FDA AND SOCIAL MEDIA

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Should a Federal GMO-Labeling Law Be a Voluntary One?

A new, federal GMO-labeling bill, the “Safe and Accurate Food Labeling Act” (HR 4432), would in effect negate the state-level GMO-labeling laws that are growing more common each day. In fact, HR 4432 came on the heels of news that Vermont was, at the time this article went to press, just steps away from passing its own GMO-labeling bill—without the infamous “trigger clause” that paralyzes, for now, GMO-labeling laws in Maine and Connecticut.

Although mandatory, HR 4432 doesn’t require GMO labeling of everyone. As a press release from Congressman Mike Pompeo (R-KS), who partnered with Congressman G. K. Butterfield (D-NC) on the bill, states, “The Safe and Accurate Food Labeling Act of 2014 would establish a federal labeling standard for foods with genetically modified ingredients, giving sole authority to the Food and Drug Administration to require mandatory labeling on such foods if they are ever found to be unsafe or materially different from foods produced without GM ingredients.” In other words, HR 4432 takes the stance that GMO ingredients are, for the most part, okay. Indeed, as Pompeo’s press release goes on to state, “Contrary to claims by activists, there is no scientific evidence that suggests that foods that contain GMOs are anything but safe.”

Leaving aside, for now, the hotbed debate on GMO safety, I spoke to Michael McGuffin, president of the American Herbal Products Association (AHPA; Silver Spring, MD), about the need for a federal versus a state law. For the record, AHPA officially advocates for a federal voluntary—and not a mandatory—GMO-labeling law.

It’s clear that a scattering of individual state laws would quickly hamper interstate commerce. Not only that, but, as McGuffin points out, “Until we have a federal standard, I’m told that there are other organizations that are now going to come up with their own brand of non-GMO [seals or verification programs]... and then there will be a third, and then a 33rd. And then how will consumers be served if what you’ve got is 33 different meanings for ‘non-GMO,’ or ‘GMO free,’ or ‘less GMO,’ or ‘hardly GMO,’ or ‘GMO friendly,’ or who knows what?” he asks.

The federal—yet still voluntary—Organic Foods Production Act of 1990 would be a good model for a federal GMO-labeling law, McGuffin says. That law defines organic regulations at the federal helm—but companies can choose whether or not to participate. If companies choose to adhere to the federal standard and comply with the rules of USDA’s National Organic Program (NOP), as determined by state or third-party certification, they can market their products as “USDA Organic.”

The Organic Foods Production Act does not prevent states from creating their own organic laws. And McGuffin says he’s undecided on whether or not a federal law forbidding states from creating their own GMO-labeling laws is the right way. But, he points out, the NOP program works so well and is so well-managed at the federal level that no state has chosen to create a law of its own. “If a federal standard is good enough, we think that states would accept a federal voluntary standard.”

“I think most legislators are not motivated to whimsically create burdens on interstate commerce [by mandating separate legislation for an individual state]. They’re not going to do that,” he adds.

We may well need a federal law, but HR 4432 will likely not be it, McGuffin predicts. “For one thing, the 113th Congress isn’t passing much of anything,” he says. “It’s a lame-duck Congress, the election is in November, and there is resistance to getting big issues addressed at this time.”

Also, “My initial sense is that this bill will be viewed as an unworkable or unnecessary compromise,” McGuffin says.

A voluntary law could be just the sort of compromise we need.

Jennifer Grebow
Editor-in-Chief
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Prop 65: Safe Harbor No More?

California plans to make big changes to Proposition 65. Prop 65 requires that products sold in California carry a warning label if the product "knowingly and intentionally" exposes consumers to any of the more than 850 Prop 65-listed chemicals "known to cause cancer, birth defects, or reproductive harm." Until now, companies have been able to rely on using a "safe harbor" warning stating, "This product contains chemicals known to the State of California to cause cancer, birth defects, or other reproductive harm." But, under newly proposed changes, marketers—including food and dietary supplement firms—must, on a product’s label, instead list the specific Prop 65 chemicals that the product contains.

California’s Office of Environmental Health Hazard Assessment (OEHHA), which implements Prop 65, says the changes are meant to make Prop 65 warnings more specific and useful to the consumer, because:

[Concerns have been voiced for many years about the lack of specificity in the current safe harbor warning language, which merely says that an area or a product ‘contains’ a chemical that is known to the State of California to cause cancer, birth defects, or reproductive harm. Members of the public currently have no simple process for obtaining information about the chemical(s) that are present [and] whether or how they are actually being exposed to a significant amount of the chemical [or] the specific toxic hazard.]

Naming Specific Chemicals

There are more than 850 chemicals on Prop 65’s list, but only 12 would requiring listing on warning labels:

1. Acrylamide
2. Arsenic
3. Benzene
4. Cadmium
5. Chlorinated tris
6. 1,4-dioxane
7. Formaldehyde
8. Lead
9. Mercury
10. Pthalates
11. Tobacco smoke
12. Toluene

The responsibility to list specific chemicals would fall on the product manufacturer, and not the retailer, OEHHA clarifies. Under the proposed rule, warnings must appear in multiple languages if a company’s labeling and marketing materials are also written in multiple languages.

Warnings should use the 12 chemicals’ general names, instead of their more-technical names. OEHHA says its goal is to keep labels “understandable” for the consumer. If chemical names sound too complex, and if warning labels are “inordinately long and cumbersome,” it would “defeat the purpose of providing understandable and useful information to individuals on the warning itself,” the agency states.

OEHHA “does not anticipate that warnings will contain more than one or two of the listed chemicals” for most products.

“Safe Harbor” Warning Is Not Sufficient

The current "safe harbor" warning—"This product contains chemicals known to the State of California to cause cancer, birth defects, or other reproductive harm"—does not give the public sufficient information on when a given toxin—such as mercury or lead—may be especially harmful to a specific population, such as children and women of childbearing age, OEHHA says.

For foods, OEHHA proposes that warnings be worded as "Consuming [italics added] this product will expose you to [xx] chemical(s)." “Using this phrase focuses the individual on the route of exposure (oral or ingestion) as opposed to the existing safe harbor language that simply says the product ‘contains’ a listed chemical,” OEHHA says.

More Information on Website

OEHHA also proposes creating a complementary website that would provide consumers with further, detailed information on a product’s Prop 65 contents.

Companies would be required to provide, via the website, a full listing of any additional Prop 65 ingredients in their products, besides the 12 chemicals required on warning labels.

For instance, a company would simply need to list pthalates on its product label, but on the website, it would need to specify whether the pthalate is di(2-ethylhexyl) phthalate, diisononyl phthalate, or di-isodecyl phthalate. Warning statements should include the website’s address so that consumers know where to find the additional information.

Companies would need to publish on the website the following details, among other information:

- The name(s) of the chemicals subject to the warning
- “The anticipated route, routes, and pathways of exposure to the listed chemical”
- The manner in which the chemical is formed, occurs in, or is added to the food
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• Specifically whether a warning is being provided for cancer, birth defects, or “other reproductive harm”
• The specific products or category of products the warning is intended to cover, including barcodes

Companies would need to submit this information online within 30 days. They must also update the information if they make any changes to a product's contents.

No More “Safe Harbor” Labeling
Many companies today preemptively label their products with the Prop 65 “safe harbor” warning, just to ensure they are “covered” under the law and as a safeguard against the Prop 65 bounty hunter lawsuits flooding the market. They may do this even if they are not sure that their products actually contain the prohibited chemicals or contain the chemicals above threshold levels that would require a Prop 65 warning.

But, under OEHHA’s proposal, companies can no longer preemptively adopt the Prop 65 warning generically; rather, they must determine whether their products truly meet or exceed the statute’s threshold limits, and only then can—and should—they include a warning.

The website’s information would help to substantiate warnings, OEHHA says, and reduce the amount of “over-warning” happening in the market today.

An “authorized agent,” such as an industry association, could submit website information on a company’s behalf, OEHHA suggests. “This provision is intended to encourage businesses to coordinate reporting through their trade groups or other organizations since many exposures to listed chemicals occur throughout an industry, not from a single product or occupational or environmental scenario.”

It remains to be seen how this option would work for nutrition companies whose ingredients may be very company-specific.

Less Litigation?
By eliminating vague warnings, the proposed regulations would make companies more secure against Prop 65 litigation, OEHHA implies. The office states, “Since the regulations would create mandatory minimum content for the warnings and also prescribe acceptable warning methods, businesses would be able to rely on their compliance with the regulations...” if faced with a lawsuit.

“I don’t think that this is going to stem the flow of lawsuits at all,” says Anthony Cortez of Greenberg Traurig LLP.

But not everyone buys this reasoning. “I don’t think that this is going to stem the flow of lawsuits at all,” says Anthony Cortez, an associate at law firm Greenberg Traurig LLP (Sacramento).

“If they were going to stem the flow of lawsuits, then all of the plaintiffs’ bar would be screaming and kicking and yelling and fighting [the proposed changes], but they’re not. They’re supporting it. And there’s a reason they’re supporting it,” he says. “Because whereas before, [companies] could just put a warning on [a product] and not have to say what [a specific chemical is], now it’s actionable. Before, a generic warning would cover you for all chemicals, but now, not only do you have to have a warning; you have to have a warning that’s exactly right.”

On the topic of avoiding lawsuits, OEHHA proposes retaining one change—a bill passed into law in 2013 by California Governor Jerry Brown that gives small companies with fewer than 25 employees a 14-day grace period to correct any infractions before they can be slapped with a lawsuit. But, as some point out, this option is more feasible for entities like restaurants compared to consumer packaged goods companies that may have difficulty relabeling all of their SKUs in such a short time frame.

New Regulations for a New Era
Proposition 65 was passed in 1988. OEHHA says it has since received numerous requests to amend the law and that its intention is also to take advantage of the benefits of technologies, such as the website, that were not prevalent back in 1988.

Above all, OEHHA stresses, its goal is to “provide more meaningful information for individuals in Proposition 65 warnings, facilitate the public’s understanding of these warnings, and make the warnings more consistent.”

OEHHA held a “pre-regulatory workshop” on April 14 in Sacramento, where critics argued that the changes would hurt businesses and fail to help the consumer. (Read expert opinions on the proposed changes, as well as any takeaways from the OEHHA workshop, at www.NutritionalOutlook.com/1406/Prop65.)

This is just a pre-regulatory proposal, and the specifications could further change by the time the proposed regulation is issued, OEHHA reminds critics.

But, says Cortez, “The takeaway from the workshop was that OEHHA is determined to implement the [proposed] regulations by the end of summer, and they are confident they will become law.”

“The proposed regulations may be amended slightly, but they are close to final,” he adds.

Given the amount of feedback it received, OEHHA has extended the comment period to June 13, 2014. The agency says it aims to complete the final regulation by summer 2015.

“I would encourage your readers not to sit by the wayside,” Cortez suggests. “There needs to be some serious response here. The door is not closed to get this shelved. I’d encourage your readers to take action.”

—Jennifer Grebow, Editor-in-Chief
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Warning Letter. Not since Dear John have two little words at the top of a letter evoked more dread—if FDA is the sender and you’re a food or a supplement company, that is.

The somewhat-good news? After a steady increase in warning letters every year (starting with 104 issued in January–March 2009 and culminating in 208 warning letters generated and posted by FDA in January–March 2013), the number of warning letters dropped by almost 50% in the first quarter of 2014. Through March of this year, FDA sent 110 warning letters to companies in various industries, including food and supplements. This is the lowest number of warning letters FDA has sent through March of any of the past five years.

However, companies would be ill-advised to view any decrease as a sign that FDA has relaxed its regulatory scrutiny.

Warning Letters
FDA warning letters do not represent final agency enforcement action, as affirmed by the D.C. Circuit Court in January 2012 in the case of Holistic Candlers and Consumers Assoc. et al. v. FDA. FDA warning letters are essentially a notice from FDA that the agency believes a company has violated the law. They demand that a company indicate to FDA how it is going to address the situation. However, as shown with increasing frequency over the last several years, if FDA is not satisfied with a company’s response to a warning letter, further action is likely and can take the form of filing a suit in court, seeking injunctive relief, and forcing companies to shut down. The key is to learn by example. Smart firms will heed the warning letters sent to other companies and preemptively adjust their own operations to avoid becoming the targets of FDA warning letters themselves.

FDA posts new warning letters every Tuesday morning at www.fda.gov. Letters can be searched by the sent date, company name, FDA district office, and subject. Of the 110 letters FDA sent during the first three months of 2014, 44 went to food and dietary supplement companies and the remainder to medical device, drug, and other companies.

Let’s take a brief look at some of the more common themes of recent warning letters sent to food, beverage, and dietary supplement companies.

Dietary Supplement Companies
Current Good Manufacturing Practices for Dietary Supplements
FDA continues to place high priority on ensuring compliance with dietary supplement GMPs (DS CGMPs). Despite only four letters posted so far in 2014 addressing alleged failures to comply with the DS CGMPs, companies should know that FDA continues to inspect dietary supplement companies with fervor to ensure compliance with DS CGMPs.

In the most recent letter to a dietary supplement company—a March 13, 2014, letter to a Florida manufacturer—FDA alleged a number of DS CGMP violations that were observed during a 2013 inspection of the company’s manufacturing facilities. Cited violations include:

1. Failure to conduct at least one appropriate test to verify the identity of a dietary ingredient (21 CFR 111.75(a)(1)(ii))
2. Failure to qualify a supplier of a component by establishing the reliability of the supplier’s Certificate of Analysis (COA) (21 CFR 111.75(a)(2)(ii)(A))
3. Failure to prepare and follow a written master manufacturing record (MMR) for each unique formulation of a dietary supplement (21 CFR 111.205(a))

In a letter to a California supplement manufacturer dated January 22, 2014, FDA cited alleged violations, including:
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1 – Clinical Study Report: NO.BTS.275/07. February 16, 2009, Esslingen, Germany

* These statements have not been evaluated by the FDA. This product is not intended to diagnose, treat, cure, or prevent any disease.
1. Failure to ensure that specification tests were appropriate and used scientifically valid methods (21 CFR 111.75(h)(1))

2. Failure to establish and follow written procedures for quality-control observations (21 CFR 111.103)

And in a January 31, 2014, letter to a Pennsylvania dietary supplement manufacturer (the second letter sent to the company in the last two years), FDA identified numerous issues, including the failure to investigate complaints and the failure to submit a Serious Adverse Event Report (SAER), as required by the DS CGMPs and the Dietary Supplement and Nonprescription Drug Consumer Protection Act.

