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Navigating the Health-Claims Landscape

By Kimberly J. Decker
Contributing Editor

Health claims have made headlines lately—and not always for the right reasons. First there was last summer's Federal Trade Commission action against the Kellogg Company, resulting in a settlement barring the manufacturer from making cognitive health claims for its Frosted Mini-Wheats cereal. Later, the Center for Science in the Public Interest (CSPI) petitioned FDA to prohibit qualified health and structure/function claims for foods. This March, FDA sent letters to 17 manufacturers, including Dreyer's, Nestlé and POM Wonderful, warning them that labeling on 22 of their products violated the Federal Food, Drug, and Cosmetic Act. And barely two months later, the Institutes of Medicine (IOM) issued a report calling into question the scientific rigor with which FDA evaluates biomarker evidence in health-claim proposals.

Surely, this isn't the press that FDA, manufacturers or Congress had in mind when the Nutrition Labeling and Education Act of 1990 (NLEA) included provisions for food companies to provide "additional health information" to consumers by way of health claims on packages. But, since the act's passage, health claims have been both a blessing and a curse, giving manufacturers an opportunity to celebrate their products' health-giving potential, and making them a popular target for skeptics. When navigating this regulatory and public-relations minefield, it's best to arm yourself with a clear understanding of the laws, as well as a healthy dose of discretion.

Politics and sausage

"Manufacturers develop products with the intent of fulfilling a need that they believe the public has, and that need covers a lot of things—certainly taste, availability and pricing, but also certainly nutrition," says Allan I. Zackler, Zackler & Associates, Oakland, CA. An attorney with more than three decades' experience in consumer products/food regulatory and marketing law, he's seen nutrition trends and regulatory moods come and go. In his view, the pendulum analogy is an apt fit.

"There really have been swings from a lot of regulation to less," Zackler says. "When problems come up, there'll be more regulation, sometimes related to the administration in office. Other times, manufacturers themselves will seek to come up with something that's acceptable to

consumers and fulfills their needs; they'll start pushing the envelope, and it gets pushed back by groups such as CSPI. A regulatory process then comes into play."

The results are thus as much products of politics as of scientific merit. And if there's any truth to the old saw that two things you don't want to see are the making of sausage and the making of laws, then you really don't want to see the making of laws about sausage. As Zackler notes with diplomatic understatement, such laws "do not necessarily comport with the science behind them. In fact, they oftentimes don't comport with the science behind them."

Content providers

Nevertheless, FDA has provided exhaustive language as to the health messages we can deliver on food labels. Responsible manufacturers would do well to familiarize themselves with the specifications outlined in Title 21 of the *Code of Federal Regulations* (*CFR*), Part 101. A handy Q&A lives at *fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodLabelingNutrition/FoodLabelingGuide/ucm064908.htm#health*.

The most basic are nutrient-content claims, which directly or by implication characterize the level of a specified nutrient in a food. (For a full definition, as well as byzantine requirements for type size, style and placement, see 21 *CFR* 101.13, Subpart D of Part 101, and Parts 105 and 107.) The main purpose of nutrient-content claims is to give consumers a context for judging the relative quantity of a nutrient in a food: Is this a "good" or "excellent" source? Is the nutrient present at "high" or "low" levels vis-à-vis the recommended daily intake? Is this a "free" or "light" food?

The regulations make explicit how much of the nutrient need be present per reference amount commonly consumed (RACC) to qualify for modifiers such as "low," "high," "good," "excellent" and otherwise. For example, to qualify as "low" in sodium, a food must contain 140 or fewer mg of sodium per RACC, or 50 mg if the RACC is small. To earn a "reduced" or "less" claim, a food must have at least 25% less sodium per RACC than a suitable reference food.

But don't get too comfy with these numbers, as in a sign of the continual flux of nutritional guidance, the recommended levels on which sodium nutrient-content claims are based may be in for an overhaul. The current percentage Daily Value is based on a maximum of 2,400 mg of sodium per day. However, the recommended daily intake above which health problems may occur is 2,300 mg. (Recommended adequate intake is a mere 1,500 daily mg, and even lower for those over age 50.) In a report issued April 2010, an IOM committee concluded, "Because using an upper level can lead people to mistakenly think that it is a desirable amount, the committee recommended that the Daily Value for sodium be changed to reflect the adequate intake for adults of 1,500 milligrams per day." FDA has yet to take action, but if and when it does, it will affect how much sodium qualifies as "low," "reduced" or "less."

Staking a claim

Beyond basic nutrient-content claims, FDA authorizes health claims that characterize the relationship of a substance in a food to a disease or health-related condition (see 21 *CFR* 101.14(a)(1)). Health claims have allowed manufacturers to balance the numbers on the NLEA-mandated nutrition facts panel with verbiage that calls attention to nutritional benefits that may not be immediately apparent in the numbers alone.

FDA-authorized health claims encompass not only explicit verbal messages, but implicit claims conveyed via symbols and "vignettes." Furthermore, the claims can address only disease risk reduction, and not diagnosis, cure, mitigation or treatment. So the statement, "Three grams of soluble fiber from oatmeal daily in a diet low in saturated fat and cholesterol may reduce the *risk* (author's emphasis) of heart disease; this cereal has 2 grams per serving," fits the health claim mold.

Thirteen such statutory health claims—linking everything from calcium and bone health to folate and neural-tube defects—have undergone FDA scrutiny. "Based on the evidence of the science presented to them," Zackler says, "FDA has determined these claims to be reasonable to make so consumers can be aware of the relationship between this food and the possibility for reducing the risk of one or another of the illnesses."

Clinching FDA approval requires meeting its significant scientific agreement (SSA) standard, which "is pretty complex," says Elaine M. Meloan, senior manager, food

labeling, AIB International, Manhattan, KS. According to 21 *CFR* 101.14, "FDA will promulgate regulations authorizing a health claim only when it determines, based on the totality of publicly available scientific evidence (including evidence from well-designed studies conducted in a manner which is consistent with generally recognized scientific procedures and principles), that there is significant scientific agreement, among experts qualified by scientific training and experience to evaluate such claims, that the claim is supported by such evidence."

Thus, Steven Young, Ph.D., technical advisor, Matsutani America Inc., Itasca, IL, advises manufacturers to "do your homework. Be sure that you have substantial scientific support for any health claim, and if using one of the FDA health claims, make certain that all the minimum requirements for the consumer product are met."

FDA may raise the SSA standard even higher in response to the IOM report "Evaluation of Biomarkers and Surrogate Endpoint in Chronic Disease." IOM urges FDA to tighten its judgment of biomarker evidence and adopt a "consistent scientific framework for biomarker evaluation" that, among other improvements, applies "the same degree of scientific rigor for evaluating biomarker use across regulatory areas, including drugs, medical devices, biologics, foods and dietary supplements."

Modern times

While the IOM report may make health-claim approval harder, it was in the interest of loosening regulatory gridlock that provisions within the Food and Drug Administration Modernization Act of 1997 (FDAMA) allowed for yet another class of health claim, the appropriately named FDAMA health claim.

Prior to FDAMA, companies had to wait until FDA published a regulation authorizing a health or nutrient-content claim before using it. FDAMA accelerated that process by permitting distributors and manufacturers to use claims from the get-go, as long as those claims arose from current, published, authoritative statements from certain federal scientific bodies, as well as from the National Academy of Sciences, any of its subdivisions, and organizations like the National Institute of Health (NIH) and the Centers for Disease Control and Prevention (CDC).

