—is that “the prebiotic is a very good fuel for the healthy groups of bacteria in the intestine, so it can create a broader change to the gut microbiota than ingesting particular strains of actual probiotics might,” Reimer says.

The Beneo OraftiSynergy1 product in particular contains both long-chain inulin and shorter-chain oligofructose prebiotic fibers derived from chicory root.

Looking Fiber-Forward
Reimer says that future applications of prebiotics for weight management in children and adolescents could include prebiotic and probiotic blends, as well as blends of galacto-oligosaccharide (another prebiotic) with chicory-root fiber. She also points to blends of prebiotic chicory-root fiber with oat- or wheat-derived fibers as an additional possibility to find the optimal fiber blend.

Soy-Protein Strategy
For the DuPont and University of Missouri study looking at feeding teenagers a high-protein afternoon snack in place of a more typical high-carbohydrate, high-fat snack (or no snack at all), 31 healthy, normal-to-overweight adolescents aged 13–19 who usually consume an afternoon snack were randomly assigned to eat either a high-protein pudding snack formulated with DuPont’s Danisco Supro XT219D soy protein; a more typical, lower-protein snack; or no snack. The researchers concluded that subjects consuming the high-protein snack had higher diet quality overall, reduced appetite over the course of the afternoon, and an increase in “cognitive flexibility” (ability to switch from one concept to another and reduced confusion/bewilderment, according to DuPont’s press release announcing the study’s results).

Lean Plant Protein
DuPont’s Michelle Braun, PhD, research scientist for the Nutrition & Health division, points to soy protein in particular as being “a lean source of high-quality, plant-based protein that meets the protein and amino acid needs of children ages three and up.” She says that “the body of literature indicates that because of its ability to impact satiety, the consumption of soy protein could be an effective tool in establishing healthier eating habits in children, helping to manage a healthy weight in children and helping to address and prevent obesity in children.”

Jean Heggie, strategic marketing lead, DuPont Nutrition & Health, adds that because of the versatility and “excellent functional performance” of soy protein, combined with increasing consumer interest in high-protein snacking, there are many applications for soy-protein ingredients today. She lists baked extruded snacks, beverages, nutrition bars, extruded crisps, clustered snacks, cereals, and snack mixes among the options.

Heggie says that DuPont’s consumer research indicates that “snacks and breakfast are the top day parts where parents are seeking healthier solutions for their children and struggling to find suitable options in today’s market. Thus,” she says, “we see these areas as tremendous opportunities for food marketers. We believe this extends to adolescents and young adults as well. All are adopting more of a snacking lifestyle; all have busy, active lifestyles” in which snacks make up a large portion of their daily food intake.

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

References
Markets Thrive for Infant Formula

China leads the way, but who is next in line?

BY MAUREEN KINGSLEY

The global market for infant formula is growing, but “the picture varies across the world,” says Anne Staudt Kvistgaard, head of pediatric sales and science development at Arla Foods Ingredients (Viby J, Denmark), a supplier to the infant-formula market.

In the United States and Europe, for instance, growth has been “low but stable for many years,” she says, while China, on the other hand, is “currently the main driver of growth” in the infant-formula sector and has been so for the last ten years. Additional key growth markets, says Kvistgaard, are Brazil, Russia, and developing Asian nations.

Yolanda Roescher, marketing communications manager for FrieslandCampina (Amersfoort, Netherlands), an ingredients supplier to infant-formula companies, points to the Middle East and Africa as regions where growth is speedingly, and Lasse Nagell, vice president, human health and nutrition sales and marketing for Chr Hansen (Hoersholm, Denmark), cites various market reports that show growth in the infant-formula market at about 7% worldwide.

Market Drivers
In the developed world, including the United States and Europe, birth rates are stable, which accounts for the relatively modest year-to-year growth in the infant-formula sector, and “the purchasing power of parents has increased,” Nagell says. “Parents are willing and able to pay for premium formula.”

In the still-developing regions of the world, Nagell explains, birth rates remain relatively high—as does the rate of urbanization, Roescher adds. These factors, along with a burgeoning middle class in these regions, all contribute to the growth of the market.

While China is the main source of market growth, some recent economic decline in the region has taken a slight toll on the market for infant formula there. Additionally, says Kvistgaard, China’s recent relaxing of its one-child policy has not resulted in notable sales increases for infant formula, and she says that “it’s possible that the promotion of breastfeeding by government health officials in China could reduce the use of infant formula. However,” she adds, “it may have a limited impact since paid maternity leave in China is only three months. This means working mothers have to return to work soon after giving birth, which can make breastfeeding after this time very difficult.”

Trends
The key trend in infant-formula manufacturing and marketing, according to Kvistgaard, is “creating formulas that more closely resemble the composition and functionality of breast milk.” To this end, she explains, scientists are spending much time and effort researching oligosaccharides, which are found in breast milk, to understand their impact on infant nutrition, as “it’s believed that they may have a prebiotic benefit, among others.”

FrieslandCampina’s Roescher points to the addition of milkfat to formula “for an...
Will organic infant formula be the next big thing? Arla Foods Ingredients’ Anne Staudt Kvistgaard tabs it a “segment to watch, one with huge potential.”

optimal fat composition and structure” as a trend, and Kvistgaard is in agreement, highlighting phospholipids in particular as an ingredient whose sales will likely grow. And at Arla, Kvistgaard adds, there is currently “a big focus on osteopontin, a whey protein that stimulates early immune development.” The company will be publishing clinical documentation on this ingredient soon, she says.

Harry Rice, vice president, regulatory and scientific affairs, Global Organization for EPA and DHA Omega-3s (GOED; Salt Lake City), cites a recent “notable study” of supplementation of infant formula with long-chain polyunsaturated fatty acids (LCPUFAs) at the University of Kansas. The team found that LCPUFA supplementation in infancy increases length- and weight-for-age, but not BMI to 6 years when controlling for effects of maternal smoking. It remains to be seen what influence this study will have on the LCPUFA-supplemented formula market.

Chr Hansen’s Nagell has observed “increased interest for adding documented probiotics to a wider range of formula brands,” and FrieslandCampina’s Roescher identifies the increase in allergies in Asian countries, and the region’s developing healthcare systems, as creating more need for specialized infant formulas.