It is important to note that, in all three cases, following FDA’s initial inspections and observation of these infractions, the companies had sent written responses to FDA but the agency found those responses inadequate. A key takeaway? Companies must not simply respond to each observation, but must provide detailed documentation of how any corrections were or will be carried out. Absent a substantial response, a company runs the risk of receiving a warning letter from FDA.

New Dietary Ingredient Notification

While the dietary supplement industry continues to wait with anticipation for a revised draft guidance from FDA regarding New Dietary Ingredient (NDI) notifications, FDA representatives have been quick to remind the industry that the obligation to file NDI notifications remains in effect, regardless of the status of any guidance from the agency.

With the NDI requirement very much active, recent FDA warning letters have cited companies for failing to meet their NDI obligations.

In its letter to the Pennsylvania company mentioned earlier, FDA indicated that the ingredient 4-etioallocholen-3,6,17-trione is a NDI (assuming it meets one of the criteria for a dietary ingredient). FDA said that a NDI notification is required, unless the company can show proof that 4-etioallocholen-3,6,17-trione has been present in the food supply as an article used for food (which would negate the need for a NDI notification). But FDA said that because the company did not submit a NDI notification, the product containing the NDI is considered adulterated.

Companies are still at risk of receiving a warning letter from the FDA if a required NDI notification is not submitted.

FDA sent a similar letter to the company in 2012, which also cited the firm’s failure to file a NDI notification for DMAA, an ingredient that underwent much regulatory scrutiny in 2012. While the number of warning letters addressing failures to submit NDI notifications has been sparse, these letters should serve as notice that companies are still at risk of receiving a warning letter from the FDA if a required NDI notification is not submitted.

Disease Claims

FDA sent letters to several companies marketing products that were labeled as dietary supplements but whose claims FDA said cause the products to be deemed drugs.

A January 31, 2014, letter to a dietary supplement company located in Utah highlighted numerous allegations of disease claims made on the company’s website. Examples included “May help fight off viruses, bacteria, toxins, and parasites,” “May provide pain relief for some individuals who have minor arthritis pain,” as well as claims mentioning the words skin sores, antiseptic, and inflammation.

In a letter to an Oregon dietary supplement marketer dated January 23, 2014, the FDA catalogued claims that included “Fucoidan...[a substance in the product] causes certain types of rapidly growing cancer cells to self-destruct” and “Laminarin [a substance in the product] is a polysaccharide helpful in the prevention and treatment of cardiovascular diseases.”

In the letter to the Utah company, FDA also cited the use of online metatags like cancer, diabetes, and autistic as indicating the company’s intent to sell a product as a drug.

These letters all serve to reinforce one of the fundamental principles of dietary supplements, as restated in the disclaimer for dietary supplements set forth in 21 CFR 101.93: namely, that dietary supplement products may not be intended to “diagnose, treat, cure or prevent any disease.”

Labeling Violations

Finally, FDA warning letters to food and supplement companies often cite labeling violations. In several letters—including a February 11, 2014, letter to a California company that packages and distributes dietary supplements—alleged labeling violations included:

1. Failure to list vitamins and minerals in the proper order
2. Failure to list “Other Ingredients” outside of the Supplement Facts Panel
3. Failure to list parts of the plant for botanical ingredients
4. Failure to include the place of business of the manufacturer, packer, or distributor
5. The inconsistency of serving size (one capsule) versus recommended use (two to three capsules, three times daily)

Expiration dating is another labeling area that FDA warning letters have frequently cited over the last several years. Dietary supplement companies have no regulatory obligation to include an expiration date, shelf life date, or “best if used by” date. However, as confirmed by letters addressing expiration dates, if a company does include such information on a label, it “should be supported by stability data [See 72 Fed. Reg. 34752, 34856 (June 25, 2007)].” FDA says.

While, at the outset, some labeling violations may seem very technical and minor in nature, there are much bigger implications, as far as warning letters go. Observing labeling violations will often lead FDA to pay closer attention to other aspects of a company’s business. Ensuring that all labeling is
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compliant is the best way for companies to avoid this added scrutiny.

**Food Companies**

**Food CGMPs/Unsanitary Conditions**

The food business can be a dirty business—or, at least, FDA believes so. The majority of FDA warning letters to food companies highlighted food safety. The bulk of warning letters to food companies addressed perceived deficiencies in food safety plans, or observations made during facility inspections of some egregiously unsanitary conditions. Of note, due to the potential health risk created by unsanitary conditions, the time frame in which these warning letters were sent was often shorter than the normal turnaround.

Examples include letters to several bakeries that were sent just over a month after the closeout of inspections of the companies’ manufacturing facilities. In a letter to a Washington bakery on March 6, 2014, FDA detailed the rampant presence of rodent pellets in the bakery’s production facilities, which violates food CGMPs requiring sanitary conditions.


Seafood processors and importers amassed more warning letters than any other group of food companies: a total of 22 warning letters in January–March 2014. The primary focal point seems to be non-compliance with the seafood Hazard Analysis and Critical Control Point (HACCP) regulations of 21 CFR Part 123.6(g) and the CGMPs for foods. Warning letters to seafood processors—like one sent to a Connecticut processor on March 24, 2014—often allege failure to implement HACCP plans, as well as failure to meet food CGMPs, creating potentially dangerous and unsanitary conditions. Seafood importers, such as the recipient of a letter dated March 6, 2014, are usually alleged to be in violation of 21 CFR 123.12, which requires importers to take affirmative steps to ensure that imported seafood complies with HACCP regulations.

Especially following media coverage surrounding several Iowa egg farms that produced a nationwide *Salmonella* scare, egg farms have received their share of FDA
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attention and warning letters. Five egg farms received warning letters during January–March 2014 for alleged violations, ranging from the failure to implement proper pest-control procedures for rodents and insects to the failure to keep wildlife out of the facilities, in violation of shell egg regulations and the Public Safety Act.

Warning letters aren’t just limited to companies on the ground. An airline services company received a 2014 warning letter for alleged food issues that could contribute to safety concerns. In a letter dated March 24, 2014, FDA asserted that a 2013 inspection of the company observed numerous violations of the Public Safety Act.

Labeling Violations
Labeling issues frequently prompt warning letters to food companies as well. In the first quarter of 2014, only one warning letter addressed labeling issues related to a food company. The January 21, 2014, letter to a Wisconsin snack food company cited a number of alleged labeling violations, in addition to alleged CGMP violations and other issues. Alleged labeling violations included:

1. Failure to properly identify a color additive
2. Failure to identify a food allergen (milk)
3. Failure to list nutrition information properly, pursuant to 21 CFR 101.9
4. Improper use of nutrient content claims like “high in fiber” (A “high in fiber” claim should only be used when a food contains at least 20% or more of the recommended daily intake (RDI), or daily reference value (DRV), but the company’s product only contained 2% fiber.)

Beverage or Supplement?
A March 27, 2014, letter to a Las Vegas marketer of liquid products is the first warning letter FDA has issued since the agency released its Guidance for Industry: Distinguishing Liquid Dietary Supplements from Beverages in January 2014. In the letter, the agency determined that the products were “represented for use as a conventional food,” despite use of the term “dietary supplement” below the nutrition information.

FDA cited a litany of factors that caused it to deem the products beverages, and not supplements:

1. The use of a Nutrition Facts Panel
2. References on the company’s website to the products as “#1 relaxation
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3. Descriptions of the products as beverages on the product labels

4. Ingredients, appearance, and packaging similar to that of typical beverage products

Because FDA considers the products to be beverages, the agency said that one of the products’ ingredients, melatonin, is present in the products as an unapproved food additive, without evidence of being Generally Recognized as Safe (GRAS). FDA also asserted that the safety of melatonin and its use in conventional food products is still in question. FDA took a similar stance on melatonin in warning letters sent to companies in 2011 for liquid products and brownies containing melatonin.

This recent letter reinforces the notion that marketers must be consistent in the marketing and advertising of products as supplements or beverages.

The Rest of the Year

While FDA was less active with warning letters during the first quarter of 2014 compared to previous years, companies should not expect the same for the remainder of 2014. As always, CGMP compliance and food safety will continue to be high priorities of the FDA, and inspections will continue with frequency.

Companies should be especially vigilant if they operate in areas covered by recently revised or final FDA guidances. Companies should expect FDA to continue issuing warning letters related to the recently released, final guidance on beverages versus supplements, just as the medical foods industry last year saw increased FDA attention after the agency revised its medical foods guidance.

In addition to beverages and supplements, be aware that these upcoming regulatory developments could influence the FDA warning letters we’ll see later this year: 1) FDA’s “gluten free” regulation, set to go into effect in September, 2) pending revisions to NDI notification guidance, and 3) pending revisions to the guidance for the labeling of ingredients as “evaporated cane juice.”

Most importantly, if that letter with the dreaded words Warning Letter should come, companies should take it very seriously and address it comprehensively to avoid subsequent FDA action.

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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NDI Draft Guidance Update

When will FDA release revised NDI draft guidance?

BY JAMES J. GORMLEY

FDA’s New Dietary Ingredient (NDI) draft guidance has become a touchstone for all interested parties concerned about reinterpretations of existing law—namely, the Dietary Supplement Health and Education Act (DSHEA) of 1994. As most know, the NDI guidance, which FDA published in the Federal Register on July 5, 2011, has evoked numerous concerns—and sustained rallying cries for guidance revision—within the dietary supplements industry at large.

Again, the central concerns with the current version of the draft guidance include:

- The draft guidance indicates that FDA could require the submission of an NDI notification from every manufacturer for every finished product that contains what the FDA considers a NDI.
- It would shift the burden of proof that an ingredient is not an NDI from FDA to individual companies.
- The guidance asserts that there are no authoritative lists of “grandfathered” ingredients—dietary ingredients that existed in the dietary supplements market pre-DSHEA (before October 15, 1994)—to establish that a dietary ingredient is an Old Dietary Ingredient (ODI) and therefore doesn’t require NDI notification. This includes any lists of pre-DSHEA ingredients industry trade associations have compiled.
- Many argue with the guidance’s definition—and list of—manufacturing processes that would lead an ingredient to be considered chemically altered and thus require NDI notification. Those who criticize the guidance’s list of what comprises chemical alteration say that the list would significantly expand the category of ingredients that would require NDI notification.
- The guidance states that human-synthesized constituents of botanical ingredients are different from those synthesized by the plant, meaning that synthetic ingredients at large would require NDI notifications.
- The guidance would impose a level of data necessary to demonstrate the safety of a NDI similar to what is required for food additives, a standard that critics argue Congress and the courts already rejected during DSHEA’s implementation.

A Look Back: Initial Industry and Consumer Response

In response to the guidance, several industry trade associations issued calls for a revised guidance. In addition to the 144,000 pages of comments ultimately submitted to FDA’s public-comment docket on the guidance, consumer groups, such as Citizens for Health and the Alliance for Natural Health, mounted sustained grassroots campaigns that generated thousands of consumer letters also calling for guidance revision.

At the end of 2011, the American Herbal Products Association (AHPA; Silver Spring, MD) stated that, if implemented as written, “[The guidance] would change the rules that have been in place for the last 17 years and significantly increase the burden on the supplement industry far beyond the intent of Congress, with no concomitant benefit for consumers.”

AHPA went on to call for the draft to be completely withdrawn, describing the draft guidance as “hugely flawed” and as “seek[ing] to erect extra legal barriers to market entry, impose food additive–type evaluative criteria, [and] require multiple NDI notifications for dietary supplements beyond those required by law,” AHPA also argued that the guidance, as written, would transform the NDI legal requirements for the marketing of dietary supplements from a notification process to one of FDA preapproval.

On December 2, 2011, Steve Mister, president and CEO of the Council for Responsible Nutrition (CRN; Washington, DC), was quoted as saying, “The draft guidance would essentially undo nearly two decades of agency practice and policy that began with DSHEA’s passage and would impose significant and unnecessary burdens on the industry, stifle innovation, and curtail industry growth—without conferring additional safety benefits to consumers.”

Possible Impact on the Market

Data from Emory University in Atlanta, GA, predicted that the NDI guidance, if adopted as originally proposed, would force between 22,240 and 41,700 dietary supplements to be removed from the market, resulting in an economic loss of between $5.6 billion and $10.5 billion.

“I can’t comment on whether the estimates in the Emory University study are too high or too low,” Michael McGuffin, AHPA’s president, tells Nutritional Outlook today. “But it is certain that the impact of the guidance as written is far higher than FDA’s own economic analysis that accompanied the promulgation of the actual NDI regulations. At that time, the agency’s financial impact discussion strongly implied that only one NDI notification would need to be submitted for each ingredient that is actually an NDI, presumably by the ingredient supplier.

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On the other hand, the draft guidance suggests that every finished product marketer that includes the NDI in its product would need to file separate submissions, “a much more consuming burden."

As to why the current draft guidance seems so off the mark to many, attorney Justin Prochnow of Greenberg Traurig LLP looks at it this way: “I truly believe that FDA believes there has been an overall lack of compliance in [the NDI] area, and it wants to see better compliance. The problem becomes that FDA has let [non-compliance] go on for so long that it is going to be hard to rein in. If every company filed every NDI that would be required under [….] FDA’s interpretation of the guidance, there would not be nearly enough personnel to handle the submissions. This is the very reason the GRAS process became voluntary.”

In June 2012, FDA agreed to re-work the draft, but has released nothing, to date. In July 2013, Representatives Frank Pallone (D-NJ) and Brett Guthrie (R-KY), along with 27 other House members, sent a letter to FDA Commissioner Margaret Hamburg urging the agency to expedite its efforts to release the draft guidance.

**Watch…and Wait**

What’s the status of the guidance today? We’re still waiting. According to CRN’s Mister, “CRN has had a series of very productive conversations with FDA about the original draft guidance, and we are optimistic that the agency will address many of the items that we had concerns with.”

“We are cautiously hopeful that the agency listened to our views and will incorporate many of our suggestions into the new draft,” Mister adds. “At this point, we plan to wait until the new draft is released before making further comments.”

“It’s time to change the dialogue from one where all we do is complain about FDA’s overreach with the issuance of its unacceptable draft NDI guidance,” says McGuffin. “We need to continue this complaint, but we also need to communicate to the trade that DSHEA’s NDI burden, as written, is an acceptable regulatory burden and that companies that address this burden professionally are successful—and then receive the return on this premarket investment by selling their NDIs.”