How it works, Meloan explains, is that after determining a claim's merit based on an authoritative statement of a scientific body, companies submit a notification to FDA with their intent to make the claim. "If FDA does not respond to the notification within 120 days," she says, "companies are free to use the claim stated in the notification."

Of course, the SSA standard applies to FDAMA claims as well, and FDA reserves the right to prohibit or modify a claim through later regulation. Regardless, the modernization has achieved its goal of expediting the establishment of the claim's science, as well as its deployment. Four health claims, including for whole grains and reduced risk of heart disease and cancer, and potassium and reduced risk of high blood pressure and stroke, have gone into circulation thanks to FDAMA.

Qualifying round

FDA relaxed the health-claim rules yet again with 2003's Consumer Health Information for Better Nutrition Initiative—albeit after its hand was forced in the matter. In the landmark court case *Pearson v. Shalala*, the U.S. District Court for the District of Columbia ruled that FDA violated the plaintiff's free-speech rights by prohibiting them from making folic-acid health claims that FDA deemed "inherently misleading." While FDA found less-than-significant scientific agreement to support the claim, it was still "directionally consistent with emerging evidence for the relationship" between the nutrient and the condition, Zackler says. "It was something that a consumer should at least be made aware of."

Thus, Meloan continues, "it was argued that FDA needed to permit claims that do not meet the SSA, if properly qualified to prevent consumers from being misled. The results of this trial led to the qualified-health-claim procedures." Specifically, companies can petition FDA with emerging evidence of a relationship between a food, food component or dietary supplement and a health condition, and after evaluating and ranking the quality and strength of that evidence, FDA may then issue a "letter of enforcement discretion" detailing the qualified health claim it will allow.

"If a company follows the requirements in the petition or notification for the qualified health claim, FDA will not object to the claim being made," Meloan says. "However, there may be times when such a statement could be misleading in context with other statements on the package,

Call 'Em Like You See 'Em

When deploying descriptive modifiers like "healthy" or "fresh" on product packages, there's no such thing as a casual deployment of language. That's one thing that Elaine M. Meloan has learned while serving as senior manager for food labeling at AIB International, Manhattan, KS. Here's a sampling of what she tells food industry professionals seeking her advice on using words wisely.

Healthy. "'Healthy' is already defined as a nutrient-content claim—Title 21 of the *Code of Federal Regulations (CFR),* Part 101.65—and takes into account the amount of total fat, saturated fat, cholesterol and sodium in a food. The food also has to be a good source of a positive nutrient, such as fiber, calcium or iron, to qualify as 'healthy.'"

Fresh. "FDA provides guidance on 'fresh' in 21 *CFR* 101.95. It has more to do with the physical qualities of the food as opposed to its nutritional value." According to the USDA Food Safety and Inspection Service, the term "fresh" on a poultry label indicates that the product has never been below 26°F. While raw poultry held at 0°F or below must be labeled "frozen" or "previously frozen," USDA requires no specific labeling on poultry stored between 0°F and 25°F.

Allergens and gluten-free. "The food allergen amendment to the Food, Drug and Cosmetic Act pretty clearly defines how allergens are disclosed on a label." This, she notes, has little effect on health claims. As for "gluten-free," she says, "a proposed regulation for gluten-free labeling was issued in 2007. Although there is not a final regulation yet, FDA does not object to companies following the guidelines provided for in the proposal."

Natural. "As we know, 'natural' is a rather vague term, and FDA has very limited guidance about its use." USDA, she notes, is the agency that's "delving in" on its meaning with respect to meat and poultry products, spelling out specific guidelines about "minimal processing" and what that specifically means. She points manufacturers to the USDA's policy manual for more precise definitions.

and FDA retains the right to use enforcement procedures to notify the company of the misleading labeling."

Here, context boils down to language. FDA makes explicit how strong a qualified health claim can be. The agency has spelled out three levels of qualification, from the strongest support ("Although there is scientific evidence supporting the claim, the evidence is not conclusive"), to moderate ("Some scientific evidence suggests… However, FDA has determined that this evidence is limited and not conclusive"), to weakest ("Very limited and preliminary scientific research suggests… FDA concludes that there is little scientific evidence supporting this claim").

Because qualified health claims "must follow the exact wording provided for in the notification or letter of enforcement discretion," Meloan urges manufacturers to read that letter carefully and "make sure your product qualifies for the claim and that you are using the proper wording." Not surprisingly, she adds, most of the claims manufacturers use are "within the category of 'approved' claims, which are unqualified and the strongest of the claims, because they don't have all that limited wording."

Structurally sound

It's precisely their linguistic hedging—and the lack of scientific consensus that it reflects—that leads groups like CSPI to criticize qualified health claims. "Not everyone agrees that these types of claims should be permitted, due to some of the very limited scientific evidence presented in the petition or notification," Meloan says. "Although the claims have qualifying language that must be included as part of the claim, some feel that they are still misleading."

Nevertheless, Meloan says, "once a claim is approved, accepted or not objected to, then any company may use it." The only case in which a manufacturer would need to provide FDA notification, she points out, "would be for structure/function claims for dietary supplements." And therein lies an especially tricky patch of the health-claim landscape for manufacturers to negotiate.

A structure/function, or S/F, claim is a statement about a dietary supplement or food nutrient's ability to maintain a normal bodily structure or function. An S/F claim cannot address a disease state, lest the supplement or food in question creep into drug territory. That's one reason why S/F claims require special attention from manufacturers.

Another is that FDA oversees S/F claims differently for supplements and foods. "Dietary-supplement manufacturers must notify FDA with the claims they are making within 30 days of marketing the product, and the supplement must contain a disclaimer stating that FDA has not evaluated the claim," Meloan says. By contrast, "structure/

function claims about nutrients in foods require neither FDA notification nor a disclaimer," she says.

This sets up competing incentives for manufacturers to market a product as either a food or a supplement. And the fact that "there isn't always a very firm line between what's a food and what's a dietary supplement, or what's a supplement and what's a drug," doesn't make that decision easier, Zackler adds. On one hand, a manufacturer can sidestep FDA approval of an S/F claim on a food. But marketing that product as a supplement, although it requires FDA approval for the S/F claim, exempts the manufacturer from establishing its ingredients' GRAS status.

"That gives you a little bit more flexibility to put in ingredients that have not necessarily been established as safe by anybody other than you," Zackler says. By contrast, food manufacturers must give FDA 75 days advance notice before using a novel ingredient. "In the absence of them saying you can't use it, then you can," Zackler says. "If FDA looks at that notice and says, 'We don't think that you've established the safety of this and therefore you can't use it,' then you can't."

Even if a manufacturer decides to market a product as a food, avoiding the need to seek S/F claim approval, the claim must still be truthful and not misleading. Should a regulatory agency question the manufacturer's claim—as FTC did with Kellogg's Frosted Mini-Wheats—the manufacturer must provide appropriate scientific evidence to defend it. "Then the question becomes, if your evidence is inadequate to convince the regulator, what are the potential consequences?" Zackler says. "And each manufacturer has its own level of risk assessment and tolerance."