Finally, Arla’s Kvistgaard calls organic infant formulas a “segment to watch, one with huge potential.”

References

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Old MacDonald, Meet FDA

How to prepare for FDA’s review of animal food ingredients

BY MICHAEL CRANE, ASSOCIATE EDITOR

For decades, the Official Publication (OP) of the Association of American Feed Control Officials (AAFCO) has been the comprehensive guide to ingredient definitions for pet food and animal feed. Amid the hodge-podge of different state and federal ingredient listings, the OP is often treated as the go-to compendium of approved ingredients for animal food, both in the United States and in many foreign countries.

“We describe it as the one-stop place for feed labeling,” says Richard Ten Eyck, ingredient definitions chair, AAFCO. “All of the model regulations, all of the state contacts, all of the common names.”

But with FDA’s Center for Veterinary Medicine (CVM) reviewing the entire OP as part of a 2007 law to ensure the federal government has its own comprehensive ingredient listings for animal food, many ingredients in the OP are facing a new level of scrutiny. Hundreds of the 900-plus ingredients in the OP currently lack federal standing, even if they have been approved by state legislatures.

FDA’s goal is to assign a federal legal definition to as many of the OP ingredients as possible, but for those ingredients lacking the information to be considered generally recognized as safe (GRAS) or approved food additives, the burden may be on animal food ingredient firms to make sure their ingredients have the necessary profile to stay on the market.

Fortunately, there are a few actions a company can take proactively to increase the chances of its ingredient earning federal approval before FDA comes knocking.

Why Is FDA Reviewing the OP?

AAFCO’s OP is considered by many to be the authoritative resource for ingredients in pet food and animal feed (it is called the Official Publication, after all). So it may come as a surprise that many of the ingredients in the OP are not currently federally compliant.

Until 2007, CVM regularly exercised “regulatory discretion” toward the ingredients in AAFCO’s OP, according to George A. Burdock, PhD, founder, Burdock Group (Orlando, FL). This meant that new ingredients could be accepted into the OP without either a feed additive petition or GRAS affirmation from FDA. And for more than 50 years, it was AAFCO’s OP that was the model for many U.S. state laws regarding animal food ingredients.

Roughly half of the more than 900 ingredients in the OP currently have no federal standing as a result of FDA’s “regulatory discretion” policy, which has largely left it up to the states to approve animal food ingredients, says Burdock. And with FDA taking such a hands-off approach, it’s AAFCO’s OP that has become the definitive guide to which ingredients are approved for use. Approved ingredient listings can vary from state to state, and FDA has its own GRAS and approved food additive listings. The OP is meant to bring all those different lists together, find the common ground, and maintain a single unified list of approved animal ingredients, says Burdock.

“The state laws that are on the books essentially recognize the AAFCO definitions and the AAFCO language,” says AAFCO’s Ten Eyck. “FDA has their set of rules that they have to follow, and AAFCO has served a useful purpose in there. The states aren’t cookie cutter to each other, and the federal law is not cookie cutter to the states, so AAFCO has served as the ‘how are we going to make sense of this and only have to do it one way.’ They kind of answered the grey area questions the industry had.”

However, FDA’s relatively hands-off approach to the animal food industry began to change around 2007, when an outbreak of pet deaths from contaminated food prompted a public outcry for greater federal oversight of the industry. In September 2007, the Food and Drug Administration Amendments Act (FDAAA) of 2007 was signed into law, which required FDA to establish its own ingredient standards and definitions for pet food. A few years later, FDA began its review of the OP.

While the review process takes place, FDA currently has a memorandum of understanding (MOU) with AAFCO that effectively maintains the status quo for now. For instance, under the MOU, AAFCO will continue to maintain definitions of the various feed ingredients and work with FDA to address any
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requests for new feed ingredients or requests to modify an existing feed ingredient definition. The arrangement will likely be renewed until FDA finishes creating its own ingredient standards, or potentially be tweaked as the process nears completion.

“I expect that it would be extended as long as we need to, until we come to the place where we have a new process in place so that all of the ingredients will fit under the legal framework of the Federal Food, Drug, and Cosmetic Act,” says Sharon Benz, PhD, Division of Animal Feeds, CVM, FDA.

So the MOU may keep up business as usual until FDA finishes its review of ingredients in the OP, but then what?

**FDA’s Methodology**

Of the more than 900 total ingredients in the OP, Benz estimates that around 400 already have some legal standing under the Federal Food, Drug, and Cosmetic Act as either GRAS or food additives. The challenge now before FDA is figuring out what to do with the rest.

“We’re looking at the ingredients that don’t meet either of those two categories,” says Benz. “We went through and we did a rough count and we expect there’s probably about 500 ingredients or so that we have to address. And we’ve been doing it in the most efficient way possible.”

It’s been at least two years since FDA first began going through the OP on a section-by-section basis, and Benz says they have “gotten through quite a number” so far. However, it’s difficult to predict when the process will be complete.

“We’re taking the burden upon ourselves to go through the book and to evaluate the information on the ingredients there and determine which ones are GRAS. If they fit into the GRAS category, if they meet that standard, then we will publish a regulation. We will put the information in a docket, make it available to the public, and publish the regulation saying they’re GRAS,” says Benz.

“‘We expect there’s probably about 500 ingredients or so that we have to address,’” says FDA’s Benz.

“I expect that there’s going to be a small few that we will not have the information to either make a GRAS determination or do an approved food additive, and for those ingredients we’re going to reach out to the industry and work with them so that we can get the information that we need to get them approved as food additives,” says Benz. “FDA is doing a lot of work in this respect.”

**FSMA AND ANIMAL FOOD**

FDA’s Food Safety Modernization Act (FSMA) will also bring two other big changes to the animal food and supplement industries: the introduction of federal good manufacturing practices (GMPs) and a new foreign supplier verification program for ingredients. Until now, there were no federally mandated GMPs for animal feed.

“It will be the first time that there will be a nationally defined and consistent set of good manufacturing standards or requirements for the pet food industry,” says Bill Bookout, president, National Animal Supplement Council (NASC; Valley Center, CA), which represents the animal supplement industry. He adds that the industry is currently “not absent or devoid of good manufacturing practice standards,” and that companies following NASC’s GMP requirements should already be in good shape for the new GMPs under FSMA.