Asked about his best guess as to when a proposed NDI final guidance might be issued, Prochnow predicts: “By July 4, 2014, the three-year anniversary of the last version.”

Will it be July 4, 2014? We will have to wait and see whether and when final guidance will signal more of—or a possible end to—the ongoing NDI battle.

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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Tips for Sourcing Non-GMO

These days, it pays for food and supplement companies to know how to find suppliers of non-GMO ingredients.

By Chris Bekermeier, PacMoore

Genetic modification involves gene-splicing biotechnology (genetic engineering) to merge DNA from different species of plants or animals to create combinations that cannot occur naturally or in traditional cross-breeding. The technology required to genetically modify food and animals in a lab was commercialized in the 1970s. The first commercial sale of a genetically modified food is typically attributed to Calgene in 1994, with its Flavr Savr delayed-ripening tomato. Unlike genetic modification, traditional cross-breeding—such as hybridization and selection—has been popular in agriculture for centuries.

GMO corn, canola, cotton seed oil, and soybeans are cash crops for today’s farmers. According to the USDA, 85% of soy, 40% of corn, and 75% of canola produced in the United States are GMOs. Today’s GMO foods are largely bred for tolerance of the herbicide glyphosate (branded Roundup). GMOs bred with glyphosate tolerance allow farmers’ cash crops to grow, while the competing weeds that try to grow around the crops are killed.

Growing Demand for Non-GMO

Although many GMO crops are classified as “safe,” there are no long-term studies available to prove the safety of their extended human consumption. Some shorter-term studies have found traces of toxins from GMO crops in humans post-consumption. For instance, in a 2011 study published in the journal Reproductive Toxicology, researchers detected Bacillus thuringensis (BT), the toxin in GMO corn, in the blood of pregnant women and their babies.1

Another argument against GMO is genetic contamination, if GMO crops cross-breed with natural varieties of the same crop. A 2013 paper published in the journal Nature details how BT corn has contaminated the indigenous corn of Oaxaca, Mexico.2 Critics of GMO foods also often claim that genetic engineering can disrupt the functions of neighboring genes in plants, giving rise to toxic or allergenic molecules and thus lowering the value of the food.

At the retail level, some consumers say that companies such as Monsanto and Syngenta have oversold the benefits of GMO crops. Some object to having GMO-patented seeds concentrated in the hands of a few corporations, marginalizing smaller farms.

While there is currently no federal labeling law to indicate foods containing GMOs, many manufacturers today still choose to label non-GMO foods specifically as such. Of course, with so much emphasis today on non-GMO products, demand for non-GMO ingredients is higher than ever.

Don’t just take a supplier’s word for it that its ingredients are non-GMO—ask to see the evidence.

But there are challenges in the non-GMO supply chain. First and foremost, the limited availability of verified non-GMO feed makes sourcing non-GMO ingredients somewhat difficult. Other challenges include supply shortages and poor crops due to bad weather or drought.

What’s more, non-GMO food is often more expensive than its GMO counterparts. Labor costs are higher because not using conventional chemicals requires hiring more workers for tasks like weeding and cleaning up polluted water. Other costs include higher fertilizer costs, the price of crop rotation—as opposed to conventional farms that can use every square inch—and certification costs.

Still, if you’re going to market a non-GMO food, you need to know how to source non-GMO ingredients, and you should know exactly what to look for in potential suppliers. Finding the right non-GMO supplier takes effort. Also, remember that GMO issues start early on. For instance, limited availability of non-GMO feed means limited availability of non-GMO ingredients.

Demand for non-GMO ingredients is higher than ever.

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Suppliers should have systems to avoid non-GMO and GMO cross-contamination.

Tips for Sourcing Non-GMO

There are a number of ways to vet a supplier’s non-GMO capabilities. To start, ask the supplier for documentation or certification.

Third-party non-GMO verification, such as certifications from the Non-GMO Project or Identify Preservation (IP), is the first thing to look for in a potential supplier. Thankfully, this sort of certification is increasingly in demand, and more suppliers will likely work to become certified. “With Whole Foods’ recent commitment to GMO labeling by 2018, the demand for non-GMO and organic grains and ingredients is likely to increase,” wrote Ken Roseboro in a recent article for The Organic and Non-GMO Report.3

Third-party verifications are increasingly important in terms of the downstream market, as they allow you to market and label your foods as GMO-free with absolute certainty. On top of a certificate, you could also require that your potential supplier provide proof, such as GMO test results, should you require it.

You should also check if potential suppliers have any documented system that aids in proper segregation of non-GMO and GMO goods, to avoid cross-contamination. Traceability is also important; seeing an entire timeline of a supplier’s products can help confirm the supplier’s claims. Where have the ingredients been during different parts of the supply chain? Where are they sourced from, and what have they been exposed to?

In the same vein, approaching the sourcing of non-GMO ingredients with an international perspective can help. Knowing where ingredients and products come from, as well as the non-GMO laws of other countries, all help to ensure that you’re getting what you paid for—non-GMO ingredients from your suppliers.

Lastly, the sign of a reliable non-GMO supplier is experience and a successful track record in supplying non-GMO goods. “You want essentially the same qualities you are seeking from your other valued suppliers,” Roseboro wrote.3 “It would be beneficial if the supplier had a history in handling organic products inasmuch as most of the protocols will be similar.” In other words, when you choose a supplier, you want to be sure it can deliver. Ask for demonstration of its track record. What other companies does it work with? Who can vouch for the supplier’s reliability in avoiding GMOs?

Going completely non-GMO requires dedication, considering the various challenges and high costs associated with the process at this time. But with controversy surging through the market over GMO labeling and GMO-related health concerns, companies may want to consider a move to non-GMO ingredients when forecasting the future of their business.

References

Chris Bekermeier is vice president, sales and marketing, of PacMoore (Hammond, IN). PacMoore is one of the leading commercial food packaging companies processing dry ingredients for the food industry. Its capabilities include blending, spray-drying, re-packaging, sifting, and custom food packaging.
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A Standard Is Born

Public standards build confidence and quality in ingredient supply chains. When does an ingredient merit a standard?

By Markus Lipp, PhD, and Nandakumara Sarma, PhD, United States Pharmacopeial Convention

Public standards, such as United States Pharmacopeial Convention monographs, help companies verify the integrity of food and dietary supplement ingredients, globally and industry-wide. While companies are not required to use monographs, there are many reasons why a company would want to.

While the United States, Europe, and other countries with strong regulatory agencies promote Good Manufacturing Practices (GMPs) for foods and dietary supplements, and take appropriate action against regulatory infractions that put public health at risk, there are still, however, numerous countries with less robust regulatory frameworks that operate primarily on the public’s trust in the safe production and distribution of foods and dietary supplements. For that reason, manufacturers and formulators of foods and dietary supplements around the world with a serious desire to protect their brands and build trust in the quality of their ingredients have adopted science-based quality standards (monographs) such as those in the Food Chemicals Codex (FCC) and the United States Pharmacopeia (USP). These standards serve as a safety net in a marketplace inundated with a continuous flow of new ingredients. USP dietary supplement monographs are also published in the Dietary Supplements Compendium (DSC), an industry-directed resource featuring relevant documentary standards, along with industry and regulatory guidance documents, supplemental information, and reference tools.

Engaging manufacturers and other stakeholders in the supply chain early on is the best way to create public standards. Intense and extensive participation ensures that standards benefit from broad input and are also likely to be widely accepted.

The process of developing quality standards with an organization such as USP may seem obscure and sometimes intimidating. In this article, we break down the process, from start to finish. In doing so, we hope to encourage stakeholder interest in “sponsoring” (helping to create) monographs for food ingredients and dietary supplements.

Stakeholder input throughout the development process is crucial to ensure that, when a monograph is ready for adoption, it is written in such a way that it does not inadvertently exclude applicability to other relevant, potentially high-quality ingredients—i.e., that it does not prevent other ingredients that should fall under the monograph’s scope from being able to comply with the monograph’s standards. After all, the end goal is to create fit-for-purpose standards that encourage quality for as

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many companies as possible, also thereby leveling the playing field in increasingly global supply chains.

Breaking Down Monograph Development

It may sound trivial at first, but one of the first hurdles an ingredient has to clear in order to be considered a potential candidate for a USP monograph is the answer to the question, “Is there proof that this food or dietary supplement ingredient meets regulatory requirements to be legally marketed?”

For food ingredients, there are several legal pathways that would green-light USP to start the monograph development process. Usually, USP scientists will accept a GRAS notification (Generally Recognized as Safe) for which the U.S. FDA has issued a “no questions” letter (www.fda.gov/food/ingredientspackaginglabeling/GRAS/default.htm). A successful food-additive petition, or sometimes even a self-GRAS determination of a food ingredient with appropriate documentation from manufacturers, may also count.

For dietary ingredients, NDI (New Dietary Ingredient) notifications without FDA objection also meet the initial requirement for creating a monograph. NDI notifications apply to ingredients marketed in the United States after October 15, 1994, when the Dietary Supplement Health and Education Act (DSHEA) established conditions for dietary supplements to be marketed in the United States. USP also evaluates dietary supplement ingredients that were in the market before 1994, for the sole purpose of determining whether an ingredient should be admitted and published as a monograph in a USP compendium. This activity is performed by a USP Expert Committee, which conducts a literature-based review of clinical studies, adverse events, and regulatory status, among other parameters (www.usp.org/sites/default/files/usp_pdf/EN/dietarySupp/admissionsguideline_vers_1.1.pdf).

USP works with 22 Expert Committees, which comprise the very core of USP’s standards-setting activities. Expert Committees are groups of volunteer experts from academia, industry, and regulatory bodies selected every five years to guide USP’s work. This is one of the early levels of engagement available to interested parties. USP is currently taking applications for the next cycle of Expert Committees, which starts in 2015. We encourage experts in foods and dietary supplements to learn more and apply for the next cycle.

Additional information that USP seeks from manufacturers when deciding if an ingredient warrants a monograph are:

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2. Whether the ingredient is prone to adulteration

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3. Whether the ingredient can be specifically identified and described


Once a new ingredient is identified as a monograph contender, and one or more sponsors has committed to working on developing quality standards, the sponsors and USP scientists work hand-in-hand to ensure all necessary tests and procedures are in place to establish the identity, purity, and quality of that ingredient. Physical samples of the ingredient (reference standards) are also developed whenever possible to accompany the monograph. Reference standards provide companies that adopt a standard with an opportunity to test their own procured ingredients against a physical quality benchmark.

The opportunities for other stakeholders (regulators, academics, other manufacturers) do not stop with the ingredient selection or the sponsor commitment; they continue even after the monograph is drafted.

Once drafted, each and every monograph is proposed in a discussion forum for public comment. At this time, stakeholders also have the opportunity to suggest other complementary tests and materials for inclusion. The FCC Forum (for food ingredients) and the Pharmacopeial Forum (for dietary supplements) are free, online tools that allow stakeholders to interact with scientists developing monographs. Through the forums, stakeholders can submit supporting evidence to increase the confidence in a proposed monograph and also help to ensure that the monograph does not exclude other potentially authentic ingredients and products.

Public comment is open for a period of 90 days, after which all comments are compiled and considered. After review and consideration of the comments, Expert Committees dedicated to either food ingredients or dietary supplements vote on whether the proposed monograph is ready for adoption. If they decide significant changes must be made, it may initiate another opportunity for public comment.

Even after a monograph is published in the USP or FCC, stakeholders can send their comments and suggestions for changes, which may trigger a review process for that particular monograph. During a review, evidence is once again collected and, in case the monograph needs a revision, the process restarts with new opportunities for input from all interested parties.
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Calling Sponsors!

USP is seeking sponsors to help develop monographs for ingredients that are not part of the Food Chemicals Codex and the Dietary Supplements Compendium. Below is a current list of the ingredients USP has prioritized for monograph development. Contact USP at stacq@usp.org for more information.

Food Chemicals Codex
- Artichoke extract
- Camelina sativa oil
- Canola protein isolate
- Cassia gum
- Conjungated linoleic acid
- C-phycocyanin
- Galactooligosaccharides
- Garlic extract
- Ginger extract
- Glyceryl monoacetate (monoacetyl)
- Hibiscus extract
- High-oleic safflower oil
- High-oleic sunflower oil
- Lactoferrin
- Pea protein isolate
- Probiotic bacteria
- Purple cabbage extract
- Rebaudioside D
- Rose hips extract
- Sodium chloride
- Sodium hypochlorite
- Xylooligosaccharides
- Yerba mate extract

Dietary Supplements Compendium
- Acai
- Aloe vera leaf juice
- Bee products
- Bitter melon
- Burdock
- Calcium citrate malate
- Dong quai
- Elderberry
- Eyebright
- Goji
- Guarana
- Hops
- Horny goat weed
- Kombucha
- Maca
- Magnesium glycinate
- Mangosteen juice
- Noni
- Olive leaf extract
- Oregano
- Papaya
- Pau d’Arco
- Probiotics
- Stevia
- Tribulus terrestris
- Vitamin and/or mineral related
- Willowbark
- Yohimbe

Case Study: Krill Oil Monograph

While USP staff will always guide the sponsor through the submission process, developing a monograph may still be a complex process. Sometimes, validation data is insufficient; tests and materials are not available, or the process to develop a reference standard is complicated; or stakeholders and scientists take longer than expected to formulate the monograph. The following case study illustrates the development of FCC and USP monographs for krill oil, an ingredient used by the industry in foods as well as dietary supplements.

USP’s krill oil monograph for food (for the FCC) began development in 2009, after previous attempts failed to bring consensus on what to include and how to conduct quantification tests, especially for omega-3 fatty acids EPA and DHA, which are linked to purported heart health benefits, among others.

In recent years, krill oil has been increasing used as a food ingredient and a dietary supplement because of its higher concentration of omega-3 phospholipids compared to most animal or plant sources. Increased usage not only raises krill oil’s profile; it opens a window for adulteration with phospholipids from other sources. Sponsors of the FCC krill oil monograph focused on establishing a unique profile of the phospholipids present in krill oil using nuclear magnetic resonance (NMR) analysis. They also worked on quantification of those phospholipids, since health effects associated with this ingredient depend largely on the type and amount of those phospholipids. Finally, sponsors also established limits for heavy metal contaminants: not more than 0.1 mg/kg for arsenic, lead, and mercury.