Enforcing credibility

Whether an agency gets around to questioning a claim is no forgone conclusion. "The manufacturers are at least a decade ahead of the regulators, for good or for bad," Zackler says. "Food manufacturers, as you might expect, have a lot invested in their products, and they have, in many respects, the best R&D facilities in the country. They can come up with a tremendous amount of data through their own research and put it into the hopper along with other groups." This leads to inevitable push and pull among parties, but ultimately, he says, "what you have is an issue where the government and industry and consumer-activist groups are all trying to make some sense of things."

Some sense has emerged, along with plenty of legalese. While the claims that FDA has sanctioned have generated their share of controversy, "when you look at the number of claims that are approved and accepted currently by FDA, you're really kind of limited in the substances that you can actually make a claim about," says Meloan. "You're talking about fiber in a lot of cases, fruits and vegetables." And who could complain about recommending more fruit and fiber?

As for dressing up "junk" food with deceptive appeals to health, FDA has plugged the loopholes by barring health claims on products that don't meet healthful levels of total fat, saturated fat, sodium and cholesterol. They've also got the "jelly bean rule," which limits use of the term "healthy" to foods low in total and saturated fat, sodium and cholesterol, and containing at least 10% of the recommended value for certain desirable nutrients like calcium or vitamin A. In any event, says Young, "work with your company's regulatory and legal team when utilizing an FDA health claim on your packaging to be sure that it complies with the FDA labeling requirements."

These rules lend credibility to the sometimes-embattled sphere of health claims. "Increased enforcement by FDA will eventually help with the consumer perception of claims on packages," Meloan says. "However, the enforcement needs to be a steady presence." And manufacturers need to keep expectations in check and act in good faith.

In an area like this, consumer perception and credibility are everything. "Consumers will look for additional information by watching more news and web-based reports for specific health concerns and clinical studies on nutrition," says Young. "They will apply what they find to improving and changing their dietary patterns and habits. Educational programs promoted by the government will also be a valued source of information and influence consumers." In the end, that's just what we want them to do.

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The Skinny on Fiber and Weight Management

By Marie Spano, M.S., R.D.
Contributing Editor

Fiber is an essential part of our diet. It helps lower cholesterol, enhances digestive health, promotes bowel regularity and improves mineral absorption. In addition, certain kinds of fiber can help keep the pounds off.

Epidemiological as well as clinical trials indicate that fiber plays an important role in weight management. Epidemiological studies show that fiber intake is inversely associated with body weight and body fat (*Nutrition*, 2005; 21:411-418), and clinical trials indicate that both insoluble and soluble fiber, when added to a person's diet while keeping energy intake constant, increase post-meal satiety and decrease subsequent hunger. Mean values for published studies show that increasing fiber intake an additional 14 grams per day for more than 2 days leads to a 10% decrease in energy intake and average weight loss of 1.9 kg over 3.8 months. Overweight and obese individuals may experience greater satiety and weight loss from the added fiber in comparison to lean individuals (*Nutrition Reviews*, 2009; 59(5):129-139).

While both insoluble and soluble fiber are beneficial for weight loss, they work differently within the body. "Insoluble fiber contains no calories and also provides physical bulk to the diet," says Jit Ang, senior vice president, research and development, International Fiber Corporation, North Tonawanda, NY. "Foods containing high levels of insoluble fiber tend to also provide more satisfaction from chewing, plus the feeling of satiety upon ingestion. All of these factors can help reduce the amount of calories consumed."

While insoluble fiber provides bulk, soluble fiber forms a gel when mixed with liquid, which slows the movement of food through the intestines, thereby keeping a person full for a longer period of time. According to Ang, "this may also slow down the absorption of other nutrients, facilitating body cells to burn more sugar for energy, rather than storing fat. By regulating insulin levels—a vital function for diabetics and those with insulin resistance—hunger is controlled, and one will eat less as a result."

Naturally occurring fiber

Fiber is a unique natural component of many foods, notably produce and whole grains. However, studies examining whole-grain sources of fiber and weight control are inconsistent, partly due to variations in study

design and because many studies do not account for initial pre-study fiber intake among participants.

Beta-glucan has been shown to be both effective and not effective in a variety of studies. In a randomized, parallel-arm, controlled trial, overweight and obese adults were placed on a 12-week weight-loss diet containing either six grams per day of oat beta-glucan or an energy-matched placebo. Those consuming the beta-glucan lowered low-density lipoprotein (LDL) cholesterol and decreased weight circumference to a greater extent than the control group. However, weight loss was not significantly different between the two groups (*Journal of the American Dietetic Association*, 2010; 110:205-214). Conversely, a study examining an energy-deficient diet plus one of two doses of beta-glucan—5 to 6 grams or 8 to 9 grams—or a control (no beta-glucan) found that the addition of oat beta-glucan did not enhance weight loss in mildly overweight women over a 3-month period (*British Journal of Nutrition*, 2010; 103:1,212-1,222).

Other studies examining cereal fiber have yielded equally mixed results in regard to weight loss. Participants who consumed 20 grams of an insoluble cereal fiber during 5 to 10 weeks of caloric restriction, in comparison to a control group (no cereal fiber), yielded no significant differences in weight loss or energy intake (*Aging, Clinical and Experimental Research*, 2008; 20:513-520).

While the addition of whole-grain sources of fiber may or may not boost weight loss, diets rich in legumes, fruits and vegetables may enhance satiety and, therefore, serve as a weight-control aid by displacing other, higher-calorie foods in the diet and improving energy density of food consumed (calories per gram weight of food). Low-energy-dense foods have fewer calories but are more filling due to their fiber and water content (*Physiology & Behavior*, 2009; 97:609-615; *Journal of Medicinal Food*, 2009; 12:100-108; *Nutrition Research*, 2008; 28:233-238; *European Journal of Clinical Nutrition*, 2007; 61:1,301-1,311).

Fiber fortification

In addition to naturally occurring fibers, there are many fiber ingredients for fortification. "Fiber combinations are proving to be very useful," says Ang. "Not only can these combinations bring important nutritional improvement—such as calorie and fat reduction—some of these new approaches can also provide unique textural properties, thereby contributing to the overall taste properties of the food."

Psyllium, a fiber from the husk of the seeds of a shrub-like herb called *Plantago ovate*, has long been known for its role in laxative products, and may be beneficial for enhancing satiety, as well. In one study, 16 healthy, non-obese subjects consumed one of five test meals (all containing the same total calories) in a randomized order on separate days. The test meals were: low in protein (2.8 grams) and fiber (7.6 grams); low in protein (2.6 grams) and high in soluble fiber (psyllium, 23.0 grams); high in protein (soy, 19.7 grams) and low in fiber (6.2 grams); high in protein (18.4 grams) and fiber (23.0 grams); and white-wheat bread. Post-meal appetite ratings were similar after all meals. However, the fiber-enriched meals decreased glucose, insulin, ghrelin and peptide YY concentrations in comparison to the other meals, indicating psyllium-rich meals may favorably modulate the body's satiety signals (*Journal of Nutrition*, 2010; 140:737-744).

Resistant starch, or digestion-resistant starch, a natural source of insoluble fiber, may contribute to weight loss by replacing higher-calorie sources of flour, improving satiety, decreasing post-meal insulin response and helping individuals eat less at mealtime (*British Journal of Nutrition*, 2010; 103:917-922; *American Journal of Clinical Nutrition*, 2005; 82:559-67; *Diabetologia*, 2003; 46:659-665).