The foreign supplier verification program may actually be the more difficult FSMA change to implement, according to Ray Matulka, PhD, director of toxicology, Burdock Group (Orlando, FL). The program will likely require a much greater degree of scrutiny for animal ingredients coming from abroad than was currently in place, says Matulka.

“All of it has to be verified so that those foreign ingredient manufacturers are meeting the same requirements of GMP and all of the other hazard analysis requirements necessary here in the states,” says Matulka. “So that’s going to be a big verification nightmare for a lot of these pet food companies.”

The final rules of FSMA’s foreign supplier verification program will be announced on October 31.
“The OP will continue to be the reference material that the states are going to use,” says Ten Eyck.

deliberately. Because there’s, by and large, very little information on these things.”

According to Burdock, many of the ingredients in the OP may need to have additional published studies in order to build the necessary research profile for FDA’s GRAS affirmation. Oftentimes, the studies need to be targeted on specific species and intended uses of animal (beef cow vs. breeding cow), and it can be difficult to find journals that publish studies on animal food ingredients, says Burdock. The entire process could be costly and time-consuming.

However, neither FDAs Benz nor AAFCO’s Ten Eyck believe the change will present substantial difficulties for most suppliers.

“We do not intend to disrupt the industry with this process,” says Benz. “I don’t see how it will make it more difficult.”

Another potential hurdle lies in the comment period for ingredients that are granted GRAS affirmation by FDA. Ingredients that are being considered for a GRAS affirmation by FDA are published in the Federal Register for a public comment period, and Burdock thinks rival companies could potentially submit comments for a competitor’s GRAS petition during this period just for the sake of throwing up a roadblock to slow down the affirmation process.

**Being Proactive**

Whether FDA accepts an animal food ingredient right away or comes back with a request for more information, ingredient firms can act ahead of time to increase the likelihood of a smooth transition. Most of the OP ingredients are already in line with the state listings, and one way to win federal approval may actually be to obtain a GRAS affirmation independent of FDA.

“The proactive companies—and we’re dealing with some of them—they’re going ahead and getting their product GRAS [affirmed] and they’re not notifying FDA,” says Burdock.

“So when FDA comes around and says ‘Alright, this material is not approved for use,’ they’re going to pull out their GRAS and say it’s compliant with federal law. And because it’s listed in the OP, it’s already compliant with state law. So they’ll be able to continue in business with that ingredient.”

There are two advantages to getting a third-party or self-GRAS affirmation without notifying FDA. For one, it means ingredient firms can possibly avoid the problem of competitors submitting challenges during the public comment period because only the FDA GRAS affirmation process requires public comment.

But it could also prevent freeloading companies from reaping the benefits of the companies who actually pay for the GRAS affirmation process. Since FDAs GRAS affirmations are made public while self-GRAS affirmations can remain private, rival companies would have a much harder time piggybacking off of a competitor’s GRAS affirmation if it is done independent of FDA.

“What a lot of folks are afraid of is if they GRAS something, these other guys that don’t want to spend any money are going to piggyback on their GRAS,” says Burdock. “If a consortium of individuals gets together, forms an ad hoc committee, gets something GRAS [affirmed] because they pool their money, they can keep the GRAS and there’s no necessity to publicize.”

In that case, less-proactive companies would not be able to benefit from the foresight of their competitors and would have to pay for a separate GRAS process.

“The people that are going to be proactive are the ones that are going to be able to stay on the market,” says Burdock. “The people that fool around, sit on their hands, and don’t do anything are going to lose market share.”

And don’t forget, FDAs Benz reminds, the FDA-affirmed GRAS or food additive programs are still viable routes for ingredient firms looking to be proactive. She adds that CVM “would be very happy to talk with them and work with them to figure out what process would be best.”

**The Future of the OP**

However many years it takes, once FDAs review of the pet food and animal feed ingredients is complete, will the OP still play an important role in clearing up the gray areas in the industry? Absolutely, says AAFCO’s Ten Eyck.

“Really none of that functionality is going away because the states aren’t changing their laws,” says Ten Eyck. He adds that just because FDA is creating its own standards, it doesn’t mean the state lists will become obsolete. There may still be discrepancies between the state and federal listings that the OP will strive to clarify. “The OP will continue to be the reference material that the states are going to use.”

FDAs Benz thinks that by bringing the OP in line with federal law over the course of FDAs review, it will put “it in a more positive light than it currently is.” She expects the OP to “continue to play a very important role in animal feed regulation.”

And one of the biggest appeals may well remain the “one-stop” convenience of the OP.

“Even as FDA develops food additive regulations, we’re grabbing the name of those and bringing them into the book as common names, so you don’t have to go read the Federal Register every week,” says Ten Eyck. “AAFCO’s going to pick those up and you’re going to be able to pick up our book online, do a quick search, and go ‘Oh, ok, that’s what I call it.’ The convenience factor will remain there.”

In short, the OP will continue to be used as a convenient and comprehensive reference material, says Ten Eyck.
Bone Health

Support Group

The science of vitamin and mineral cofactors for bone health

BY IRFAN QURESHI, ND

Loss of bone density impacts 54 million Americans, putting them directly in the path of danger of developing osteoporosis. Osteoporosis significantly increases risk of fracture, with studies suggesting that one in two women and one in four men over the age of 50 will experience a broken bone as a result. Estimates suggest that by 2025, osteoporosis will be the source of three million fractures and over $25 billion in healthcare costs each year.1

Combating osteoporosis is a lifelong endeavor requiring prudent lifestyle choices. This includes exercise and also diet, with evidence indicating that nutrition plays a major role in promoting skeletal health.2 Consuming the necessary vitamins and minerals from food as well as from dietary supplements should be an important pillar of any bone-health program. Take calcium. Calcium is well-known for its benefits to bone mineral density, as it is the most abundant mineral in the human body.3

Calcium’s effects, however, depend heavily on the actions of several other vitamins and minerals, including vitamin D, magnesium, vitamin K2, and zinc. We call these cofactors, and they are believed not only to be critical to bone health but also to be most effective when present together in adequate amounts.