USP’s monograph for krill oil as a dietary supplement ingredient was proposed in July 2013 and was well received by major stakeholders, who actively participated in the development process. In addition to the ingredient monograph, dietary supplement product monographs for krill oil capsules and delayed-release capsules were also proposed. These three monographs are scheduled to become official in the USP-NF in December 2014.

Reason to Participate

While FDA does not require manufacturers to conform to FCC or USP standards for food ingredients (unless they are referenced in FDA regulations) or dietary supplements (unless they are labeled as USP), manufacturers that adopt these standards can offer their customers the confidence that their ingredients are authentic. Science-based evidence of an ingredient’s integrity is at the core of increasing consistency and trust in the food and dietary supplement supply chains.

While USP does not play a direct role in establishing the safety and efficacy of foods and dietary supplements, its rigorous quality standards can help. That alone should provide market value to manufacturers that want to stand out in a crowd of new ingredients and products. And this should make it worthwhile for industry members to participate in the monograph process.

Markus Lipp, PhD, is the senior director of food standards, and Nandakamara Sarma, PhD, the director of dietary supplements standards, for the US. Pharmacopeial Convention (USP), which is responsible for publishing the Food Chemicals Codex and the Dietary Supplements Compendium. Other USP staff that contributed to this article are Gabriel Giancaspro, PhD; Carla Mejia, PhD; Anton Bzhelyansky, PhD; Donna Kaye Wilson, PhD; and Claudia Costabile, M.A. Visit www.usp.org.
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Food and Drinks for Bone and Joint Health

They’re not targeting who you think.

BY INNOVA MARKET INSIGHTS

Considering the strong bone health and joint health needs of the aging population, it’s surprising that a large number of food and drink products promoted for bone and joint health target other populations instead. The baby food market is the biggest user of bone-health and “added calcium” claims. As for joint-health food and drinks, the greatest number of products point to our furry friends over in the pet food market.

The good news is that more consumers in the mainstream seem to understand the link between calcium and bone health. This has sparked more product development with mainstream positioning. Bone-health claims are more prevalent today, but the numbers indicate there is still a lot of room to grow. Just over 0.6% of global food and drink launches recorded by Innova Market Insights in 2013 featured bone-health claims. This figure goes up to 1% if we include “added calcium” claims. By contrast, food and drinks featuring joint-health claims are still few: just 0.1% of global food and drink launches.

Bone Health

While baby food was the leader in bone-health and “added calcium” claims in 2013, accounting for 32% of total global bone-health food and drink launches, dairy products were not far behind. In 2013, dairy foods accounted for just under 30% of global bone-health food and drink launches. These two categories dominated, followed by pet food and cereal products, which came in at 13% and 6%, respectively.

Looking at the dairy sector in terms of product type, milk and dairy drinks led bone-health and “added calcium” claims. Milk and dairy drinks represented 40% of total bone-health dairy launches in 2013. Next up were alternative dairy drinks (20%) and yogurt (20%). (Note: If you look at the percentage of bone-health launches in each product’s specific market, however, the leader changes. Nearly 14% of total alternative dairy drink launches featured a bone-health claim. But a smaller 9% of the—admittedly larger—milk and dairy drinks market used bone-health claims, and just 3% of the yogurt and drinking yogurt/fermented market touted bone-health claims.)

Of the bone-health specialty brands targeting the dairy market, perhaps most notable is Calin from Yoplait, which has been on the French market for a number of years as a high-calcium, fresh cheese product. In France, the brand extended in 2011 with a Calin+ range of bone-health yogurts for women over the age of 55 and again in 2013 with the addition of two active-health drinks.

The Calin+ range also launched in the UK in summer 2012. In the UK, the brand is launched in 2010, Smart Balance’s Buttery Spread with Calcium is a good source of calcium (100 mg) and an excellent source of vitamin D (50% daily value), as well as an excellent source of ALA omega-3 (350 mg/serving). Positioned squarely on a bone-health platform with the tagline “Calcium + Vitamin D for Strong Bones” prominent on packaging. The marketing, however, does not target older women as strongly as it does in France. Rival dairy brand Danone also has an offering: its Densia bone-health yogurt and drink brand in a number of countries, including Spain, Japan, and Brazil.

Other active-health drink makers are leveraging bone health to add value to their existing lines. Benecol, the cholesterol-lowering dairy drink brand with plant sterols, extended its product range in the UK in late 2013 with two dairy drinks, one of which is Benecol Plus Bone Health with added calcium and vitamin D.

Beyond dairy, bone-health claims are popping up in spreads. In the United States, the Smart Balance healthy spread range launched a Buttery Spread with Calcium. And in the UK in 2013, Dairy Crest added three functional-food lines to its Clover spreads range, under the brand name Clover Additions. Products include Clover Additions Strong Bones, marketed as rich in vitamin D and a source of calcium.

Joint Health

The joint-health food and drinks market is much less developed than the bone-health food and drinks market. While interest is
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growing in joint-health dietary supplements, this excitement has yet to move into the mainstream food and drinks market in any significant way.

In 2013, pet food accounted for 80% of global product launches with a joint-health positioning. Once we exclude pet food, however, product activity looks highly fragmented. The next clear user of joint-health product claims would be soft drinks, accounting for just under half of total joint-health food and drink launches. Some of these soft drinks, however, may be positioned as supplement-style products. Joint Juice is one of the earliest examples. The brand launched the first ready-to-drink glucosamine supplement in the United States in 2001. Since then, it has added an Easy Shot variant, including Extra Strength Easy Shot in 2013 containing 1500 mg of glucosamine, 1200 mg of chondroitin, and the Hyal-Joint proprietary protein and collagen ingredient blend.

Some other soft drinks make multibenefit promises, including Michelle’s Miracle Original Tart Montmorency Cherry Concentrate, which is marketed as promoting healthy joints and supporting sleep patterns and anti-inflammatory response. Frieda’s Moab Rejuvenate Açai Juice Superfruit Blend touts omega-3 fatty acid DHA for heart and brain health, as well as natural, plant-derived glucosamine for joint health. The Xango juice drink, meanwhile, focuses on the superfruit properties of mangosteen to support respiratory health, immune health, heart health, and intestinal health, as well as joint health.

Extending Beyond Supplements

While food and drinks for bone and joint health continue to launch, it’s clear that the market, particularly for joint-health products, remains largely confined to supplements. Otherwise, products target specialty markets such as baby food for bone health and athletes for joint health.

Considering the aging population and interest in maintaining active lifestyles, there is a greater opportunity for these kinds of products in the mainstream market. Developing convenient products with a good taste profile is key to tempting consumers, particularly in the United States, away from dietary supplements and toward specifically formulated food and drinks.

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When must companies take control of consumer-generated content?

BY JOHN E. VILLAFRANCO AND KATIE BOND, KELLEY DRYE & WARREN LLP

Social media is a powerful cog in today’s marketing machine. It’s dynamic. It’s personal. It gives consumers a voice. But as valuable as consumer-generated content is, it’s not without risk.

A company, for instance, may diligently follow FDA’s rule that claims to treat or prevent a disease cannot be made for dietary supplements.1 Consumers, however, are not beholden to FDA’s rule.

On a company’s website or social media page, consumers can make statements such as “Product X is helping me steer clear of any colds this winter” or “I’ve overcome my type 2 diabetes with Product X.” Scenarios like these beg the question: When it comes to social media, are companies responsible for the regulatory correctness of consumer-generated content?

FDA recently addressed this question head-on in guidance for drug companies. No similar guidance, however, has been provided for dietary supplement companies, and questions persist.

Guidance for Drug Firms

In January, FDA issued draft guidance providing recommendations to drug companies on submitting online promotional materials on submitting online promotional materials— including online promotions—at the time of initial dissemination.2 The new guidance covers which online materials FDA expects drug companies to submit and what FDA believes are best practices for making submissions.

One portion of the guidance, in particular, has raised questions over consumer-generated content. The passage indicates that drug companies need not submit “independent” consumer-generated content.

Specifically, the guidance states that, in FDA’s view, a drug company “is not responsible for UGC [user-generated content] that is truly independent of the firm (i.e., is not produced by, or on behalf of, or prompted by the firm in any particular).” The guidance explains further that “FDA will not ordinarily view UGC on firm-owned or firm-controlled venues such as blogs, message boards, and chat rooms as promotional content on behalf of the firm, as long as the user has no affiliation with the firm and the firm had no influence on the UGC.”

As support for its stance, FDA cites Section 230 of the Communications Decency Act (CDA). Section 230 states that “[n]o provider...of an interactive computer service shall be treated as the publisher or speaker of any information provided by another content provider.”

Congress originally enacted the CDA to censor online pornographic material. Section 230, however, has been interpreted as providing protection to any company offering an online forum for third-party postings. This protection has been hailed as enabling a level of Internet freedom that is unique to the United States. With the protections of Section 230, companies like Facebook and YouTube can exist without undue liability for their users’ posts. Likewise, companies
Section 230: Not So Clear for Dietary Supplements

Although dietary supplement companies are not obligated to submit their marketing materials to FDA at the time of dissemination, their marketing is subject to postmarket regulation by both FDA and the FTC.

FDA Guidance

FDA has not issued any guidance for dietary supplement companies similar to what it recently issued for drug companies. Moreover, FDA actions on at least one occasion suggest that the agency might view Section 230 differently for the purposes of dietary supplement marketing.

A 2011 FDA warning letter appears to conflict with FDA’s stance in its recent drug guidance. In the warning letter, FDA alleged that a dietary supplement company had made unapproved “therapeutic claims” (i.e., claims to treat or prevent a disease) not only on its website but also on its Facebook page. FDA stated, specifically, that the Facebook page “include[d] numerous testimonials...which make disease claims such as ‘When I started taking OM24, within days my osteoarthritis was relieved’ and ‘I totally control my diabetes and blood pressure with the tablets.’” It is not clear whether the company itself or consumers posted the testimonials. If it was the latter, then it appears that FDA would hold a dietary supplement company responsible for consumer-generated content, regardless of the protections of Section 230 of the CDA.

FTC Guidance

The FTC’s Endorsement Guides address the use of testimonials and other third-party statements used in advertising, including advertising for dietary
supplements. In 2009, the FTC issued a revised version of its Endorsement Guides. Among other things, the FTC sought to articulate when a third-party statement in online media might be considered “advertising” that is subject to regulation. The FTC stated that the “fundamental question to ask is whether, viewed objectively, the relationship between the advertiser and the speaker which case there is no endorsement, or (2) acting on behalf of the advertiser or its agent, such that the speaker’s statement is an ‘endorsement’ that is part of an overall marketing campaign...”

This “test” does not answer, to any satisfactory degree, the question of whether consumer-generated content might be the responsibility of advertisers, in the FTC’s view. It remains an open question, for instance, whether, in the FTC’s view, simply providing a platform for posts or seeking certain types of posts (e.g. “Tell us why you like Product X”) might equate to “sponsorship.”

In the five years since the FTC issued its revised Endorsement Guides, the agency has taken enforcement action that has helped further clarify its views on more straightforward issues, such as gifts and payments to bloggers.

The FTC, however, has yet to address the range of questions surrounding consumer-generated content that is spontaneously posted to company sites.

What’s a Dietary Supplement Company to Do?
Against this regulatory background, dietary supplement companies are left to wonder what to do about consumer-generated content appearing on their websites and social media pages. The strict legal answer is that Section 230 of the CDA applies equally to dietary supplement companies and drug companies—meaning that independent, consumer-generated content is largely not a liability. No company, however, wants to be the test case if FDA or the FTC decide to take

No company wants to be the test case if FDA or the FTC decide to take an aggressive stance.
an aggressive stance (or, in the case of FDA, continue an existing aggressive stance).

In the absence of clear guidance, each company will need to carefully consider Section 230 and chart its own path based on its own business model and risk tolerance.

The route of least risk is obviously to decline to provide any means for consumers to post on company websites or social media sites. But that may not be feasible or desirable in today’s social media-rich environment. A more open, “middle ground” might be to review comments periodically and remove those statements that implicate high-risk areas—e.g., statements suggesting disease treatment or prevention and “too good to be true” weight-loss claims.

Companies allowing any consumer-generated content should bear in mind that the protections of Section 230 may not be unlimited. Similar to the manner in which FDA’s drug guidance seeks to exempt only content that is truly “independent,” courts have found that certain actions by website owners will prevent Section 230 from applying. For instance, in a decision last year that has created controversy, a court held that Section 230 did not protect a website owner who “intentionally encourage[d]” the postings at issue and “adde[d] his own comments ratifying or adopting the posts.”

The website owner was being sued for defamation and libel over the postings. In another case, the Ninth Circuit held that immunity did not extend to the website Roommates.com because the company had offered drop-down menus that prompted third-party statements that were alleged to be discriminatory in violation of fair-housing laws.

A dietary supplement company allowing consumer-generated content will need to assess how it requests and presents third-party content, in light of the existing case law. This is, of course, especially true if a company chooses to allow free-flowing consumer-generated content, without any monitoring or deletions.

View references online at www.NutritionalOutlook.com/1405/Global_Regulations/Social

John E. Villafranco is a partner in the advertising and marketing practice at Kelley Drye & Warren LLP in Washington, DC. Villafranco is highly respected for offering comprehensive legal advice that emphasizes risk analysis and sound business practices for corporations involved in advertising and marketing. He can be reached at jvillafanco@kelleydrye.com. Katie Bond provides regulatory counseling and litigation support regarding matters involving the FTC and the FDA to marketers of a variety of consumer products, including dietary supplements, foods, weight-loss products, cosmetics, and sports equipment.
Here in 2014, there is little doubt that functional foods represent a market segment with continued growth potential and staying power—that is, if the ingredient and food industries can do it right. In fact, functional foods and beverages are poised to "the hottest growth area of the next decade"—and, in the United States specifically, "a significant growth category"—according to Jeff Hilton, chief marketing officer and cofounder of BrandHive, a marketing firm representing health and wellness brands.

Indeed, supplementation through food and beverages (termed convergence) keeps gaining traction, particularly in the current key wellness areas of energy and performance, healthy aging, immunity, digestion, cardiovascular function, joint support, weight loss, and diabetes. A quick tour of one’s local large supermarket reveals such functional ingredients as calcium, fiber, vitamins, minerals, omega-3 fatty acids, hemp, probiotics, proteins, and more, in foods and beverages ranging from snack foods and frozen desserts to juices and beverage shots.