A single-blind crossover study in 20 healthy young men found that consuming 48 grams of resistant starch, divided equally between two mixed meals and in comparison to a carbohydrate-matched placebo, led to significantly lower total energy consumption at meals and lower post-meal insulin, but no difference in subjective ratings of appetite. This study indicates that meals high in resistant starch may be useful in helping manage blood sugar and food consumed (*British Journal of Nutrition*, 2010; 103:917–922). Additional studies indicate that, in doses of 8.0 to 9.6 grams, both resistant starch and corn bran can boost satiety to a greater extent than polydextrose (*Nutrition Research*, 2009;29:100-105), and improve glucose tolerance when included at a meal through greater colonic fermentation (*American Journal of Clinical Nutrition*, 2008; 87:645-654).

In a small study examining a blend of oats and barley, seven overweight and obese adults were placed on a

calorie-restricted diet and given 4 grams per day of the blend. Satiety was enhanced after the test meal and, at the end of the 14-week study, participants lost an average of 3.07 ± 3.13 kg (*Journal of Medicinal Food*, 2007; 10:720-724).

Cellulose fiber expands in volume and may, therefore, enhance feelings of fullness and satiety while delaying gastric emptying (*Obesity*, 2008; 16:2,272-2,280). However, few studies have examined the effect of cellulose on factors that may contribute to weight loss over time. In a double-blind, placebo-controlled 8-week diet and exercise intervention study, 22 obese women were given either a 400 mg proprietary blend of modified cellulose and cetylated fatty acids or a placebo (400 mg magnesium stearate). Both groups experienced significant decreases in body weight, body fat, leptin and insulin. The supplemented group lost significantly more weight and body fat in comparison to the placebo group after the 8-week period, and this group also experienced favorable changes in adipocytokines, the cytokines secreted by adipose tissue (*European Journal of Applied Physiology*, 2009; 105:665-672).

Galactomannan is a soluble fiber that slows gastric emptying, enhancing fullness. Few studies have been conducted on galactomannan, and a large dose may be necessary to enhance satiety, which may, in turn, decrease the palatability of the food. In one clinical trial using galactomannan fiber, an 8-gram dose was necessary to increase mean ratings of satiety and fullness and reduce ratings of hunger and prospective food consumption in comparison to 0 or 4 grams of galactomannan fiber (*Phytotherapy Research*, 2009; 23(11):1,543-1,548).

Glucomannan is a soluble fiber that may increase post-meal satiety. Few studies have examined glucomannan intake and long-term weight loss. However, one double-blind, placebo-controlled 16-week trial found that a mixed-fiber supplement (3 grams *Plantago ovata* husk and 1 gram glucomannan) taken two or three times daily significantly increased post-meal satiety in comparison to placebo, though there were no significant differences in weight loss between the groups (*British Journal of Nutrition*, 2008; 99(6):1,380-1,387).

Human data on inulin is limited, but animal studies indicate that this fiber may boost satiety by modulating gastrointestinal peptides (*British Journal of Nutrition*, 2004; 92(3):521-526). In addition, one human trial shows that inulin may enhance satiation. In this study, 38 men and women were given 180 calories of orange juice and either a high-energy-density yogurt (440 calories; 0.9 calories per gram weight of yogurt) with or without 6 grams of inulin, or low-energy-density yogurt (180 calories; 0.4 calories per gram weight of yogurt) with or without 6 grams of inulin. All versions of yogurt were more satiating than the orange juice, and the low-energy-density yogurt with inulin added was as satiating as the high-energy-density yogurt, indicating that the addition of inulin to yogurt may enhance satiety (*Journal of the American Dietetic Association*, 2009;109:1,862-1,868).

"Depending on the application, certain fibers may function better than others in a given food application," notes Ang. "For example, fine-particle-sized fibers can contribute to smoother consistency and better mouthfeel. As a result, these are the fibers of choice to use for reducing the caloric contents of food products and also for the development of high-fiber products."

According to Ramakanth Jonnala, project leader R&D, International Fiber Corporation, "longer-particle fibers can provide different functionalities in food systems, including improved cling in sauces and dips, increased volume in bakery products, improved yield and nutrition in meats, reduced shrinkage in cooking processes, better moisture retention and management in all food systems, among other benefits."

The choice to use a specific fiber or fiber blend depends on the desired food or beverage texture, mouthfeel and nutrition objective. The role of fiber as a weight-loss tool varies depending on the type of fiber, total fiber consumed in one sitting, and regular fiber-consumption patterns. Food manufacturers should work closely with fiber suppliers to ensure the fiber ingredient blends well into the food or beverage and meets any desired marketing claims.

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I Feel Good: Ingredients and Immunity

By Kimberly J. Decker
Contributing Editor

Ten years ago, when Stuart Reeves, Ph.D., started examining the immune effects of products at Embria Health Sciences, he had a memorable exchange with an academic immunologist. "She said, 'You know, you're going to find that immunologists are beginning to look at digestion and nutrition, and nutritionists are beginning to look at immunology, because they are a lot more linked than we thought they were,'" recalls the director of research and development at the Ankeny, IA, company. "And she was absolutely right."

So linked are nutrition and immunity that the relationship has captured the attention of researchers, clinicians and the consuming public, whose interest has turned immune-enhancing foods and beverages into one of the fastest-growing sectors of the functional-food category. Manufacturers keen to get in on the action need grounding in the basics of immune function, and in the compounds and ingredients that help it function better.

All systems go

If Joe Consumer doesn't fully grasp immunity's intricacies, he's in good company. The scientific community is still teasing out immunity's mechanics. As the body's defense against foreign invasion, the immune system is often likened to a castle whose moats, ramparts and battalions provide successive layers of defense. Barriers like skin and mucous membranes, as well as the cough reflex and enzymes in tears and sebum, provide "innate" immunity, a first line that acts without specificity against pathogens, antigens and other "non-self" substances. Phagocytes called natural killer (NK) cells also rove the bloodstream, indiscriminately scavenging what they identify as foreign.

When the innate defenders fail, the next layer of immunity kicks in. This cell-based, or adaptive, response comprises the action of white blood cells known as B and T lymphocytes. The former produce antibodies that bind to antigens and ultimately destroy them, while the latter go after the antigens themselves, and also release cytokines that help control the immune response. In theory, this layered setup protects us from illness and infection. In practice, it often falls short or overreaches. Any number of culprits cause the immune response to fail, including genetics, pollution, oxidizing free radicals, aging and everyday stressors. "Anything that stresses you stresses your immune system," says Cheryl Sturm, marketing director, Embria Health Sciences. "Everybody deals with stress in a slightly different way. So every one of us has a personal immunity balance point."

Diet is crucial to striking this balance. "Just eating a well-balanced diet of vegetables, fruits, whole grains and everything else we're supposed to eat is the most-critical thing," says Kevin Mehring, global business director for dietary supplements and immune health, Danisco Health and Nutrition, Madison, WI.

Probiotic Appeal

Consumers clearly have immunity on the brain. With outbreaks of everything from SARS and swine flu to pertussis and food poisoning heating up headlines, one need only hint at the prospect of the next global pandemic to put people on the defensive. "Food and beverage manufacturers are responding to increased consumer demand for products that deliver immune health benefits," says Rich Mueller, president and CEO, Biothera, Eagan, MN. "We believe that media coverage of pandemics like West Nile virus, bird flu and H1N1 in recent years has played a major role in educating consumers about the importance of immune health to their overall health."