Vitamin D

Vitamin D is a crucial cofactor for bone health, as it regulates calcium balance and directly affects the osteoblast cells responsible for bone building and bone remodeling. Several studies link vitamin D deficiency with a higher risk of falls and fractures.4

Today, vitamin D deficiency is increasingly recognized as a worldwide epidemic, illustrated by the fact that more than 60% of postmenopausal women have inadequate serum levels of 25(OH)D, a common marker used to assess vitamin D status. The Institute of Medicine (IOM) defines vitamin D deficiency as serum levels of 25(OH)D less than 50 nmol/l (or 20 ng/ml). Vitamin D deficiency is a significant public health concern, and even populations of countries with abundant sun exposure often don’t meet target levels.5

But some newer clinical studies assessing vitamin D supplementation are yielding conflicting results. Ahead, we take a look at several.

For a Cochrane Database review, Alison Avenell and colleagues looked at interventional studies using vitamin D, or vitamin D in combination with calcium, and assessed the benefits of these nutrients for preventing hip fractures. Their review included 53 studies consisting of 91,971 participants categorized as postmenopausal women or older men.

Based on the research reviewed, the authors concluded that there is a lack of high-quality evidence that vitamin D intervention alone will prevent hip fractures in this population; however, they said, there is high-quality evidence that vitamin D in combination with calcium results in a small reduction in hip fracture risk. Also, they noted strong evidence linking the combination of vitamin D and calcium supplementation with a statistically significant reduction in the risk of new non-vertebral fractures.

The studies reviewed used a broad range of vitamin D doses, which may have impacted results. The authors emphasized that, while vitamin D is important for bone health, it was clear that the combination of vitamin D and calcium supplements was more effective than vitamin D alone for preventing fractures.

Kirsti Uusi-Rasi and colleagues in Finland aimed to determine the effect of exercise training, vitamin D, and the combination of both on reducing the risk of falls in older women. This two-year randomized trial included 409 white European women between the ages of 70 and 80 with a history of at least one fall during the previous year and no vitamin D use. The women were randomized into four groups: placebo, vitamin D (800 IU/day) without exercise, placebo plus exercise, and vitamin D (800 IU/day) plus exercise. The exercise routine comprised strength and balance training. The primary outcome was the number of monthly reported falls. The study also assessed bone density and measures of physical functioning, including muscle strength, balance, and mobility.

According to the researchers, vitamin D was not found to enhance the effect of exercise on physical functioning; however, vitamin D maintained femoral neck bone density measurements and increased trabecular density in the tibia.

Erin LeBlanc and Roger Chou are two of the contributing authors responsible for conducting a review on vitamin D for the U.S. Preventive Services Task Force. This task force determined that intervention with vitamin D was associated with an overall 11% decreased risk for falls. In an invited commentary accompanying the Uusi-Rasi study, LeBlanc and Chou state that adding the data from this well-conducted trial to the data they reviewed earlier does not change their conclusion supporting the potential benefits of vitamin D. They caution generalizing the results from this new study because the current study doesn’t represent the diversity seen in the U.S. population, they say. They also suggest that the dose of vitamin D (800 IU/day) may have been too low to enact change, considering that experts generally recommend daily doses between 1000 IU–2000 IU, especially in individuals at increased risk of falls. LeBlanc and Chou conclude that because of the low cost and low safety risk of vitamin D–based intervention, vitamin D should be kept in the armamentarium for prevention of falls.

In a Korean study, Hyeonmok Kim and colleagues from the Asan Medical Center at the University Of Ulsan College Of Medicine in Seoul conducted a study on 1,209 men and women aged 50 years and older to determine the association of vitamin D and femoral neck strength. The researchers analyzed bone mineral density measurements along with measures of femoral neck strength (including compression strength, bending strength, and impact strength) and found that both were significantly higher with increasing levels of vitamin D, and that these benefits were especially pronounced in women.

Additional clinical research provides important insights into the effects of vitamin D beyond direct effects on bone tissue. In a study evaluating the effects of vitamin D on bone mineral density and fracture risk, Jane Cauley, from the University of Pittsburgh, and colleagues enrolled 2,067 women with an average age of 48.5 years and who were entering menopause. In the study, women from multiple ethnic groups were followed for an average period of 9.5 years, with researchers measuring serum levels of vitamin D as 25(OH)D at the third annual clinical visit. Bone mineral density and fractures were determined at each annual visit. The average 25(OH)D level was 21.8 ng/ml, and 43% of the women had serum levels lower than 20 ng/ml.

Women with 25(OH)D levels greater than 20 ng/ml had a 45% reduced risk of non-vertebral fractures.
Magnesium makes up nearly 1% of bone mineral content. Magnesium is directly required for the transport of calcium ions across cell membranes. Inadequate magnesium intake has been shown to result in low blood levels of calcium as well as resistance to some of the actions of vitamin D.

"Magnesium is necessary to convert vitamin D into its active form so that it can 'turn on' calcium absorption," says Todd Johnson, director of marketing at Albion Minerals (Clearfield, UT), a leading manufacturer of mineral chelates.

Decreased magnesium content causes bone to become more brittle. "Research has shown that magnesium deficiency is a frequently occurring disorder that can lead to loss of bone mass, abnormal bone growth, and skeletal weakness," Johnson says.

Unfortunately, it’s become clear that people aren’t getting enough magnesium through diet alone. Worse still, magnesium deficiency is more common in the elderly,13 potentially placing the population at higher risk of osteoporosis and other bone-health defects.

Experiments conducted in mice bone marrow cells have found that magnesium deficiency results in increased formation of bone-resorbing osteoclast cells.14 But recent studies showed that in female rats with sufficient calcium intake, magnesium supplementation led to increased bone mineral density and bone size by improving bone tissue metabolism.15

Sara Castiglioni and colleagues from the University of Milan in Italy identified several mechanisms whereby deficient magnesium levels adversely impact bone.16 First, magnesium deficiency leads to an altered structure of apatite crystals in bone, decreasing stiffness as well as bone’s load-bearing capacity. Magnesium deficiency also decreases the activation of vitamin D. By contrast, correcting magnesium deficiency through supplementation has been shown to normalize vitamin D metabolism. Magnesium deficiency also leads to low-grade inflammation, which is detrimental to bone health. Magnesium may additionally act as an important buffering agent, thereby protecting against osteoporosis onset.