Convergence seems to be an area worthy of ingredient suppliers’ attention and investment, as well as the attention and investment of premixers and firms providing technologies for incorporating ingredients into foods and beverages. However, functional foods do present challenges along with great opportunity, so suppliers who are ready to channel time, R&D, and resources into this market segment are advised to do their homework and learn from those already competing successfully in the convergence game.

**Ingredient Challenges**

Having a valuable, sought-after ingredient is one thing; getting it into a food or beverage matrix successfully is another. The latter can be complicated, but challenges are overcome through inventiveness, creativity, and the rigorous application of science.

Russ Hazen, PhD, premix innovation manager at Fortitech Premixes by DSM (Schenectady, NY), admits that there are technical issues involved in the formulation of any product, but the primary factors for functional foods are nutrient stability and organoleptics. For instance, he describes the high heat, humidity, and pressure sometimes involved in extruding food products or processing them with steam. "Many nutrients do not tolerate these conditions well, particularly some of the B vitamins and vitamin C. Even the fat-soluble vitamins like A, D, and E are susceptible to oxidation during processing," he says. These sensitive nutrients can still be added to products, but the conditions of processing must be considered when selecting the amount of nutrients to add.

One solution to this problem is to add overage, Hazen explains, to account for expected losses. "By conducting stability tests in the finished product, these overages can be optimized to account for the specific losses seen in the manufacturing of a specific product."

Thomas Douglass, category director, food and beverage, Corbion Caravan (a premixer based in Lenexa, KS), agrees with Hazen on this point. He advises that the anticipated loss of each nutrient caused by such processing stresses as heating, pasteurizing, baking, or shearing, in addition to shelf-life stresses, must be part of the formula from the beginning. And Bob Green, president, Nutratech Inc. (West Caldwell, NJ), concurs: "Many functional foods and beverages require miscibility and water solubility to properly mix in the ingredient. With Advantra Z—our thermogenic bitter orange extract for diet, fitness, and energy—we continue to address and refine these qualities."

Michael Crabtree, sales manager, sports nutrition and supplements, Bioenergy Life Science (Minneapolis), says that for his company, it is the susceptibility of D-ribose to react with amino acids, particularly those amino acids with high-charge functional groups, which can prove tricky. This hurdle can be
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negotiated, he says, by “avoiding mixing ingredients that have conjugate electrostatic natures.” Or, Crabtree offers, “Elimination chelation agents, such as copper, zinc, and others, can be added to attenuate the electrical attraction of the target ingredients.”

Even a time-tested ingredient like insoluble fiber can prove difficult to incorporate into functional foods, Jit Ang, executive vice president, research and development for International Fiber Corp. (North Tonawanda, NY), says that working insoluble fiber into food products requiring a smooth mouthfeel or a small serving size can be very challenging. This is because most insoluble fibers contribute some chalkiness or grittiness to end products, and a serving of food must contain at least 2.5 g of fiber to make a fiber claim. “This limits the scope of food products that can be targeted for insoluble-fiber fortification,” Ang says. But, he adds, to overcome this limitation, his company is “currently developing a new class of insoluble fibers that is ‘smoother’ and therefore less gritty.”

Probiotics have been in the market for a while but present some challenges to certain foods. “Traditional probiotics like Lactobacillus acidophilus are very, very difficult to keep alive during processing,” says Michael Bush, senior vice president, Ganeden Biotech Inc. (Cleveland). His company’s star ingredient, the probiotic strain GanedenBC30, forms spores and is therefore harder during processing. “We have been able to overcome most of the usual probiotic challenges by the sheer physical makeup of the organism itself, and we’ve also become good at knowing where in a particular food application we should integrate the probiotic to get the best from it, especially through process,” Bush explains. “For example, say we’re talking about a [nutrition] bar. There are a few places you can add the probiotic. If the bar is enrobed in chocolate, you can add the probiotic to the chocolate. If it’s bound with honey, you can work it in there. But you’ll need to determine how long the probiotic will be in there, how hot it’s going to be. You want to be sure you’re not forcing the germination of the bacteria.”

In the case of the bar, Bush says, Ganeden would normally blend the probiotic in with the mix of dry ingredients, then the manufacturer would roll out the bar and pack it. Ganeden would shelf-life test the finished product in its own microbiology lab to ensure the probiotic count is above spec at the end of shelf life.

For drinks, solubility is the key. Agglomeration can come to the rescue and increase the solubility of an ingredient when that ingredient is mixed with liquids, says Walt Zack- owitz, director of specialty ingredients for Innovative Food Processes (IFP; Faribault, MN). Agglomeration can also enhance “flow-ability” and assist with ingredient dosing and dispersion when working with a formula requiring expensive ingredients, he says.

**Even a time-tested ingredient like insoluble fiber can prove difficult to incorporate into functional foods.**

As for ensuring desirable organoleptics, the appropriate product form is crucial, Fortitech’s Hazen says. Encapsulating ingredients and changing processing procedures may be required to retain desirable sensory qualities.

Flavor masking is one option, of course, adds Bob Verdi, PhD, business director, health and wellness, for flavors supplier Virginia Dare (Brooklyn, NY). “Most functional ingredients will contribute off’ flavors to foods and beverages and present challenges to the product developer,” Verdi says. “Two areas where there is a lot of [flavor masking] activity are vegetable-protein enhancement and natural, high-intensity sweeteners, such as stevia.” The proteins can contribute beany, musty off’ flavors that require masking, he explains, and the sweetness profile of stevia can be made to more closely resemble that of sucrose via masking as well.

In addition to seeking innovative and scientific methods for overcoming chemical and technical formulation challenges, ingredient suppliers are also advised not to underestimate the importance of open, detailed, two-way communication with the marketer. “Too often purchasing departments will come to us and ask for a product with few to no specifics on what they actually need,” says Stacy Peterson, president and owner, ConnOils LLC (Big Bend, WI). “We can provide a lot of customization so that formulations work or can be tweaked to work with minimal time and expense. When we have all the specifics we need from the customer, it is uncommon for the initial material to fail.”

Learning from customers what didn’t go well in their trial process, if anything, Peterson adds, is critical. “More and more, food and beverage customers are coming to us for new ideas, especially sports nutrition folks. We love when they share their trial findings with us so that we can lend additional support to help them meet their needs. Usually the outcome is very successful.”

Ingredient suppliers will find the greatest success, Peterson concludes, “when open communication occurs that allows everyone involved to make the right decisions.”

**Efficacy in Dosing**

Ingredient suppliers understand that their respective ingredients provide the maximum health benefit only when the dose—in the case of functional foods and drinks, the amount present in the end product—is sufficient. Suppliers themselves must remain ever-vigilant about educating marketers on this matter—and on the price point involved.

“Efficacious doses can be characterized as being typically on the higher end of the ingredient’s dosing spectrum,” says Bioenergy’s Crabtree. “This poses inherent challenges to formulating ingredients at levels that can be successfully marketed.”

He adds that food companies generally operate on thinner profit margins than liquid-system companies do. The reasons for this discrepancy, Crabtree explains, include food companies’ navigation of more stringent regulatory oversight as well as food productors’ significantly higher cost and greater financial risks associated with a failed product launch. “These things all contribute to a higher price point,” Crabtree says. “And this higher price point exacerbates the likelihood of the price playing an important role in the dose.” However, he warns, “A fairy dusting of this and that does nothing for the consumer, directly impacts the morale of the target customer, and does not stimulate the desire to repurchase.”

Ganeden’s Michael Bush agrees that pixie dusting is still a problem in today’s functional foods market. “Pixie dusting is an issue across
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the board when you're looking at functional foods. In some cases, people just don’t want to pay the money to put an efficacious dose of any functional ingredient into a food product. We actually have standards for our customers that require them to use what is our tested minimum [dose]. They have to put an efficacious dose in, or we won’t work with them."

After all, if a supplier’s ingredient—due to a low dose—appears not to work, it reflects as poorly on the ingredient supplier as it does on the marketer. Bush encourages the industry to self-police on this issue.

Ingredient supplier and encapsulator Balchem Corp. (New Hampton, NY) is frequently asked by formulators what constitutes a meaningful or efficacious dose of choline, which the company provides. Kristine Lukasik, director, applications, scientific, and regulatory affairs for food and nutritional ingredients, has a thoughtful and research-based answer at the ready: "Choline intake in the United States is around 75% of what is recommended. Our typical suggestion, then, is addition of choline at 10% to 20% of the adequate intake—55 to 100 mg—which neatly addresses that intake gap and entitles the manufacturer to leverage the nutrient-content claims available for choline." This advice, she says, may go some way toward minimizing marketers’ temptation to fairy dust.

Innovate, Learn, Document, and Communicate

Ingredient suppliers, premixers, and firms with the most advantage in the functional foods space are those that provide the following: ingredient-protecting technologies, an in-depth scientific knowledge of the ingredient at hand (and documentation of that knowledge), a willingness to innovate and invest in R&D, a high regard for open communication with and education of marketers, and an awareness of the food industry’s constraints. To that end, International Fiber Corp.’s Ang advises, "It is always best if the project is not rushed but goes through all the required product development stages. This will result in the development of a final product that is superior in eating qualities and will have a higher degree of acceptability and sustainability in the retail marketplace."

Balchem’s Lukasik states, "There is no substitute for solid science, particularly in the form of clinical studies and formulation stability data."

Additionally, Ganeden’s Bush reiterates the importance of documenting the ingredient’s safety and efficacy. "We believe that the only way for a company to have a legitimate ingredient is to make sure it is documented as safe and effective," he says. "FDA GRAS designation is becoming more and more important. Our advice is to either invest in your ingredient or don’t participate in the market."

BrandHive’s Hilton advises suppliers to proactively "bridge the gap" between their ingredient and product applications. Bring in the food scientists, he urges, and meet the food and beverage people halfway in terms of R&D. "Participate more actively in this discussion to establish credibility for your ingredient with the food and beverage companies, and instill confidence."

And, finally, Bioenergy’s Crabtree offers the following counsel for the food manufacturers themselves: "My advice to them is to exercise simplicity when developing their products. Take a qualitative approach to development by using only the ingredients for which the regulatory bodies have the highest regard. Functional-ingredient overkill by adding as many functional additives as possible typically has a negative impact on the ingredient sourcing and cost."

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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Managing Blood Pressure
Where nutraceuticals stand in the fight

BY KIMBERLY J. DECKER

It almost sounds like a form of torture, but renal denervation—a treatment in which a clinician steers an electrode-tipped catheter into the arteries of the kidney to kill the nerve endings with two-minute zaps of radiofrequency energy—looked, until recently, like a promising treatment for patients with resistant hypertension. But then came a study (Bhatt DL et al.) published this April in The New England Journal of Medicine showing no significant difference in blood pressure outcomes between patients who received the treatment and those who underwent a “sham” procedure.

The news likely disappointed physicians desperate for a new arrow to add to their antihypertensive quiver. But in sending them and the medical community back to the drawing board, it may have done us all a favor—for when it comes to dealing with hypertension, the drawing board isn’t such a bad place to be. Because a multitude of variables—from heredity to obesity—contributes to hypertension, any approach to battling hypertension needs to be just as multivariate.

In a time of rising healthcare costs and rising hypertension rates, it’s worth remembering that good old-fashioned “lifestyle” factors, including the use of supplements, can take the pressure off our healthcare spending and our vascular systems.

Taking a Toll
Simply put, hypertension, or high blood pressure, is a measure of how much blood the heart pumps and the resistance the arteries exert against its flow. “The more blood your heart pumps and the narrower your arteries, the higher your blood pressure,” explains Harry B. Rice, PhD, vice president, regulatory and scientific affairs, Global Organization for EPA and DHA Omega-3s (GOED; Salt Lake City).

We express blood pressure as a ratio of the systolic pressure (measured in mmHg) generated when the heart beats to the diastolic pressure generated as it rests between beats. Roughly speaking, a “safe” blood pressure might be somewhere around 115/75 mmHg, whereas the generally accepted cutoff for “high” blood pressure is 140/90 mmHg or above.

As Sanni Raju, PhD, RPh, CEO and chairman, Natreon Inc. (New Brunswick, NJ), points out, “Many doctors do not prescribe any medications until they see blood pressure readings of 140/90 mmHg.” Alas, doctors are seeing more of those readings these days. In fact, current blood pressure statistics, as reported by the Centers for Disease Control and Prevention (CDC), are what Rice calls “eye opening.”

To wit, one in every three adults—fully 67 million Americans—has high blood pressure, while roughly the same percentage has pre-hypertension: not quite high enough to qualify as “high,” but still high enough to merit attention. Of those Americans with high blood pressure, less than half (47%) have their condition under control. No wonder hypertension costs the country some $47.5 billion annually in healthcare services, medications, and lost productivity.

Perhaps more costly, though, are the more serious implications. As Raju notes, “Hypertension can lead to heart disease, coronary artery disease, stroke, aneurysms of the arteries, and peripheral arterial disease and is a cause of chronic kidney disease, ultimately reducing life expectancy.”
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Heart Health

With potential consequences that dire, the medical community has tried to learn more about how hypertension arises, and how best to treat it when it does. And as far as Kelley Fitzpatrick, director of health and nutrition, Flax Council of Canada (Winnipeg, MB), is concerned, it’s about time. Hypertension, she believes, “is a disease that we haven’t paid as much attention to from either the pharma or non-pharma side.”

What we do know is that hypertension can be either primary or secondary. Secondary hypertension “is caused by certain conditions affecting the kidneys, heart, endocrine system, arteries, et cetera,” Raju says. It can be associated with adrenal gland

HYPERTENSION DURING PREGNANCY MAY RELATE TO MAGNESIUM DEFICIENCY

Despite its many wonders, pregnancy exposes women to potential health complications—one of which is high blood pressure. But a link may be found in magnesium deficiency during pregnancy.

Writing in the Archives of Gynecology and Obstetrics, European researchers explain that blood pressure can shift quite significantly, with typical decreases during the first trimester and a return to pre-pregnancy levels during the third trimester. In as many as 10% of women, however, blood pressure increases around week 30 of pregnancy, and “if the systolic/diastolic blood pressure reaches 140/90 [mmHg], it is defined as pregnancy-induced hypertension.”

Hypertension during pregnancy can lead to eclampsia, if not other negative consequences, but these European researchers are questioning whether the risk of hypertension can be avoided with proper nutrition. To see if magnesium deficiency makes pregnant women especially susceptible to hypertension, the researchers recruited 61 first-time pregnant women to consume 300 mg of magnesium citrate or placebo, from week 25 of pregnancy until childbirth.