In fact, Mueller says, a 2008 survey by the International Food Information Council (IFIC), Washington, D.C., found that 87% of consumers have a current or future interest in products that improve immune-system function. "In addition to the IFIC data," he continues, "a 2009 Nestlé survey found that mothers identified immunity as the most-important benefit for their two- to five-year-olds." He also notes that a 2010 prediction from SPINS, Schaumburg, IL, was, "The recent flu scare still weighs heavily on consumers' minds and products that give the immune system an extra boost will continue to do well."

With health-care costs on the rise, the prospects for such products look even better. Getting sick exacts a heavy toll, and consumers wager that paying a little more upfront for a food or drink that can ward off sickness may shield them from paying a *lot* more in treatment and lost productivity later on. Cheryl Sturm, marketing director, Embria Health Sciences, Ankeny, IA, attributes this thinking to "the trend toward prevention that we're seeing." According to the Health and Wellness Trends database study from the Natural Marketing Institute, Harleysville, PA, consumers cite boosting the immune system as the No. 1 thing they can do to prevent illness. "Not only do they feel good about that, but they're buying into this prevention-over-treatment regimen," she says. "They may not understand all the complexities of the immune system, but they know that keeping it healthy is something proactive that they can do."

"The bottom line is that our gastrointestinal tract is a large immune organ," says Mehring. The gut mediates anywhere from 70% to 80% of immunity. Gastrointestinal mucosa, stomach acid and intestinal enzymes all participate in this interaction. But our natural gut flora—the beneficial bacteria adapted to inhabit our gastrointestinal (GI) tracts and aid in digestion—also play a role.

Gut instincts

"The microflora in your digestive system 'talk' to your immune system," Reeves explains. "There's increasing work showing that the diet that you eat can change that microflora—the bacteria—in your digestive system. And if you change the population, then you change the conversation." Consuming beneficial probiotics, including lactic acid bacteria and bifidobacteria, appears to turn that conversation in an immuno-positive direction.

Probiotics out-compete pathogens like *Clostridium* and *E. coli* for space and nutrition in the gut to grow. This lowers the incidence of illness—as does probiotics' ability to alter gut pH to a level inhospitable to intruders. Probiotics also directly affect immune health—both innate and adaptive—by triggering proliferation of the cells that produce immunoglobulin A (IgA), an important mucosal antibody, and of T cells and natural killer cells.

Probiotics have proven in clinical trials to reduce the number and duration of respiratory tract infections and dental caries in children, and are linked to the prevention of acute diarrhea in children and traveler's diarrhea in adults. How they do this isn't entirely clear. "We understand that when you take probiotics, you see changes in a few key biomarkers," notes Mehring. "I think what's not understood is what is happening with probiotics on a very specific level to cause that change. The absolute mode of action is not as well understood as we'd like it to be."

One thing we do understand is that probiotic benefits are strain-specific. "We're talking about a microorganism that is a living being with a genetic makeup," Mehring says. "What is it about this specific probiotic strain that makes it more likely to impact something like atopic eczema, versus another in the same genus and species that shows no impact, or maybe even a better impact?"

Consider Danisco's probiotic strains *Lactobacillus rhamnosus* HN001 and *Bifidobacterium lactis* HN019. "There are multiple studies that have looked at these strains separately

and in combination for the immune-related condition atopic eczema," Mehring says, "and what they showed is that the HN001 had a very positive impact on lessening the severity in children, but the HN019 did not show a positive impact."

Similarly, Mike Bush, vice president, business development, Ganeden Biotech, Inc., Mayfield Heights, OH, notes that, though his company markets a number of probiotic strains closely related to its flagship *Bacillus coagulans* GBI30608, "they do very different things," he says. "They metabolize different carbohydrates very differently. They germinate at different temperatures. They produce different levels of lactic acid. So these are very closely related strains that have, in some cases, very different characteristics or mechanisms of action."

Finding an application and processing regimen that allows the probiotic cultures to survive is also key to producing a specific immune result. "Typically, when we're working with foods, we're hoping that consumers, on a daily basis, can consume anywhere between 500 million and 2 billion CFU," Bush says. Those sound like huge numbers, but in the context of some probiotic-fortified products, where "you're looking at 10 billion or maybe 50 billion CFU per day," he notes, they're utterly achievable. The biggest threats to probiotics are pH, moisture and heat. Yogurt and fermented dairy products are preferred probiotic vehicles because they present an ideal environment for the cultures, and the cool storage conditions keep dormant cells from germinating before conditions are right. "You're putting something like cottage cheese, ice cream or yogurt in a refrigerator," Mehring says. "So, in essence, you're controlling temperature all through the supply chain."

While refrigerated dairy is common, Bush notes his company has launched a probiotic-boosted tea, as well as muffins, bars and convenience foods. "Their organism is a spore-former, so it is exceptionally heat, acid, bile and pressure tolerant," he says.

Feeding the troops

Probiotics need a steady source of nutrition to maintain their well-being. That nutrition source is a prebiotic, typically a fermentable soluble fiber.

While traditional dietary sources of prebiotic fibers include inulin, oats, soybeans, barley and other plant materials, some single out galactooligosaccharides (GOS) derived from dairy as the model prebiotic. According to Lorraine Niba, Ph.D., marketing manager, Americas, FrieslandCampina Domo, Paramus, NJ, GOS delivers a three-part package of immunity support. By serving as a fermentation substrate for probiotics, it encourages their proliferation in the colon. "Secondly," she says, "this increase in population helps inhibit adherence by pathogens to the colonic mucosa." Thirdly, by yielding short-chain fatty acids as a fermentation byproduct, GOS lowers colonic and fecal pH, "further depleting pathogenic bacterial levels," she says.

One GOS, in powder and clear syrup forms, is designed for use in infant foods, beverages, dairy products, bakery products and nutritional bars. It's water-soluble at room temperature, and neither its structure nor its effectiveness is "impacted by typical processing conditions such as heat or acid treatment," Niba says. Odorless and colorless with clarity in solution, it's innocuous in most formulations, and 2.5 grams per serving suffice to qualify a product for a prebiotic claim.

Another prebiotic fiber gaining notice is larch arabinogalactan, or LAG, harvested from larch trees. LAG shores up immunity by feeding probiotic bacteria, serving as a source of the short-chain fatty-acid fermentation products that lower gut pH, and working directly on the immune system.

Brian Rodriguez, technical marketing and scientific affairs manager, Lonza Inc., Allendale, NJ, notes that pretreatment of human peripheral blood mononuclear cells with LAG correlates with enhancement of natural killer cell cytotoxicity, apparently through the action of cytokines. "In cell culture," he explains, "LAG induced an increased release of interferon gamma (IFN gamma), tumor necrosis factor alpha (TNF-alpha), interleukin-1 beta (IL-1 beta), and interleukin-6 (IL-6). It was found that the IFN gamma was most responsible for the observed enhancement of NK cytotoxicity."

Lonza uses a water-extraction method to produce its LAG ingredient, notes Rodriguez. Its highly branched structure makes it readily soluble in hot or cold water, and it maintains stability over a wide temperature and pH range. The company processes the ingredient to minimize odor and flavor, and any remaining "woody note," as he characterizes it, succumbs easily to flavor adjustment at typical use levels. (Studies suggest delivering 1.5 to 4.5 grams per day to achieve immune benefits.) The ingredient contains the polyphenolic flavonoids taxifolin and quercetin. "These have been shown to display a wide range of biochemical properties, including antioxidant and chemoprotective effects," he says.