But that’s not all. Metabolic acidosis is common in aging adults consuming a western diet and has been shown to influence calcium loss from bone, inhibit the activity of osteoblasts, stimulate osteoclast activity, and negatively affect bone mineralization. By also buffering excess acidity, it is likely that magnesium further protects against the development of osteoporosis.

In an analysis of women participating in the Women’s Health Initiative Observational Study, Tonya Orchard and colleagues estimated total magnesium intake and compared this to overall bone mineral density.17 They found that postmenopausal women consuming greater than 422.5 mg of magnesium daily had higher hip and whole-body bone mineral density than women who consumed less than 206.5 mg of magnesium daily on average. Interestingly, however, the incidence of hip and total fractures did not differ across different intakes of magnesium in this cohort. In fact, the risk of lower arm and wrist fractures increased with higher magnesium intakes. The authors posit that this may be because the women who had the highest magnesium intakes were more physically active and thus likelier to experience falls.)
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Another recent study confirmed the benefits of magnesium to physical performance in postmenopausal women. Nicola Veronese and colleagues from the University of Padova in Padova, Italy, enrolled 139 healthy women with an average age of 71.5 years in a randomized controlled trial in which participants were allocated to a control group or were supplemented with 300 mg of magnesium daily for 12 weeks. Exercise and fitness ability were assessed at baseline and again after 12 weeks.

The group supplementing with magnesium showed significant improvements in physical performance compared to the control group, suggesting that magnesium supplementation is an important factor in delaying the onset of deterioration of physical performance associated with age.

**Vitamin K2**

Vitamin K—and more specifically vitamin K2, the menaquinone form of vitamin K—continues to shine as a vitamin that supports multiple aspects of bone health. Vitamin K2 plays a direct role in transporting calcium from circulation into bone tissue by activating (carboxylation) two key calcium transport proteins in the bloodstream: matrix Gla protein, which transports calcium from circulation into bone, and osteocalcin, which reduces calcification of arteries and plays a significant role in bone development.

Furthermore, vitamin K2 has been shown to work hand in hand with vitamin D in multiple ways. Vitamin D enhances the absorption of calcium from the intestinal tract into circulation, while vitamin K2 aids calcium’s transport into bone tissue. Additionally, vitamin D promotes the production of osteocalcin from the bone-building osteoblast cells, while K2 serves to activate osteocalcin to perform its calcium-transport function.

Research continues to validate vitamin K2’s benefits to bone health and heart health. Two common supplemental forms of vitamin K2 are menaquinone-4 (MK-4) and menaquinone-7 (MK-7), with the number designations referring to the length of the molecular side chains.

Z.-B. Huang’s group from Zhejiang, China, conducted a meta-analysis assessing the role of vitamin K2 in the prevention and treatment of osteoporosis in postmenopausal women. In reviewing 19 randomized controlled trials consisting of 6,759 participants, the authors found that in postmenopausal women with osteoporosis, vitamin K2 supplementation achieved significant improvement in vertebral bone mineral density and reduction in the overall risk of fractures. Vitamin K2 also led to a decrease in under-carboxylated (inactive) osteocalcin, thus favoring bone mineralization.

Earlier, Martinus Knapen and colleagues from the Netherlands conducted a three-year, placebo-controlled study in healthy postmenopausal women to assess the effects of vitamin K2 MK-7 on bone health. Participants supplemented with 180 mcg/day of MK-7 or a placebo.

MK-7 supplementation led to increased bone strength and a decrease in the rate of decline of bone mineral content and bone density that normally occurs as a result of the aging process. The researchers also found less loss of vertebral height in the mid-back compared to placebo treatment, suggesting that MK-7 is a nutritional factor impacting both bone density and strength in postmenopausal women.

**Zinc**

Zinc is essential to human health. It plays a critical role as a structural component of proteins, acts as an enzymatic cofactor, and functions as a transcriptional regulator for a large array of cellular and biochemical processes. Studies in cultured osteoblasts have shown potent stimulation of bone formation following exposure to zinc, leading to enhanced deposits of calcium. Additional studies found that by inhibiting nuclear factor-kappa B, a potent mediator of inflammation and bone resorption, zinc was able to suppress the differentiation of osteoclasts, inhibiting bone resorption.

Sadly, zinc deficiency is also widespread in the global population—a fact that animal research has shown may impact the normal physiological action of vitamin D on calcium metabolism and interfere with the anabolic activity of vitamin D on bone tissue.

Payal Bhardwaj and colleagues from Punjab University in Chandigarh, India, conducted a study in a rat model of postmenopausal osteopenia to investigate the impact of zinc supplementation on prevention of bone loss. They found significant changes to the cortical bone structure in rats in which estrogen deficiency was induced, including poor microarchitecture and resorbed areas of bone tissue. Zinc supplementation was able to arrest these changes, while improving overall bone microarchitecture, enhancing antioxidant defenses in bone tissue, and improving regulation of several markers of bone metabolism.

Additionally, a meta-analysis by Jianmao Zheng and colleagues from Sun Yat-sen University in Guangzhou, China, looked at published human studies relating serum levels of several minerals to the incidence of osteoporosis and concluded that low serum levels of zinc seem to be an important risk factor for this disease condition.
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Calcium is one of the most important minerals in the human body. Its positive effect on bone health and essential role in a number of vital body functions are widely recognized and supported by various research studies. Over the last several decades, growing consumer awareness of the health benefits of calcium and its potential to combat osteoporosis has pushed the demand for calcium-enriched foods to an all-time high. While calcium fortification continues to be a major topic within the entire food industry, formulating beverages can be a challenging task, and not every solution that is available on the market will be suitable. This article outlines the main considerations for beverage formulators and identifies various calcium solutions that are suitable for the development of appealing calcium-enhanced beverages.