At week 37, the magnesium group managed an average diastolic blood pressure significantly lower than placebo (72 mmHg compared to 77 mmHg), and fewer magnesium users held a diastolic blood pressure equal to or greater than 15 mmHg (a predictor of pre-eclampsia). The researchers also observed an inverse relationship between magnesium excreted in urine and diastolic blood pressure. No significant differences were found in systolic blood pressure, which is generally the more fluctuating of the two blood pressure readings.

This isn’t the first time that magnesium deficiency has been tied to increased risk of hypertension, but studies have yielded both supporting and countering results. Furthermore, this study has limitations, including its small sample size and a lack of recording of dietary magnesium intake during pregnancy.

Protina Pharm. GmbH (Ismaning, Germany) provided Magnesium Diasporal supplements for the study. High amounts of magnesium can also be found in foods such as pumpkin seeds, spinach, and chard. — Robby Gardner, Associate Editor

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tumors, for example, and unlike primary hypertension tends to appear abruptly. The condition "needs medical intervention," he continues, "and there are many effective pharmaceuticals for its treatment."

Primary hypertension, also known as essential hypertension, is more common and derives from lack of exercise, a "modern" diet poor in fresh fruits and vegetables, obesity, smoking, excess alcohol consumption, stress, genetics, and an imbalanced intake of minerals like sodium, potassium, magnesium, and calcium. The condition tends to creep up gradually, usually over many years. Considering the number of Americans who don't exercise or eat healthily, it's not surprising that this type of hypertension is on the rise.

Hypertension pharmaceuticals may often provide only symptomatic relief and require lifelong use. "In addition," Raju says, "most of them have side effects." Indeed, the true cost of pharmaceutical treatment includes far more than just the drugs' sticker price—although, with the population aging, those costs are only going to rise. Fitzpatrick says.

While it's largely secondary hypertensive patients that may spiral into what Fitzpatrick calls "this unending cycle of drugs," even primary hypertensives often, on doctors' advice, turn to pharmaceuticals. It's a judicious decision, as "high blood pressure is a serious condition for which a physician should be consulted," Rice notes.

But pharmaceutical intervention might not be the answer alone. "Lifestyle modifications," Rice says, "may allow an individual to delay, indefinitely, the use of prescription blood pressure–lowering medication."

Indeed, by reversing behaviors that lead to primary hypertension in the first place—by exercising more, losing weight, quitting cigarettes, reducing alcohol intake—primary hypertensives may also reverse the upward trend in their blood pressure measures.

Perhaps no other lifestyle change is more effective at this than diet. "An excess of sodium, carbohydrates, saturated fats, trans fats, and sugars are dietary culprits in hypertension," Raju says. Avoiding these triggers while increasing consumption of fruits, vegetables, beans, fish, whole grains, and other "whole" foods "is essential to preventing or mitigating" the condition.

Yet even diet has its limits. Consider, for example, the issue of sodium. A 2013 Institute of Medicine (IOM) report (Strom BL et al.) concluded that no rational reason exists to reduce sodium consumption below 2,300 mg/day—much higher than the 1,500 mg/day that national dietary guidelines recommend for the prevention of heart attacks and stroke. Further, Raju notes, "A low-sodium diet is important to reducing the risk of hypertension, but the body needs a balanced intake of sodium, potassium, magnesium, and calcium. Thus, one cannot eliminate sodium completely."

Even setting aside our evolving thinking on sodium, maintaining the sort of gold-star diet that experts recommend as optimal for vascular health takes more work than many of us can afford. "In today's fast-paced society," Raju notes, "unfortunately, not many people have time to eat nutritionally balanced fresh foods or exercise regularly."

And that's where supplements come in. As Anil Shrikhande, president, Polyphenolics (Madera, CA), says, "Supplements fill the gap of inadequate dietary habits and help maintain normal blood pressure." Offering the advantages of lower cost compared to pharma, prescription-free access, and consumer appeal, supplements may also produce fewer, if any, side effects and have a general record of safety.

Among the supplements already identified as having a positive effect on blood pressure are resveratrol, vitamin D, anthocyanins, magnesium, Pycnogenol, coQ10, omega-3 fatty acids, acetyl-L-carnitine, and melatonin, Raju says. "Many of these work by blocking the angiotension-converting enzyme—ACE—and improving endothelial function," he notes. And while we still have a lot to learn about how these nutrients effect their beneficial changes, here's some of what we do know.

**DHA+EPA**

These days, it’s hard to find a condition that doesn’t respond positively to the long-chain omega-3 fatty acids DHA and EPA. Hypertension is no exception. In fact, a meta-analysis, published this March in the American Journal of Hypertension (Miller PE et al.), looked at 70 randomized controlled trials (RCTs) involving adults given DHA and EPA...
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via seafood, fortified foods, or dietary supplements. The results indicated that omega-3s equal, and in some cases exceed, the effect of recommended lifestyle changes like increased exercise and reduced alcohol and sodium in lowering blood pressure.

The study, which GOED funded, showed the most significant effects among subjects with existing high blood pressure. In these subjects, DHA and EPA produced an average decrease in systolic and diastolic blood pressure of 4.51 and 3.05 mmHg, respectively.

In addition, Rice points out that though nonselective beta-blockers have long been the “first-line treatment” for primary hypertension, “this is changing due to the associated side effects, as well as limited benefits.”

In fact, he notes that a recent Cochrane Review (Wong GWK, Wright JM) on the blood pressure–lowering efficacy of nonselective beta-blockers for primary hypertension reported that these reduce blood pressure by an average of 8 mmHg systolic and 5 mmHg diastolic. “While these results are slightly better than those associated with omega-3s”—4.51 mmHg systolic and 3.05 mmHg diastolic—“omega-3s don’t increase the risk of mortality. [And] while newer blood pressure–lowering drugs decrease blood pressure much better than nonselective beta-blockers, side effects are still an issue,” he says.

Whole Flaxseed

Long-chain DHA and EPA aren’t the only omega-3 fatty acids with blood pressure–lowering potential. We don’t really know how the flaxseed exerts these effects, Fitzpatrick says, as the research hasn’t revealed the mechanism of action. It’s likely that flax’s ALA played a part, as may have its fiber and lignan content. But bioactive peptides in flax present another “very interesting area of ongoing inquiry,” she says, as these peptides serve as ACE inhibitors, helping to dilate blood vessels. Whatever the reason, “Researchers agree that it’s probably a synergistic effect of all of the above” that makes flax effective, Fitzpatrick says. Stay tuned.

Grape Seed Extract

A very different seed—that of the grape—could contain the ingredients for yet another supplement with antihypertensive capabilities.

According to Shrikhande, Polyphenolics’s unique grape seed extract, which goes by the name MegaNatural-BP, “opens the door for reducing blood pressure before it gets to the hypertension range.”

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NEW STUDIES POINT TO VITAMIN D FOR LOWER BLOOD PRESSURE

New evidence supports higher vitamin D levels for lowering blood pressure. The Vitamin D Council, a nonprofit group, has updated its health summary with studies (from 2013 and 2014) looking at this relationship. Current research on vitamin D for hypertension is somewhat limited, making these studies a welcome addition.

A meta-analysis published in the European Journal of Epidemiology¹ last year found a dose-dependent link between vitamin D levels and hypertension: each 10-ng/ml increase in vitamin D led to a 12% lower risk of hypertension. Specifically, the researchers looked at baseline levels of circulating 25-hydroxyvitamin D and found that those with the highest levels of vitamin D had a 30% lower risk of developing hypertension compared to those with the lowest vitamin D levels. The meta-analysis encompassed 283,537 patients and 55,816 incidents of hypertension.

Statistics show a significantly higher rate of high blood pressure in African-Americans than in whites, and that the black population tends to have lower circulating levels of 25-hydroxyvitamin D. A 2013 study published in Hypertension² looked at whether vitamin D3 can help this segment of the population. Researchers conducted the study over three months during two winters (a period of lower access to sunlight) and evaluated, in randomized, double-blind fashion, 250 subjects with normal hypertension, in four study arms: placebo, 1000 IU cholecalciferol (vitamin D3) daily, 2000 IU D3 daily, or 4000 IU D3 daily. They evaluated subjects’ blood pressure and 25-hydroxyvitamin D status at baseline, 3 months, and 6 months and found a dose-dependent relationship between vitamin D status and hypertension. For each 1-ng/ml increase in plasma 25-hydroxyvitamin D, subjects saw a significant 0.2-mmHg reduction in systolic blood pressure. Researchers concluded that three months of oral vitamin D3 supplementation “significantly, yet modestly, lowered systolic blood pressure” in blacks—although they noted that some subjects may have been taking blood pressure medication.

Finally, a small, 15-subject study published in 2014 in the Journal of the Renin-angiotensin-aldosterone System (JRAAS)³ looked at whether vitamin D3 may help to reduce the activity of the renin-angiotensin system (RAS), which regulates blood pressure. (An overactive RAS can increase blood pressure.) Subjects took a high, 25,000-IU dose of vitamin D3 once per week for two months. Researchers found that vitamin D3 supplementation helped “blunt systemic RAS activity” and reduce hypertension.

How does vitamin D help to lower blood pressure? According to research, vitamin D may not only help regulate the RAS but may also bind to the receptors of cells that lead to arterial plaque, helping to reduce a buildup of these cells, the Vitamin D Council says. But, the council notes, “researchers still aren’t sure what causes the blood pressure system to become overactive and don’t know yet for sure how vitamin D can help to control its activity.”

Research on vitamin D and hypertension is still very much emerging. More is needed, the council says, in light of the fact that many existing studies have a small sample size and that results between studies have been inconsistent. The authors of the European Journal of Epidemiology meta-analysis agree: “The evidence on the association between baseline vitamin D status and risk of incident hypertension in general populations is limited and has not been reliably quantified,” they wrote.

The Vitamin D Council takes a cautious approach. “If you have hypertension or you are trying to prevent hypertension and want to take vitamin D, it is unlikely to make your hypertension worse or cause you any harm, as long as you take less than 10,000 IU per day. However, we also can’t say for sure if it will help to prevent or treat hypertension.” — Jennifer Grebow, Editor-in-Chief

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* Clinical Trial conducted by Morton Scientific Group, Cambridge, Ontario, Canada
Shrikhande says, “It is a strong antioxidant and maintains its action in keeping the major blood vessels supple, as in a healthy person.” In very high hypertensives, the ingredient even “acts as a synergizer to maintain normal blood pressure,” he says. Also of note: it may be safer than some pharmaceuticals, with “no complications, side effects, or interactions” reported as adverse events.

Gooseberry and Ashwagandha

Two other nitric oxide inhibitors attracting attention also come from the plant world: Phyllanthus emblica, also known as Indian gooseberry or amla, and Withania somnifera, or ashwagandha. In multiple randomized, double-blind, placebo-controlled clinical studies, Raju says, extracts of both botanicals have improved endothelial function in type 2 diabetics currently on conventional treatments, as well as in subjects with symptoms of metabolic syndrome—in both cases by increasing production of nitric oxide.

Also promising is their ability to decrease levels of C-reactive protein, a biomarker for inflammation, by upwards of 50%. This is “a highly significant reduction that may also contribute to reduced blood pressure, as inflammation is believed to be involved in causing many diseases,” Raju says. The botanicals appear to increase the body’s production of glutathione, a natural antioxidant, and reduce total cholesterol, LDL, and triglyceride levels while increasing levels of HDL, too, “all of which reduces plaque formation in the blood vessels, thus helping reduce blood pressure,” Raju says.

His company sells extracts of Indian gooseberry and ashwagandha under the respective names of Capros and Sensoril, and has put them to the test in multiple double-blind, placebo-controlled crossover clinical trials. In studies of healthy subjects subjected to cold-pressor and mental stress, Raju says, both products have shown an ability to lower radial and aortic systolic and diastolic blood pressure, as well as the augmentation index (AIx), an indirect measure of arterial stiffness. Conversely, they significantly increase the subendocardial viability ratio (SEVR), a measure of the inflow and outflow of oxygen to the heart muscle—something we’d all like to see occur with ease.

Alas, for those with hypertension, it may not be so easy. But they and their medical professionals have lots of tools to improve the situation. As Raju says, “Lifestyle and dietary changes have to be the mainstay for hypertension management, but the more we learn, the more we learn that supplements can help.”

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. Contact her at kim@decker.net.
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Omega-3 fatty acids derived from oily fish and other sources are essential structural components of human cell membranes and play significant roles in moderating inflammation. Among the family of omega-3 fatty acids, docosahexaenoic acid (DHA) and eicosapentaenoic acid (EPA) have been well-researched for their ability to support heart health, including helping to prevent heart disease, helping to normalize blood fats such as triglycerides, and maintaining healthy blood pressure levels, as a recent meta-analysis attests. (Read about this meta-analysis on page 56.)

But, the potential benefits of omega-3 fatty acids extend beyond heart health. Recent strong evidence points to their beneficial impact on patients with critical illnesses, an area of omega-3 research that hasn’t garnered much mainstream attention but is significant nonetheless. Furthermore, evidence from recently published investigations highlights emerging indications, including unique, cognitive benefits of omega-3s, especially on memory function, as well as potential in addressing sleep-related issues.

Omega-3s

Beyond the Heart
Omega-3 benefits for brain health, sleep, and critically ill patients

BY IRFAN QURESHI, ND

Fish Oils for Critical Illness
A fair amount of evidence points to the benefit of omega-3 fats from fish oil in patients with critical illness. Among other actions, omega-3 fatty acids have potent anti-inflammatory effects that are believed to be of primary usefulness in these cases. Researchers have found that the administration of fish oil as continuous infusions as a component of a post-surgical enteral nutrition protocol has the potential to improve patient outcomes and reduce morbidity and mortality.

Jacquelyn Glenn and Paul Wischmeyer conducted a review of clinical trials encompassing the use of fish oils in critically ill patients with lung injury, including those with acute respiratory distress syndrome (ARDS). Their examination of trials published between 1999 and 2012 found that the continuous administration of an enteral nutrition formula containing fish oil was associated with significant reductions in 28-day mortality, intensive care unit (ICU) length of stay, and time on a ventilator, compared to standard formula administration.