Oxidation detox

Oxidation weakens the body's natural defenses, so it's no surprise that protecting against oxidation strengthens immunity.

"If you don't have enough oxidative protection," notes Ram Chaudhari, Ph.D., FACN, CNS, senior executive vice president and chief scientific officer, Fortitech, Inc., Schenectady, NY, "then you deplete immune capacity and trigger inflammation, where cells are slowly going to give up their natural defense." He cites good, old-fashioned vitamins and minerals as bulwarks against that damage. Carotenoids, vitamin C and vitamin E improve the capacity of innate immune cells to fight off infection and goose the proliferation of T-cells. Vitamin D is a membrane antioxidant that boosts innate immunity and protects against bacterial infection, he adds. And the antioxidant minerals copper, zinc and selenium regulate redox-sensitive transcription factors, while also affecting cytokines. Physiological amounts of zinc have reduced morbidity and mortality associated with respiratory and diarrheal diseases in developing countries, he notes.

Many botanicals also demonstrate antioxidant and immunoprotective behavior. Grape-derived ingredients, such as extracts of seeds and skin, contain potent polyphenolic antioxidants and may exhibit antiviral and antibacterial properties. "Grape seed proanthocyanidins may affect immune functions by increasing natural killer cell cytotoxicity and lymphocyte proliferation," notes Cecily Hawkins, associate scientist, H.I.T.S., Wild Flavors, Inc., Erlanger, KY. Studies show that green tea may increase lymphocyte proliferation, prevent inflammation and act against viruses and bacteria. Shiitake mushrooms are rich in beta-glucans that bind to lymphocyte surfaces and activate macrophages, T-helper cells, natural killer cells and other effector cells, she says. Shiitake may also increase production of IgA.

One patented blend of grape skin, grape seed, shiitake and green tea extracts standardized to 25% polyphenols and rich in antioxidant compounds "protect the body from the damaging effects of free-radicals," Hawkins notes. Clinical testing shows the product reduces the duration and severity of symptoms associated with the common cold. Clinical studies settle on 1.76 grams, taken twice daily with 100 mg of vitamin C, as effective in reducing symptoms of the common cold. "Depending on the application," she says, "you can typically use the full dose per serving." It's a dry, water-soluble powder suited for use in enhanced waters, juices, smoothies, shots, bars and frozen treats, she says. It's process- and condition-stable, although it does contribute a dark-purple color and noticeable astringency to formulations.

Masking flavors can usually take care of the off notes, Hawkins says. "Our flavor chemists have produced two new flavors that fit with the blend's inherent taste profile," she says. "One is a natural wild cherry flavor and the other is a natural Pinotage wine flavor."

Flame throwers

Among oxidation's less-desirable side effects is inflammation. Yet inflammation is also a crucial step in the immune response. "Inflammation, in the right place at the right time, is a definite good thing," Reeves says. "It's a sign that the immune system is bringing everything to bear on a problem. If you've got a cold or flu, you're going to get inflammation in some of your nasal passages and your lungs, and this is the immune system doing what it's supposed to do to fight off an infection."

It's when this inflammatory response goes into overdrive for no good reason that problems like allergies and autoimmune disorders result. Balance is key. Some foods and ingredients, and the compounds within them, help restore immunity's balance by modulating the inflammatory response. "What the right natural product can do," Reeves says, "is not attack the symptoms, but attack the root cause, which is this imbalance in the immune system."

One such product begins as baker's yeast (*Saccharomyces cerevisiae*), which undergoes aerobic fermentation during its growth. The yeast is added to a nutrient broth of proteins, fiber, vitamins, minerals and antioxidants, and the whole mix is subjected to a second, anaerobic fermentation. "When yeast is deprived of oxygen," Sturm explains, "it fights back by excreting metabolites. So we take that whole broth that has the beneficial parts of the yeast, the metabolites and all the nutrient content, and we dry the whole thing down to a very complex group of substances that actually becomes a single ingredient."

It affects an immune response, Reeves says, by "altering the flow of information" to and from the immune cells lining the gut. "And once you start interacting with those cells," he says, "you can start changing the messages being sent." Human clinical trials showed that subjects taking the product had significantly fewer colds and cases of the flu, and those they had were of shorter duration. He attributes this to the product's

ability to boost levels of IgA. They've also linked the product to stimulation of natural killer cell and B cell activity.

"In some of the work that we've done, we've actually shown that we can raise certain immune markers and suppress others in the same person at the same time," Sturm says. "That's what substantiates the balance claim."

The ingredient is heat-stable and has a three-year shelf life. The dried powder is dispersible—not soluble—in beverages. At higher concentrations, it contributes a golden-brown hue to products, but in a tea or citrus drink—or in a baked good—the effect would go unnoticed. GRAS in all foods and beverages at up to 3 grams, the ingredient has demonstrated effectiveness in adults at much lower doses—around 500 mg, Sturm says.

Another yeast-derived immune balancer not only defends against outside invaders, it "can be considered an immune modulator—a compound that helps restore normal immune function, whether too high or too low," says Rich Mueller, president and CEO, Biothera, Eagan, MN. A gluco 1,3/1,6 polysaccharide harvested from the cell walls of a proprietary strain of yeast, the product works by activating immune cells called neutrophils "to more quickly recognize and kill foreign intruders," he says. It does this without overstimulating the immune system.

The product is available in both soluble and dispersible forms. Mueller notes that both are stable to the heat, pH, chemical and pressure conditions typical to food and beverage processing, withstanding even UHT sterilization and retorting. A 200-mg daily dose, which can be incorporated into a typical 8-oz. beverage serving, demonstrates efficacy in most adults, he says.

Omega factor

Yeast fermentates aren't the only ingredients that modulate inflammation associated with the immune response. The omega-3s docosahexaenoic acid (DHA) and eicosapentaenoic acid (EPA), both long-chain polyunsaturated fatty acids (lc PUFAs), "have a major influence on the immune system in that they are anti-inflammatory," notes James Elliott, Ph.D., director, nutrition science affairs, DSM Nutritional Products, Inc., Parsippany, NJ.

Our bodies metabolize DHA and EPA to messenger molecules called eicosanoids and lessen inflammation. "Since many diseases, such as heart disease, have as their mechanism a constant state of inflammation," Elliott says, "this is a protective mechanism that keeps the immune system in balance."

A high degree of unsaturation makes long-chain omega-3s readily oxidizable. "In use, omega-3 lc PUFA oils should be handled to reduce exposure to oxygen as much as is practical," Elliott says. This means "incorporating into foods and beverages without excessive aeration that would accelerate oxidation," he notes. Metal ions, such as those contained in salts or in water used for formulation or production, can also compromise stability. Many DHA and EPA producers formulate their ingredients with antioxidants to stanch oxidation, after first removing any oxidized lipids from the unprocessed oils. Food matrices that protect the omega-3s from exposure to air, and packaging that reduces oxygen permeability, also increase shelf life.

Manufacturing DHA and EPA from fish oils processed to eliminate the oxidized lipids, aldehydes and ketones that promote oxidation, off odors and off flavors optimize immune-effectiveness "by removing objectionable molecules and stabilizing against further oxidation," says Elliot.

Anthony Palmieri, market segment head, DSM, says they outfit some of their dry omega-3 ingredients with a patented beadlet technology that protects micro-sized active particles in a water-soluble shell. "These small particles can then be more readily absorbed," he says.