**Calcium: “The Super Nutrient”**

The human body contains more calcium than any other mineral. About 99% of the entire body’s calcium can be found as hydroxyapatite in the bones and teeth. Besides being an essential element for the development and maintenance of strong bones and teeth, calcium also plays an important role in regulating a number of vital biochemical processes in the body, including blood clotting, muscle contraction, cell proliferation and differentiation, and regulation of nerve impulses. Furthermore, calcium controls nutrient absorption, fat digestion, and metabolism. Because human blood only contains a small fraction of the total amount of calcium in the body, maintaining adequate blood levels of calcium is essential to ensure normal cell function. Insufficient calcium intake, on the other hand, will cause the blood calcium level to drop, and the body may start pulling calcium from the bones.

The human body requires quite a large amount of calcium (compared to other essential nutrients) in order to reduce the risks of various chronic diseases, such as osteoporosis, hypertension, and even some types of cancers. According to the U.S. National Institutes of Health, a typical adult between the ages of 19 and 50 needs 1000 mg of calcium each day, while the recommended amount for children, adolescents, menopausal women, and people above the age of 50 is even higher.

**Calcium for Life**

Although calcium intake is important throughout life, particular attention needs to be paid during childhood and adolescence. Calcium is vital for a strong bone structure during these critical stages of rapid growth and is absorbed more effectively than at any other time in life. As the human body ages, bone mineral density begins to decline, increasing the daily amount of calcium required. However, if bone mass declines more quickly than the body is able to replace it, bones will get weaker—to the point that even the slightest fall or bump can cause fractures. The decline of bone mass is a natural process; still, changes in diet and lifestyle...
have caused the number of osteoporosis sufferers to increase exponentially. According to the International Osteoporosis Society, approximately nine million people per year are currently experiencing fractures due to brittle bone structures, with the number of hip fractures expected to increase fourfold by 2050.5

Ensuring an adequate calcium intake can help reduce the effects of naturally decreasing bone mass and delay the onset of osteoporosis.6 While the positive effects of calcium on bone strength are well documented and widely accepted, recent studies also point to a number of other benefits that come with a high-calcium diet. Findings from a recently published U.S. study, for example, indicated that increased calcium intake can reduce, by 44%, the risk of developing hyperparathyroidism, a hormone condition common in postmenopausal women.7

Fortified Beverages: A Viable Solution
Traditional calcium sources such as cheeses, yogurt, and most of all milk are by far the biggest sources of calcium in most diets. Although alternative calcium-rich food sources are available for people who do not consume dairy products or who are lactose intolerant, they rarely provide the recommended daily amount. As a result, consumers are increasingly looking for alternatives or additional calcium sources that will help them achieve adequate calcium intakes and cater to a broader range of dietary needs.

Rising consumer interest in healthy nutrition is driving growth in the functional foods market, with the world market for functional foods and drinks predicted to reach $130 billion by 2015.8 While calcium fortification can be found across all types of food sources, beverages have proved to be a good medium for enhancement, as they are convenient and widely consumed across many demographics.

Calcium fortification is possible in nearly all beverage categories, including waters, sports drinks, soft drinks, soya milk, and fruit juices. Even with various ingredient solutions available, finding a calcium source that will enhance the mineral content of beverages without losing their consumer appeal is not always easy. Depending on the type of drink, its consistency, taste profile, appearance, and health claim, manufacturers will need to consider a number of factors, such as bioavailability, solubility, concentration, and flavor, before deciding which calcium source
is ideal for their product. Selecting the right ingredient from the right supplier ensures the perfection of formulation and significantly speeds up time to market.

Bioavailability Matters
Calcium’s bioavailability is possibly one of the most important aspects to consider, as it determines how well the body is able to absorb the calcium into the blood. On average, an adult human body is able to absorb about 30% of the calcium consumed, while the rest is discharged, unused.9

Although calcium in milk is the most bioavailable, research has demonstrated that calcium absorption from carbonate, acetate, lactate, gluconate, and citrate salts of calcium is similar to that of whole milk.10 However, establishing the bioavailability of calcium sources is not as straightforward as generally assumed and is highly dependent on a number of factors, such as the amount consumed, age and physical state of the consumer, diet habits, and type of food.

While calcium is best consumed with a meal, as the prolonged transport will benefit the overall absorption level, some ingredients, such as sodium and caffeine, can decrease the effectiveness of the calcium source. Vitamin D and some fats, on the other hand, can stimulate its absorption.

Although the most common calcium salts, such as carbonate, citrate, lactate, and gluconate, show comparable absorption levels when consumed with a meal, the same cannot always be said in the case of beverages. One study showed that calcium lactate and gluconate delivered more bioaccessible calcium when consumed with a glass of water, making them the preferred choice for a wide variety of beverages, including sports drinks and clear products such as flavored waters.11

Solubility or Concentration?
Besides a high level of bioavailability, beverage manufacturers are also looking for high solubility, a short dissolution time, and sufficient calcium content. While some of the most common calcium sources, such as calcium citrate and phosphate, are less soluble, calcium lactate and calcium gluconate have demonstrated high solubility at both low and neutral pH and dissolve quickly even at low processing temperatures.

However, solubility often comes at a price: concentration. While calcium citrate and phosphate boast calcium contents of 21% and 38%, respectively, they are frequently unsuitable for beverages due to their poor solubility. Calcium lactate and calcium gluconate, which are highly soluble, contain only 9%–14% calcium. As a result, the amount of calcium salt that is required to achieve the desired health claim is higher. Nevertheless, for the majority of beverage formulators, solubility will be the deciding factor, because lactate and gluconate allow sufficient fortification without affecting important features like taste and appearance.

Calcium: The Sixth Taste?
Maintaining the original flavor of the beverage is critical for all manufacturers who are looking to add value to their products. While the importance of calcium in the human diet is widely acknowledged, adding it to beverages has historically been difficult due to its bitter taste profile.

Many consumers are highly averse to calcium’s distinctive taste and avoid high-calcium foods, such as collard greens and kale. Some have even suggested naming calcium “the sixth taste” due to research indicating the existence of a calcium-sensing taste receptor on the human tongue.12

Although less-soluble solutions such as calcium citrate and calcium phosphate are known to be less bitter than most other calcium salts, they can have a chalky flavor and sandy mouthfeel. As a result, manufacturers are increasingly attracted to calcium sources with a more neutral taste profile, such as calcium lactate or calcium gluconate, in order to maintain the palatability of their beverages without the need for masking agents or stabilizers.