In infants, intestinal failure is a condition that sometimes occurs as a result of certain gastrointestinal infections, which then leads to a significant portion of the small intestine being surgically removed. It is a condition associated with severe nutrient malabsorption. During the interim period after surgery, patients generally receive most of their nutrition through a combination of enteral feeding and parenteral intravenous nutrition. Current standard protocols often involve the intravenous infusion of soy-based lipid formulas; however, this often leads to complications, including cholestasis (disrupted or blocked flow of bile from the liver to the intestines), which is associated with high morbidity and mortality in infants. Recent trials have investigated the use of fish oil–containing formulas as alternatives to traditional soy-based lipids in these cases.
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Qing Yang and colleagues from Wake Forest University in Winston-Salem, NC, assessed the benefits of early enteral feeding of fat and fish oil in premature infants who had undergone surgical bowel resection and found that this led to a decreased need for intravenous lipid therapy, increased uptake of nutrients through enteral nutrition, lower risk of cholestasis, and greater gains in weight and length compared to the control group receiving standard care.\(^3\) Taken together with previous studies in patients with intestinal failure showing benefits using lipids from fish oil, this research indicates favorable outcomes from this simple and cost-effective intervention and significant reductions in both morbidity and mortality.

**Memory and Prevention of Dementia**

The relationship between dietary fat intake and cognitive development has been examined previously in several research studies. While the essential omega-3 fatty acids have been linked to various cognitive benefits, the research remains somewhat ambiguous regarding clinical results.

Carol Baym and colleagues from the University of Illinois in Urbana, IL, suggest that a potential reason for these mixed research findings is that studies have tended to use assessment techniques that are often not well suited to delineating the specific interactions of essential fatty acids with brain structures.\(^4\) Looking at the interactions of nutrients and specific brain areas, and assessing the cognitive processes influenced by those areas, should yield better outcomes in reaching conclusions about the effects of different dietary fats on cognitive development.

In this light, the research team conducted a study to assess the impact of dietary fat intake on hippocampus function in 52 healthy children aged 7–9 residing in the East-Central Illinois area.\(^5\) Specifically, the researchers assessed the impact of dietary fat intake on relational memory function, which is significantly influenced by the hippocampus, and contrasted this with item memory retention ability, known to be largely hippocampus-independent. Item memory encompasses functions like remembering simple facts. Relational memory, on the other hand, plays a role in scholastic achievement and learning and involves the formation of memories surrounding complex situations that require interpretation and organization.

In the study, children completed a memory task that was designed to assess both hippocampal-dependent as well as hippocampal-independent memory function. A standardized food-frequency questionnaire was used to assess dietary intake. The results of the study indicated significant positive associations between the intake of omega-3 fatty acids and accuracy regarding the relational memory indicators. In contrast, saturated fatty acid intake was negatively correlated with both relational and item memory task performance. No clear correlation was observed (positive or negative) for omega-3 fat intake on item memory abilities, indicating the preferential influence of omega-3 fatty acids on hippocampus function.

Ultimately, the results of the study indicated that children who consumed more omega-3 fats as a part of their diet had superior relational memory compared to those children consuming lower amounts.

While the study mentioned above showed that omega-3 fatty acids support hippocampus function and development in children, at the other end of the age spectrum the loss of total brain volume and atrophy of the hippocampus are indicators of dementia, including Alzheimer’s disease. Studies indicate the importance of DHA and EPA in maintaining brain structure and function. DHA makes up approximately 40% of the fatty acid profile in grey matter of the human cortex, and Alzheimer’s patients have been reported to have decreased serum, brain, and neuronal levels of DHA and EPA compared to individuals without dementia.\(^5\)

James Pottala and colleagues set out to assess the relationship between red blood cell concentrations of DHA and EPA and brain volumes.\(^7\) The researchers analyzed MRI scan data from 1,111 postmenopausal women that were included in the Women’s Health Initiative Memory Study. The Women’s Health Initiative was a randomized placebo-controlled trial designed to test the effects of hormone replacement therapy in women. The Memory Study included a subset of these women who were free of dementia at the time of enrollment and between the ages of 65 and 80. Red blood cell fatty acid levels and MRI scans were taken as a part of the Memory Study. There was a mean time differential of eight years between the fatty acid analysis and the MRI scans.

James Pottala’s group analyzed this data and concluded that higher omega-3 concentrations (omega-3 index; a measure of total red blood cell EPA + DHA) were associated with larger total brain and hippocampus volumes, as assessed by MRI. While additional research is needed, these results suggest that higher omega-3 fatty acid tissue levels that are achievable through diet and supplements may be a promising approach for delaying brain aging and the onset of dementia.

**Nutrition, Fatty Acids, and Sleep**

An additional area of emerging research is the potential role that fatty acids play in sleep problems in children. Adequate sleep is essential for cognitive function and emotional wellness, while contributing broadly to health overall. Poor sleep is linked to aspects of Attention Deficit Hyperactivity Disorder (ADHD) and other behavioral and learning difficulties. Along the same lines, adequate essential fatty acid intake is associated with healthy cognitive function and overall health. Essential fatty acids are critical for the optimal performance of cells throughout the body because of the crucial structural and functional role they play. Deficits especially in the intake of omega-3 fatty acids DHA and EPA have been implicated in ADHD and other learning and behavioral issues.

Given the similar associations and outcomes common to poor sleep and fatty acid deficiencies, Paul Montgomery and colleagues at the University of Oxford in the UK investigated the association between blood concentration of fatty acids and subjective measures of sleep in 395 healthy children aged 7–9. In a 16-week randomized trial, they further explored supplementation with DHA (600 mg/day) versus placebo in 362 of these children who were underperforming in reading.\(^6\) Analysis of blood fatty acid levels and subjective sleep measures found that higher blood DHA status was significantly associated with better sleep.
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In the 16-week study including DHA supplementation, no significant effects were evident across the whole sample; however, in a subgroup analysis in individuals with clinically significant sleep issues, DHA supplementation was found to improve total sleep disturbance scores.

Furthermore, a subsample of 43 individuals underwent a pilot study in which actigraphy was used to measure sleep patterns. After 16 weeks of DHA supplementation (600 mg/day), significant improvements were noted in sleep duration (average increase of 58 minutes in the DHA group versus placebo), with improvements seen in sleep efficiency as well as less night waking.

Although more studies are needed, the evidence from these investigations indicate that DHA supplementation plays a positive role in enhancing sleep parameters in children with sleep issues.

The Future of Omega-3s

Emerging research clearly suggests that science is just scratching the surface with regard to the benefits of omega-3s for human health. With well-established indications for supporting the heart and brain, and reducing inflammation, these essential fats occupy a crucial place in any diet and supplement regimen. However, as newer studies continue to explore the unique mechanisms of these critically essential molecules, it is inevitable that their useful potential will extend to even more broad and diverse areas.

References


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

Tapioca Takeover

With consumers avoiding corn ingredients, tapioca syrup has much to gain.

BY ROBBY GARDNER, ASSOCIATE EDITOR

For decades, corn has jam-packed the North American food space, especially as a sweet syrup. But tapioca syrup is quickly stealing some of corn’s business. Despite corn’s historical versatility as food, feed, and even biofuel—and the federal subsidies that make U.S. corn production so cheap—much of today’s maize is genetically modified. Understandably, a lot of manufacturers and consumers are not stoked about this.

Fortunately for everyone, tapioca syrup can be a one-to-one corn syrup replacer, and it’s not genetically modified. Since, in many applications, tapioca syrup and corn syrup can be used interchangeably, let’s familiarize ourselves with the non-native tapioca syrup.

Sourcing and Production

The source of tapioca syrup is cassava, or manioc. A brown-skinned tuberous root that grows in parts of Asia, Africa, and South America, cassava is plucked from the ground, ground into starch, and then, with the helpful use of acid hydrolysis or modern-day enzymes, broken down further into syrup. The resulting syrup is sweet, but only because of this final stage of processing.

“Starch has no sweetness value,” says James Morano, PhD, vice president of new products and business development for Suzanne’s Specialties (New Brunswick, NJ), a supplier of tapioca syrup and other natural sweeteners. “All of the sites that would give you sweetness are tied up in that large starch molecule. The starch molecule is basically a polymer of tens of thousands of monomers, but they’re all tied together in such a way that the sweetness is gone.”

Once the large starch molecules are broken down into polymers, the taste of cassava is, at last, quite sweet. But it can be variable. The longer the hydrolysis takes place, the sweeter the syrup. Particular sweetness is measured as DE (dextrose equivalent) levels.

Range and Function

DE levels for tapioca and other starch-based syrups can range from the low 20s (anything lower, FDA says, is maltodextrin) to the 90s (a DE100 would just be dextrose). Everything in between is made possible through highly technical expertise in enzymatic hydrolysis.

“It’s like you’re a conductor of the symphony,” says Prescott Bergh, director of marketing and sales for Ciranda Inc. (Hudson, WI), another syrup supplier. “Each enzyme is playing a different instrument, and you have to give it its time to work.”

Tapioca syrups, depending on their DE levels, will have different functions in foods and beverages. Low-DE syrups are highly viscous, which gives them good binding properties (say, in a granola bar or cereal cluster), but they lack

Tapioca Around the World

Tapioca syrup processors get their cassava from all around the world, but some countries have more advanced capabilities than others. Technical skills aside, these are the top global producers of cassava, according to tons produced.

<table>
<thead>
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<th>Country</th>
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SOURCE: FOOD AND AGRICULTURE ORGANIZATION, FAOSTAT, ACCESSED APRIL 7, 2014. HTTP://FAOSTAT.FAO.ORG
High-DE syrups are very sweet, but their reduced viscosity makes them poor binders.

considerable sweetness. Meanwhile, high-DE syrups are very sweet, but their reduced viscosity makes them poor binders.

The DE level and overall sugar profile of a tapioca syrup can influence multiple other factors, such as crystal control in ice cream, crunch of a bar, body of a baked good, and thickness of a sauce. Manufacturers should consult with syrup suppliers to find a syrup that meets their particular desires.

Color and Form
Choosing the appropriate syrup color is another option for buyers. When syrup sugars are heated, a Maillard reaction, or browning of the sugar, occurs. This can be accompanied by a noticeable caramel flavor, too.

Higher DE levels will impart more of this browning, but some processors can still offer clear, high-DE tapioca syrups. A lighter color may be preferable in applications where weak, non-synthetic colors are relied upon. Tan, browner syrups will, of course, have their own uses, too.

Although syrups are known for their usual liquid formats, today’s suppliers make these ingredients available as powdered solids, too. Syrup solids hold up better in dry mixes such as flours or cake mixes, where spraying syrup would likely result in clumping.

Rice Syrup
While tapioca is a viable alternative to corn syrup, it isn’t the only one. Rice syrup, in fact, shares many of the same sweet qualities.

“If you compare a DE42 rice syrup, a DE42 corn syrup, and a DE42 tapioca syrup, you’re going to get the same situations,” says Joe Hickenbottom of Malt Products Corp. (Saddle Brook, N.J), “Solids, viscosity, sweetness, adaptability, and use—they’re so similar across the three syrups that you really can’t tell the difference.”

As rice syrup continues to become a more domestic crop in North America, usage of this syrup will continue to grow with that of tapioca. Will corn rebound and share in that bright future?

Comfort in Agave
Researchers confirm novel uses for agave.

BY ROBBY GARDNER, ASSOCIATE EDITOR

Although most prized for its tequila-making sugars, agave appears to have a fiber component with an equally appealing effect—on stool samples.

Research on agave inulin now suggests that this fiber can benefit human digestive health via increased and softened stools. The cushy benefit has been observed with other inulin sources—especially the most researched of them, which is chicory—but agave fiber was basically without published clinical trials on this relationship.

In what appears to be the first published trial on agave and gastrointestinal health, researchers from the University of Illinois at Urbana-Champaign assigned 29 adults to consume 5 or 7.5 g of agave inulin for 21 days, or maintain their normal diet without intervention—in crossover fashion. Some poor sap then analyzed stools at days 16 to 20 of each period in hopes of finding improvements with agave inulin in the diet.

As expected, agave inulin increased bowel movements, while also softening stool, but supplementation came with what were characterized as mild intestinal reactions, including bloating and stomach rumbling—especially with the higher dose. The benefit of “being regular” is perhaps worth the mild side effects.

But enough about digestion: the experience of agave as a sweetener is of much more enjoyment. And a research team in Mexico is particularly interested in agave when used in granola bars.

Writing in LWT Food Science and Technology, the researchers sought to, in oat-based granola bars, partially replace honey and wheat flour with agave syrup and fiber. They didn’t just use agave syrup and inulin—a slightly sweet source of soluble fiber—but they added ground, insoluble agave fiber. This particular fiber, they say, is an unused byproduct of conventional agave syrup and inulin extraction.

“Currently, the demand of agave heads for tequila production is over one million tons annually but, due to lack of proper planning and control, agave yields are frequently greater than demand, resulting in annual losses over 200,000 ton of agave heads,” said the researchers.

Repurposing insoluble agave fiber may improve the healthful qualities of granola bars, but so can using agave syrup. As Grace Carter, U.S. sales director for The Idea Company (San Diego), says, agave syrup is already popularly used in nutrition bars because of its low-glycemic properties.
Gummy Decisions

Should gummy manufacturers use gelatin or pectin?

BY ROBBY GARDNER, ASSOCIATE EDITOR

Not a moment too soon, gummies are enjoying life beyond the confectionery aisle. SPINS market data indicate that for the year ending March 23, 2014, vitamin and mineral gummies alone saw a 24% jump in sales. From fiber to fish oil, manufacturers are increasingly marketing health products as these confectionery treats, but the decision to make health products as gummies can bring manufacturers to a crossroads: should they use gelatin or pectin? Despite the many methods for formulating gummies today, these two gelling agents remain the most popular, and a case can be made for using either.

Gelatin

Gelatin is a processed protein from collagen, extracted from the hides and bones of pigs, cattle, and, to a lesser extent, fish. The ingredient is a byproduct of the meat industry, and it would not be widely available if not for this larger industry supporting it.

Gelatin has what is technically referred to as “thermal reversibility.” This means that gelatin can transition from a solid state as candy to a melting condition at body temperature and ingestion. “For orally ingested foods and supplements, this allows for a more intense, rapid release of flavor,” says Lara Niemann, marketing director for gelatin supplier Gelita USA (Sergeant Bluff, IA). “With other hydrocolloids, you don’t get the same flavor sensation, because that hydrocolloid is not melting, so to speak, when it’s in your mouth.”

Another potential advantage of gelatin formulations is the ingredient’s inherent sheen, capable of producing gummies with brilliant, almost transparent color. With or without gelatin, manufacturers often coat gummies in powdered sugar, so there are other ways of achieving visual brilliance; still, researchers say gelatin’s combination of sheen and melt-in-mouth texture has yet to be duplicated by any polysaccharide.