Diane Hnat, senior technical marketing manager, DSM, notes that manufacturers should remain cognizant of the GRAS levels approved for the intended use. "The level of EPA to mitigate inflammation for any particular individual might be well above what can be dosed into a single serving of food," she says. "As well, since PUFAs are macronutrients, not micronutrients, the impact not only on the taste of the finished product but their effects on texture are also important to note. Major reformulation of a product might be needed to emulsify the oil or rebalance the mouthfeel."

That's a lot to keep in mind. But the bottom line for immune-enhancing products—indeed, for any food that claims a functional benefit—is results. Unless consumers ultimately feel better themselves—or at least believe they do—they won't come back for a second serving.

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Photo: United Soybean Board

The Many Faces of Soy

By Marie Spano, M.S., R.D.
Contributing Editor

Soyfoods have been popular for hundreds of years in Asian countries, but they hit the spotlight in the United States just over a decade ago when FDA approved a health claim relating soy protein to heart health. Since that time, new research has outlined the potential health benefits associated with the consumption of soybeans, soy proteins, soybean oil and soy isoflavones.

The whole bean

Soybeans are legumes that are high in fiber, potassium and folate, and contain all of the essential amino acids, making soy protein a complete protein. In addition, soybeans contain antioxidant isoflavones and the omega-3 fatty acid alpha-linolenic acid.

Numerous epidemiological studies have looked at the association between soyfood consumption and disease risk in Asian populations. Collectively, the research indicates soy intake is associated with a reduced risk of prostate cancer in men (*American Journal of Clinical Nutrition*, 2009; 89:1,155-1,163) and breast cancer in women (*Journal of the National Cancer Institute*, 2006; 98:459-471; *British Journal of Cancer*, 2008; 98:9-14). However, clinical studies haven't supported the breast cancer benefits noted in epidemiological studies. A plausible explanation for this discrepancy, and one voiced by some of the leading experts in the field, is that to derive protection against breast cancer, soyfoods need to be consumed during childhood and/or adolescence. What is especially noteworthy about this hypothesis is that the evidence suggests that consuming just one serving per day can reduce risk later in life by as much as 50% (*Journal of Nutrition*, 2009;139:796S-802S).

In addition to the epidemiological data on cancer risk, clinical trials indicate that soy protein lowers low-density lipoprotein (LDL) cholesterol by 4% or 5% (*Journal of Nutrition*, 2009; 139:796S-802S). Since each 1% decrease in LDL lowers heart disease risk by 1% to 2%, the effects of soy protein are significant. Furthermore, "when soyfoods replace higher-saturated-fat protein sources in the diet, soyfoods will further reduce cholesterol," notes Mark Messina, Ph.D., president, Nutrition Matters, Inc., Port Townsend, WA. "The overall effect is that soyfoods may reduce heart-disease risk by 10% or more. Plus, soyfoods may reduce heart-disease risk unrelated to their effects on elevated cholesterol levels, which is just one risk factor for heart disease."

Soy protein particulars

Soy protein is a complete protein that boasts a high protein-digestibility corrected amino acid score

Photo: Pioneer Hi-Bred

(PDCAAS; a measure of the amino acids humans need combined with the digestibility of the protein). "Research indicates that soy protein's satiating effect is similar to other proteins," says Michelle Braun, nutrition science specialist, Solae, St. Louis. "And though soy protein is on par with other proteins in producing satiety and aiding in weight management, it offers a clinically proven and unique advantage of reducing the risk of heart disease by reducing LDL-cholesterol levels. Therefore, incorporating soy protein into weight-loss diets is an effective way to improve satiety, aid weight control, improve diet quality and reduce the risk of cardiovascular disease."

In addition to its effects on satiety, soy protein can be used for the maintenance, repair and recovery of muscle tissue in response to physical training. However, soy protein does not stimulate muscle protein synthesis to the extent that whey, milk proteins and egg do, presumably because soy has a lower leucine content (*FASEB Journal*, 2010; 24:97.5; *American Journal of Clinical Nutrition*, 2007; 85:1,031-1,040).

Focus on isoflavones

According to Messina, "much of the recent interest in the role of soy in disease prevention and health promotion is because, among commonly consumed foods, the soybean is essentially the only nutritionally relevant source of isoflavones. Isoflavones have estrogen-like effects, although they are different from the hormone estrogen." These isoflavones are associated with many of the positive benefits of soy, including the decrease in breast and prostate cancer risk, as well as a decrease in hot flashes in post-menopausal women. Furthermore, "the isoflavones in soyfoods have been shown to directly improve the health of arteries," he says. "And finally, although still speculative, clinical studies suggest isoflavones may improve skin health."

Label and health claims

Title 21 of the *Code of Federal Regulations* (*CFR*), Part 101.82, outlines the FDA-approved health claim for soy protein and risk of coronary heart disease. Issued in 1999, this claim describes the relationship between diets that are low in saturated fat and cholesterol and also include soy protein, and risk of coronary heart disease: "25 grams of soy protein a day, as part of a diet low in saturated fat and cholesterol, may reduce the risk of heart disease. A serving of [name of food] supplies __ grams of soy protein."

To qualify for this claim, the food must be:

- Low in saturated fat and low in cholesterol as defined by *CFR* 101.62;
- Contain at least 6.25 grams of soy protein per reference amount customarily consumed;
- Meet the nutrient content requirement in *CFR* 101.62 for a low-fat food, unless it consists of, or is derived from, whole soybeans and contains no fat in addition to the fat inherently present in the whole soybeans it contains or from which it is derived.

Soyfoods are a healthy addition to the diet, adding nutrients and antioxidants. In addition, there's something unique about soy for decreasing breast and prostate cancer risk, and also lowering one or more risk factors for heart disease. Stay tuned for future research uncovering the health benefits of soybean oil enhanced with the heart-healthy omega-3 fatty acid stearidonic acid and any potential benefits of the soy peptide lunasin in the fight against cancer.

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Maintaining Flavor & Functionality: Reducing Sodium

By Cindy Hazen
Contributing Editor

According to an April 2010 report from the Institute of Medicine (IOM), "Strategies to Reduce Sodium Intake in the United States," the average American consumes about 50% more sodium than recommended in the Dietary Guidelines for Americans. Currently, average consumption is more than 3,400 mg of sodium per day. To meet the recommended level of no more than 2,300 mg daily will require a coordinated approach, "requiring new government standards for the acceptable level of sodium," according to the IOM report. "Manufacturers and restaurants/foodservice operators need to meet these standards so that all sources in the food supply are involved and so that the consumer's taste preferences can be changed over time to lower the amounts of salt in food."

Further, the report recommends that "the FDA set mandatory national standards for the sodium content in foods—not banning outright the addition of salt to foods, but beginning the process of reducing excess sodium in processed foods."

Excess sodium in the daily diet contributes significantly to high blood pressure, which affects nearly 75 million people aged 20 or older, according to FDA. "Success in reducing sodium intake will require national coordinated action," the agency agrees. "Over the coming weeks, the FDA will more thoroughly review the recommendations of the IOM report and build plans for how the FDA can continue to work with other federal agencies, public health and consumer groups, and the food industry to support the reduction of sodium levels in the food supply. The Department of Health and Human Services will be establishing an interagency working group at the agency on sodium that will review options and next steps."