What Works for Your Product?
Consumers are increasingly looking for beverages that help them maintain the recommended calcium level in order to avoid bone loss or degradation and other related complications in later life. Fortified beverages are regarded as a convenient way to increase the daily intake of calcium, but their development has proven to be a challenge to manufacturers. Although a lot of calcium ingredients are available, not all of them fit the criteria that beverage formulators are looking for. Careful consideration is required in order to develop great-tasting drinks that are high in calcium and offer lucrative and sustainable market opportunities.

Hans Schinck, market manager, confectionery and food, Corbion (Lenexa, KS), is responsible for the development and implementation of the company’s global market strategies for confectionery, beverage, and other food markets.

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CONSUMER food and beverage trends are complex and ever-changing. Food Ingredients Europe 2015 (Fi Europe) is the perfect place for food industry professionals to gain new ideas and knowledge, and to source ingredient innovations to keep up with the pace of the market. Traceability, clean label, and “natural” claims are among the hot spots of focus at this year’s Fi Europe show.

As the world’s largest food ingredients show and the must-attend event for Europe’s food and beverage industry, Fi Europe and the co-located Natural Ingredients (Ni) 2015 are designed to help companies grow their market share and find everything they need to create the next great product. Online registration is now open for the 2015 edition, taking place December 1–3 in Paris.

More than 1300 ingredient suppliers have already confirmed they will be exhibiting at the show, including global powerhouses Roquette, Cargill, Brenntag, ADM, FrieslandCampina, Barry Callebaut, DSM, and Naturex.

This year will see the return of the show’s New Product Zone, a display of the industry’s latest and often newly launched product innovations. Innovation Tours and Discovery Tours will provide visitors the opportunity to discover innovations in key areas, while the Global Market Forum will present educational seminars on key industry topics, including those by industry thought-leaders Euromonitor, Leatherhead, and Innova Market Insights. For ease and convenience, the show’s Supplier Finder Desk will assist visitors with sourcing key ingredients and exhibitors, and the show’s mobile app will further help visitors plan their day.

The event will run concurrently with the Food Ingredients Europe Conference, which will cover topical issues facing the food ingredients industry, provide crucial insights on leading scientific innovations and winning marketing strategies, and explore the hottest ingredients trends driving new product development and consumer spending in the food and beverage industry. Also taking place at the show, the renowned Food Ingredients Excellence Awards will recognize leading ingredient manufacturers and their latest innovations in key areas.

A truly global, one-stop shop for networking, ingredient sourcing, and educational opportunities, Fi Europe is the year’s key industry event. Visitors can take advantage of early-bird prices by registering online today at www.Fi-Europe.eu.
The Japanese health ingredients market is one of the fastest growing in the world. Japan represents the second largest dietary supplements market in the world, after the United States, and Japan’s supplements market is five times larger than Europe’s largest supplements market, Germany. Japan’s market specializes in traditional herbal products, sports nutrition products, weight-management products, and more.

Even more importantly, Japanese consumers are very interested in trying new and innovative products. Products that target health management are very popular in Japan, whose aging population continues to grow. With 24% of the general population now over 65 years of age, Japan’s population as a whole is the oldest of any country within the Organization for Economic Co-operation and Development (OECD). (Source: OECD, Japan 2013.)

Health Ingredients 2015 (Hi Japan) will take place October 7–9 at the Tokyo “Big Sight” Exhibition Center. As Asia’s biggest and most advanced functional and health ingredients exhibition for food, beverages, supplements, and cosmeceuticals, this is the most important event for any food professional to attend in 2015.

Celebrating its 25th anniversary last year, Hi Japan proudly looks back on its success story in Asia. Today, the show enjoys a large group of international exhibitors and visitors. Hi Japan 2015 will feature some of the world’s most advanced functional ingredients, natural food ingredients, organic products, food additives, cosmeceuticals, supplements, and contract manufacturing services.

The show will be co-located with S-tec (Safety Technology) Japan, the only exhibition in Japan featuring the most advanced technologies in food safety and quality. Awareness of food safety is at an all-time high in Japan, and thus investment in quality control, testing, monitoring equipment, and food security systems are on the rise. S-tec Japan not only focuses on this highly specialized segment of the market, but also provides the best opportunity to meet production and R&D professionals from food manufacturing companies.

Japan already leads development and innovation when it comes to functional and nutritional food, with lifestyle changes and growing concerns such as weight management, antiaging, and “beauty from within” helping to drive extensive growth. Hi Japan & S-tec Japan 2015 are your fastest route to expand into the pioneering Japanese health and beauty industry, to meet top Japanese and international exhibitors, and to source the most innovative functional and health ingredients in the region.

The 26th edition of Hi Japan promises to be a huge success, featuring more than 600 exhibitors from leading Japanese and international companies; 40,000 visitors from 30 countries; and more than 350 exhibitor presentations. Visitors can register on the official Hi Japan website before the event for free at www.HiJapan.info.
For Fat Loss, Low-Fat Diet Beats Low-Carb? NIH Study
Hall KD et al., “Calorie for caloric, dietary fat restriction results in more body fat loss than carbohydrate restriction in people with obesity,” Cell Metabolism. Published online August 12, 2015.

Amidst the many diet fads consumers follow, it’s difficult to know which approach is best. National Institutes of Health (NIH) researchers are cutting through the noise with new study data published online in August in the journal Cell Metabolism. With researchers pegging fat loss “a more important goal than weight loss in the treatment of obesity,” the results of their highly controlled study show that, for purposes of body fat loss, a low-fat diet outperformed a low-carb diet.

The researchers performed their study on obese people: 10 males and 9 females with a mean BMI of 35.9 ± 1.1 kg/m². To ultimately control subjects’ dietary intake, subjects were housed as inpatients at the NIH Clinical Center for two-week inpatient periods, separated by a 2–4 week washout period.