For all of gelatin’s versatility, gelatin’s animal source can create obstacles. Pig gelatin is, by and large, the most popular source of today’s commercial gelatin, but the porcine source represents a problem for both halal and kosher diets, as these cultural doctrines forbid the consumption of any part of the pig.

In response, two gelatin suppliers, Gelita and Geliko LLC (New York City), have partnered to secure what is likely the only cattle-derived, certified kosher gelatin on today’s market. And it wasn’t easy to achieve it.

“The certification process is very cumbersome and complex, because it all starts with the sourcing of raw material (the hide), which has to be obtained not only from kosher slaughter, but kosher-certified animals,” says Geliko president Zach Rubin. “This means you need, from slaughter, to be able to identify and trace every single hide that goes into your production. Furthermore, all of the hides must be kosher salted, and processed and transported in a certain way.”

Thanks to gelatin’s long history of use—and because of the conundrum surrounding what exactly organic livestock is—gelatin is on USDA’s National List of Allowed and Prohibited Substances, meaning it can be used up to 5% in certified organic food and beverage products.
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Pectin

The plant-based nature of pectin is likely a relief for some manufacturers, who would otherwise be without a very large vegetarian and vegan consumer base. While this gelling agent can be found in numerous plants, a great majority of production comes from just a few of them.

Citrus peel is the most widely used source of pectin, followed by the likes of apple and sugar beet, which bears pectin used for different purposes altogether. Citrus peel and apple are used in classic gelling applications such as jams, jellies, and gummies. Suppliers say these pectins create only slightly different textures, and apple peel is browner in color.

Beyond the plant-based distinction of pectin, this ingredient differs from gelatin in that the resulting eating experience is, despite being gel-like, markedly different.

"With pectin, one gets a much cleaner, shorter bite, with no chewiness and no elasticity," says Neil Gordon, technical support manager for food applications at CP Kelco (Atlanta). "So when you’re comparing the two as gelling agents for [gummies], the final texture is completely different. Of course, both are very good, very effective, and very functional."

Gordon says pectin also comes with a very different melting point—one that is higher than gelatin’s. This explains pectin’s shorter bite and lack of melt-in-mouth character, but it also explains a potential advantage to transport. In hot countries or supermarkets that are not air-conditioned, pectin-based gummies may hold up better than gelatin-based gummies, which may risk sticking together (i.e., melting and resolidifying). Formulations of both pectin and gelatin could provide a rather unique solution here.

At the end of the day, pectin can list as a basic source of dietary fiber, although consumers would need to consume quite a lot of gummies in order to see a real dietary fiber increase.

WHO’S GUMMY NOW?

While tracking recent gummy launches, Nutritional Outlook has learned that Aker BioMarine ASA (Oslo, Norway) is now offering a Superba krill oil gummy bear product. Pledging the same omega-3 doses in a single serving of gummies as a capsule of krill oil, Aker premiered these little guys at the Vitafoods trade show held this month in Geneva. The company says its gummies are a result of several months of collaboration with dedicated gummy manufacturers.

Discerning fish oil consumers are likely aware of the prevalence of fish oil gummies on the market. The future inclusion of krill gummies on an industrial scale should balance out the playing field.
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Minerals in Ancient Grains Are Celiac-Friendly


Ancient grains are trending globally, but their exotic origins are just part of the selling point. Many of the cereals and pseudocereals that make up this unofficial family of crops are gluten-free, and some are even rich in minerals.

Portuguese and Argentinean researchers just finished nutrient analyses for three ancient grains native to Argentina: quinoa, amaranth, and purple corn. Compared to rice, which is frequently used in gluten-free grain products, all three grains tend to offer significantly more minerals, while at the same time competing with—if not surpassing—rice in protein and fiber. Quinoa and amaranth scored especially well in most mineral categories.

“As we can see, the consumption of quinoa and amaranth could cover higher nutritional requirements than rice,” said the study’s author. “Amaranth has a higher contribution to mineral intake, even higher than quinoa. This has a high importance for people who have celiac disease, since almost all gluten-free cereals have a poor content of calcium, magnesium, and iron.”

While the results reinforce the desire for farmers to grow ancient grains even in non-native habitats—Japan now grows amaranth, for example—the researchers note that their data conflict with previous results from studies on the same crops grown elsewhere. “This needs to be taken in consideration when compilers aggregate data,” said the author, noting that the United States and Canada, for example, borrow the same nutrient data for quinoa and amaranth for their respective food composition databanks.

The data gathered from this study are based on crops grown specifically in the Jujuy province of Argentina. Conflicting results from crop analysis performed elsewhere could easily be due to plant genotypes, local soil, and even the types of fertilizers used. This chance of significant nutritional differences from the same grain should be of interest to manufacturers when they are selecting their ingredient suppliers.

Stop Craving Sweets? Spinach Could Help

A spinach ingredient’s appetite-suppressing effect may be linked to glucagon-like peptide 1 (GLP-1), a hormone involved in appetite control. In addition to helping spur GLP-1 production, the ingredient may also specifically target the desire for sweet foods, according to an abstract detailing the ingredient’s latest human clinical trial, presented at the Society for the Study of Ingestive Behavior meeting.

Postprandially, the gut produces two key appetite-modulating hormones: peptide tyrosine tyrosine (PYY) and GLP-1. Higher levels of these hormones can spark increased satiety and, by effect, weight loss. Certain nutrients can stimulate the production of these hormones.

It appears that Appethyl, a proprietary spinach-derived ingredient, is one of those ingredients, at least when it comes to modulating GLP-1. The latest clinical study—not yet published—showed an increase in GLP-1 release in human subjects following a dose of Appethyl, said R&D firm Greenleaf Medical AB (Stockholm, Switzerland). The company licensed Appethyl from Sweden’s Lund University in order to bring the ingredient to market.

The three-month study involved 36 overweight women aged 40 to 65. Subjects were given a daily blueberry shot with or without 5 g of Appethyl at breakfast. Researchers measured the subjects’ blood glucose, insulin, and GLP-1 levels six hours after intake on both the first and last day of the study. Additionally, the researchers used the Visual Analogue Scale to judge subjects’ urges for sweet, fat, and salty foods.

Appethyl subjects exhibited a significantly increased release of GLP-1. In addition, their desire for sweets fell. Researchers say that the increased release of GLP-1 happened by the last day of the study; by contrast, the lower sweets cravings kicked in on day one of the study.

According to Greenleaf Medical, “The conclusion of the study was that the suppression of sweet taste may be coupled to the release of GLP-1 and that this release occurs through delaying food digestion, as the active components in Appethyl, known as thylakoids, temporarily inhibit pancreatic lipase for about two hours.” The company also says that thylakoids may slow digestion of carbohydrates.

Greenleaf Medical launched its first Appethyl product in Sweden last year. According to the company, Appethyl was the number-one selling nutraceutical in the largest health food store chain in Sweden within weeks of its launch, selling $1.2 million worth of product in the first week alone.
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Soy Protein

A heart-healthy ingredient that promotes weight management

By Michelle Braun, Dupont Nutrition & Health

Obesity levels have dramatically increased over the past three decades and remain alarmingly high among children and teens. As an ingredient with well-documented nutritional attributes for weight management, soy protein can play a role in combatting this present-day crisis.

The following is a review of the latest supporting data, as well as an overview of soy protein’s nutritional benefits.

Background

For more than 5000 years, soy has been a fundamental part of the diets of millions of people worldwide, with its earliest uses tracing back to ancient China. Since landing on U.S. soil in the early 19th century, soy, and its production and distribution, has seen a dramatic transformation—from first being recognized as a low-cost, high-protein feed ingredient for livestock farmers, to now being widely commercially available in thousands of soy food products for human consumption. Driven in part by FDA’s backing of a soy heart-health claim in 1999, the popularity of soy food products has spiked over the past two decades.

The soybean is a legume from the botanical family Leguminosae. It is not only low in saturated fat and cholesterol-free but is touted as a nutrient-dense food, partly due to its high proportion of protein content, or soy protein. Nearly 40% of soybean calories are derived from protein, compared to 20%–30% in other legumes. As such, increasing protein content with soy protein can create healthful options by displacing calories derived from sugar and fat.

Impact on Obesity

Latest figures show that one-third of U.S. children and teens are overweight or obese.1 Perhaps most worrisome, though, is that up to 80% of overweight children will likely remain overweight into adulthood.

While obesity is a very visible condition, it can be accompanied by the development of unseen and asymptomatic (but serious) health conditions in childhood, including high blood pressure and cholesterol. If left unaddressed, these effects can have a lifelong impact, leading to diseases like type 2 diabetes, heart disease, and some cancers.2

Protein Nutrition

Childhood is a particularly important time to optimize nutrition and instill good dietary habits. During a growth spurt, a child’s body has a strong drive to build fat-free mass.3 Protein is the primary tissue repair and growth nutrient in the body, and high-quality dietary proteins with the appropriate amino acid pattern are needed to stimulate protein synthesis and other metabolic pathways. Soy protein is easily digested and one of few widely available vegetable sources that provide all nine essential amino acids in the appropriate amounts, making it a noteworthy source of protein to help support healthy growth and development during this critical time.

Currently, more than a quarter of a child’s recommended caloric intake is consumed in the form of snacks. On average, children consume 2-3 snacks per day,4 or nearly 700 calories.5 For this reason, considering the nutritional value of snack selections is critical to promote healthy weight and diet in children.

Soy and Satiety

The consumption of a healthful snack can serve a role in nutrition but also satiety. A study presented at Experimental Biology 2014 showed that replacing one daily afternoon snack with a high-protein snack containing soy resulted in statistically significant reductions in hunger ratings from adolescents, compared to a similar setting where subjects received a high-fat snack or no snack.6 Satiety can support weight management by helping to control caloric intake. When the feeling of fullness is reached faster, fewer calories may be consumed at the next meal or over the course of a day.

Consumption of high-protein snacks also correlated to a reduction in unhealthy evening snacking in the study. Both outcomes reiterate the potential for soy protein to replace calories derived from sugar and fat.

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**Soy and Heart Health**

While many studies have documented the benefits of soy protein in helping to manage body weight, less emphasis has been placed on soy’s heart-health benefits.

A study presented at the American College of Cardiology in March 2014 found that roughly a third of children, ages 9 to 11, have borderline or high cholesterol.\(^7\) In children and teens, replacing animal protein with soy protein as part of a low-fat diet has been shown to decrease total cholesterol and LDL cholesterol.\(^8\) Soy protein, as part of a diet low in saturated fat and cholesterol, has been shown to reduce the risk of heart disease and can be an effective tool for children at risk of developing heart disease.\(^9\)–\(^10\)

**Application**

Value, improved taste, convenience, and nutritional benefits are just a few characteristics that consumers demand in today’s marketplace. While further studies are needed to better understand the full nutritional potential of soy protein, the ingredient has demonstrated practical benefits that make it a viable option for supporting new food choices. To meet these demands, soy protein products are versatile and can deliver a vast and broad spectrum of functional solutions—including solubility, emulsification, and viscosity—all while delivering great taste.

**Soy protein, as part of a diet low in saturated fat and cholesterol, has been shown to reduce the risk of heart disease.**

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Michelle Braun, PhD, is a nutrition researcher with soy ingredients provider DuPont Nutrition & Health (St. Louis).
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<td>626/912-9998</td>
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<td>BioCell Technology LLC.</td>
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Where Is Cocoa Headed?

Suppliers discuss innovations and challenges in today’s cocoa and chocolate markets.

BY ROBBY GARDNER, ASSOCIATE EDITOR

Cocoa is much relied upon, but what is in store for this plant’s future? What are the next trends in cocoa and chocolate products, and what can we expect of cocoa’s environmental future? These are questions that should be front of mind for manufacturers, so Nutritional Outlook caught up with Courtney LeDrew, marketing manager for Cargill Cocoa & Chocolate (Minneapolis), and Vaagn Arakelyan, director of cocoa trade for Cocoa Family (Duarte, CA).

Where are your cocoa farms located?

Cargill: The Ivory Coast, Ghana, Cameroon, Brazil, Indonesia, and Vietnam.

Cocoa Family: The Dominican Republic.

Does your cocoa have particular aroma or taste characteristic of its growing region?

Cargill: Beans from the Ivory Coast typically have a good chocolate taste impact, low acidity, and fruity and nutty notes. Beans from Ghana usually have a strong chocolate flavor, while beans from Indonesia can have a lower chocolate impact, with acidic and fruity notes.

Cocoa Family: Dominican fermented cocoa beans are very rich in flavors. The taste characteristic can depend on the form of fermentation that the beans go through more than which region they are from.

What do you think is the next trend in cocoa marketing for manufacturers?

Cargill: There will be more and more foods spliced together with unconventional flavor combinations to entice consumers hungry for new experiences. Consumers will see more limited-edition innovation and cross-branding, with well-known brands venturing into new categories.

Cocoa Family: Much development has to be done on the farm level to skip overburning of cocoa beans, so that the beans will [retain] their own flavor.

What’s an interesting cocoa or chocolate development recently executed by your company?

Cargill: We have introduced a protein line, in response to market needs. Chocolate and protein pair well together, and we now offer innovative protein coatings and drops, including confectionery protein wafers, milk confectionery protein wafers, white chocolate protein drops, and cocoa confectionery protein drops.

Cocoa Family: We now offer cocoa nibs sweetened with coconut sugar.

Cocoa sustainability is getting increased attention, with concern for potential soaring-high prices and the threat of climate change. What should manufacturers be most concerned about when selecting sustainable cocoa ingredients?

Cargill: It’s really important that we secure a long-term supply of high-quality beans and invest in developing a sustainable cocoa supply chain that supports farmers and their communities for many years to come.

Cocoa Family: We may see a spike in pricing due to cocoa demand and not enough farm development.

Do you believe there will be enough cocoa to supply global demand for the years to come?

Cargill: We have seen demand for sustainable cocoa continuing to grow. As a result, we have remained focused on scaling up our commitments and activities to enable more farmers to benefit from improved yields and incomes; to enable more cooperatives and farmer organizations to get certified; and to achieve more available volumes of certified beans and products. We’re confident we’re heading in the right direction to not only deliver products to meet our customers’ commitments, but also to support a sustainable long-term cocoa supply chain.

Cocoa Family: We may see a spike in pricing due to cocoa demand and not enough farm development.
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