For the first week of each study period, subjects were fed diets similar to what they typically consumed in terms of carbohydrate (50%), fat (35%), and protein (15%) content, with a total energy intake of 2,740 ± 100 kcal/day. Subjects were also made to exercise on a treadmill for one hour daily to establish a constant level of physical activity. During the following week, subjects were fed either a reduced-carb diet (140 g carbohydrate and 108 g fat) or a reduced-fat diet (352 g carbohydrate and 17 g fat), keeping total caloric and protein content between the two diets constant. Overall, both diets were 30% lower in calories compared to the subjects’ typical (baseline) diet.

Subjects on the reduced-carb diet did experience decreased insulin secretion, increased fat oxidation, and increased body fat loss compared to baseline. Subjects on the low-fat diet did not exhibit significant changes in insulin secretion or body fat oxidation—but they did lose significantly more body fat (89 ± 6 g/day of body fat) compared to those on the reduced-carb diet, who lost 53 ± 6 g/day of body fat.

Discussing the results, the researchers acknowledged the current popularity of low-carb diets. “While low-fat diets were popular in the latter part of the 20th century, carbohydrate restriction has regained popularity in recent years, with proponents claiming that the resulting decreased insulin secretion causes elevated release of free fatty acids from adipose tissue, increased fat oxidation and energy expenditure, and greater body fat loss than restriction of dietary fat.”

But, they said, their study showed that, “In contrast to previous claims about a metabolic advantage of carbohydrate restriction for enhancing body fat loss, our data and model simulations support the opposite conclusion when comparing the [reduced-fat] and [reduced-carb] diets.”

The researchers also made sure to point out that these study results are not easily replicated outside of a controlled lab setting, however, and that their study “relied on strict control of food intake, which is unrealistic in free-living individuals...We did not address whether it would be easier to adhere to a reduced-fat or a reduced-carbohydrate diet under free-living conditions.”

In addition, they pointed out, longer-term studies are needed: “It could be argued that perhaps the fat balance and body fat changes would converge with continuation of the diets over the subsequent weeks.”

Protein Helps Elderly Preserve Lower Muscle Mass, Strength

Ensuring adequate muscle mass and strength in lower extremities is crucial for older adults; without it, elderly people risk higher rates of falls, fractures, and other debilitating injuries. As it stands, adults begin losing 1%–2% of muscle mass each year starting at age 50. Dietary protein intake has been shown to contribute to muscle status, and now Harvard Medical School researchers are pulling data from the past to examine the role that protein intake—and different types of protein—plays in muscle mass and strength in this vulnerable population.

The researchers pulled data from the Framingham Offspring Cohort, a study started in 1971 primarily to examine risk factors of cardiovascular disease. Using cross-sectional protein-intake data from the years 1995–2001, researchers analyzed the protein intake of roughly 2600 men and women with a mean age of 59. Mean total protein intake was 80 g/day for men and 76 g/day for women. Measurements of subjects’ leg lean mass and isometric quadriceps strength were taken between the years 1996 and 2001.

Lean muscle mass in the leg was found to be highest in subjects with the highest level of total protein intake. The researchers also looked at types of protein—specifically, the effects of animal protein versus plant protein. High animal-protein intake was linked to increased muscle mass in men and women. Plant protein intake was not.

But the highest quartile of plant protein intake was initially linked to a higher level of quadriceps strength. According to researchers, muscle strength—or the lack thereof—strongly determines physical disability and mortality in older adults. But when researchers adjusted the data for fruit and vegetable intake, they no longer found a significant association between plant protein intake and muscle strength. “There could be several reasons for this observation,” they wrote, among them that “it may be difficult to isolate the effect of plant protein from other beneficial nutrients of fruits and vegetables, such as antioxidants and carotenoids.”
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Partially hydrogenated oils (PHOs) are beating a hasty retreat in the United States after FDA announced in June that food manufacturers have three years to remove the artificial trans fats from foods. The move may lead to healthier Americans, but what will food manufacturers turn to as a replacement for PHOs?

Canola oil, coconut oil, soybean oil, and others are all potential candidates—options that food manufacturers began phasing in long ago—but the most attractive substitute may actually be palm oil. Its combination of formulation flexibility, abundant supply, and cost efficiency put palm oil at the front of the pack. The big challenge is ensuring it’s produced sustainably.

The Best Replacement?
Palm oil supplier Cargill (Minneapolis) sees palm oil as the number one replacement for PHOs “due to the functionality and cost competitiveness of palm oil,” says Changjian Ji, tropical oils merchant; dressings, sauces, and oils, Cargill. Ji adds, “we do expect to see an increase in palm oil sales in the U.S. due to the recent trans fat ruling.”

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The current global supply of palm oil is more than ready to accommodate a boost in U.S. demand, according to Kalyana Sundram, PhD, deputy CEO, Malaysian Palm Oil Council (MPOC; Kuala Lumpur, Malaysia). Sundram, however, doesn’t see palm oil as becoming the dominant PHO replacement, but rather an interim “filler fat” until other oils and alternate fat-modification processes can become more functional and less expensive.

But in the meantime, palm oil should allow many food manufacturers to switch away from PHOs in a cost-effective manner without compromising product characteristics or quality, says Sundram.

Environmental Challenges
Concerns about its environmental impact have dogged palm oil production for years, but there are ways to ensure that palm oil is produced sustainably. One is the Roundtable on Sustainable Palm Oil (RSPO), which Cargill’s Ji calls the “primary global sustainability standard for palm oil products.” RSPO offers use of its logo on products that meet its sustainability mandates.

Another way to make production more sustainable may be to increase oil yields per hectare of land cultivated. Although the oil palm tree is already one of the most prolific producers of oils and fats, the biological limitation is actually three or four times greater than the current average yield of 4 metric tons of oil per hectare, says MPOC’s Sundram. Scientists are working to increase that yield, such as by mapping the oil palm genome in 2013.

Reducing dependence on human labor is also a priority, and Sundram says the Malaysian government is offering a $1 million reward for innovative ideas to enhance mechanization of the industry.

There’s definitely a lot of momentum behind palm oil, and it’s a market that may be poised for even greater growth as U.S. food manufacturers make the non-PHO switch. ExcelVite’s See thinks it’s likely that European countries will soon follow FDA’s lead and pass PHO bans of their own—opening up even more opportunities for palm oil in coming years.

Palm fruit could soon become the source of one of the most popular non-PHO oils on the U.S. food market.
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