A pinch of perspective

Michael G. Tordoff, Ph.D., faculty member, Monell Chemical Senses Center, Philadelphia, questions the efficacy of national mandates. "The IOM is proposing a dietary experiment involving the entire U.S. population, and I think there is a strong argument to be made for some initial research to see if there is a chance such a grand manipulation will work," he says.

Tordoff splits the sodium debate into two issues. The first is whether sodium reduction will be helpful. "My reading of the literature is that the greater good would be a drop in blood pressure of most people, which would lead to less chronic disease. This would be beneficial," he says.

"The second issue is whether sodium restriction is truly practical," Tordoff says. "My view is that stopping smoking

MARKET SNAPSHOT

Consumer Perception

A recent study from HealthFocus International (HFI), St. Petersburg, FL, revealed that, while nearly two-thirds (65%) of all consumers express some concern about sodium intake, 79% do not know the recommended daily intake level. Further, only 29% check the sodium content of the foods they buy. Further, the study found more than half of consumers (55%) reduce salt at the table, and nearly two-thirds believe sea salt (78%) is a healthier alternative. For the most part, consumers do know the types of foods that contribute significant amounts of sodium—french fries and other fast-food items, as well as processed meats—but only one-third of them avoid such foods.

The NPD Group, Port Washington, NY, made similar findings. In its "National Eating Trends" report released in April 2010, the company notes a gap between consumers' concerns about the amount of sodium in their diets and their actual consumption of low-sodium and sodium-free foods. Despite rising concern about sodium consumption, the number of people consuming low- or no-sodium foods has decreased.

or drinking alcohol will be easy compared with reducing sodium intake. There is a strong desire to consume salty foods, motivated by powerful physiological controls. It is unknown but quite possible that reducing the sodium intake of all foods (as the IOM recommends) will simply shift people's preferences from what they eat now to foods with relatively high sodium content. So, even if the sodium content of every food is reduced, it won't be very helpful if we all switch from eating fruit to potato chips."

The hope is that gradually reducing sodium in food will lead to a gradual drift downward in sodium preferences. "There are a couple of studies (by Gary Beauchamp and colleagues) suggesting that prolonged consumption of low-sodium foods will lead to a lowering of sodium preferences," Tordoff says. "However, the studies involve 'perfect' low-sodium diets with no relapses, and they show that it takes around six weeks to see this reduced sodium preference. On the other hand, consuming high-salt foods increases sodium preference in just 24 hours. It seems very unlikely indeed that there won't be occasional lapses of eating high-salt foods that will reset our preferences to like high concentrations of salt."

In Tordoff's view, salt replacers have limited utility from a taste perspective. "The fact is that sodium taste transduction involves a very simple ion channel, and there is little opportunity to modify its action; unlike, for example, sweet transduction, which involves a relatively large receptor with multiple binding sites, and so several targets for artificial sweeteners."

Beyond saltiness

"The combination of sodium and chloride has a long history of use in foods and has become a baseline for our salty taste perception," says Janice Johnson, Ph.D., applications manager, Cargill Salt, Minneapolis. But saltiness is just the tip of the iceberg. "In addition to salty taste, salt also acts as a flavor enhancer, helps balance and round out the overall flavor profile, and suppresses bitterness in products such as canned vegetables," she says

Among the many functions that salt provides, "in meat products, it solubilizes protein and enhances hydration," says Linda Kragt, technical services manager, Morton Salt, Chicago. "It helps regulate enzyme activity in cheese and also creates the expected texture. It controls the yeast activity in yeast-leavened breads and strengthens gluten so that doughs are more machinable. In many products, salt has a preservative effect by lowering the water activity and inhibiting bacterial growth."

Salt's role in controlling water activity "provides the right environment for desired microbial growth in many fermented products, such as cheese and meats," says Johnson. "It is critical for the non-sodium substitute to provide the same impact on water activity to ensure the desired flavor and texture profile that is attributed by the desired microorganisms."

Because sodium chloride is so adept at multitasking, it's important that the product designer understands and addresses all of the attributes sodium chloride brings to the formula.

"The developer should assess the roles of salt in the product and consider if other ingredients might be required to substitute for key functions that salt provides," advises Kragt. "In certain products, a lower salt content may result in a reduced shelf life. It may be necessary to modify the packaging or change the processing technique. To compensate, other ingredients may have to be added or increased, such as use of a salt alternative, antimicrobials or acidulents. Any of these changes need to be tested to ensure shelf stability, as well as consumer acceptability."

Aaron Graham, director technical innovation, Griffith Laboratories, Alsip, IL, finds that reducing sodium in an existing product is especially difficult and complex when the goal is to create a product match. Because of the many functions that salt may provide, salt substitutes may be helpful in reducing sodium and producing a salty flavor or mouthfeel, but fall short in delivering the other desirable properties.

Foods that contain multiple components, such as pizza, are more difficult to reformulate because the developer may have to reduce sodium in each item: sauce, cheese, meat topping and dough. "Also, products where salt has multifunctional effects, such as processed meats and poultry, are challenging to reduce sodium. A variety of approaches may be needed to provide the expected taste, yield and texture, as well as maintain the shelf life," says Kragt.

Different cheeses have a wide range of sodium levels—with lower sodium content found in fresh mozzarella and Swiss, and higher sodium content in specialty cheeses like feta and blue. "Salt and low pH are two important factors that help keep cheese safe from unwanted microbial activity, and salt does quite a bit for flavor," explains Mark Johnson, interim director and senior scientist, Wisconsin Center for Dairy Research (WCDR), University of Wisconsin, Madison. "In the past, we have found there is a limit on how far we can go to remove salt from cheese before people start to notice, but research on new technologies is helping change that."

Researchers at WCDR have applied for a patent on a process to make a loaf-form, low-fat process cheese using the same basic cheesemaking method used to develop a low-fat mozzarella cheese. "This process involves removing sufficient calcium during the manufacture of the cheese base and replacing melting salts normally used in process cheese with emulsifiers like mono- and diglycerides. The calcium may be re-added during the cheesemaking process to provide the low-fat, reduced-sodium cheese with all the positive nutrients found in full-fat cheese," says Mark Johnson. He believes it is important to note that the salt found in cheese only makes a minor contribution (less than 8%) to the overall U.S. dietary consumption of sodium.

Hidden sodium

A significant challenge lies in identifying and attending to the less-obvious contributors of sodium. "Sodium alone is not used as an ingredient in food products," says Janice Johnson. "There are many ingredients that contain sodium, and they have many functional roles, such as preservation, leavening and flavor. For example, sodium and potassium lactate both act effectively as a preservative in meat products." The developer will have to examine the sodium contribution of various ingredients in the formula and identify those that will need sodium reduction.

According to John Brodie, technical service manager—bakery, Innophos, Cranbury, NJ, nearly all the sodium in baked goods comes from salt, sodium bicarbonate and leavening acids. "Most formulators start sodium reduction by looking only at replacing salt, which can be difficult to replace without affecting taste," he says.

In chemically leavened products such as cakes, muffins, donuts, pancakes and biscuits, salt can contribute about 30% to 50% of the total sodium. "Sodium acid pyrophosphate (SAPP), a widely used leavening acid, will contribute 20% to 35%," Brodie says. "Sodium bicarbonate will contribute 20% to 35%. By replacing SAPP with a calcium-based leavening acid, you can reduce sodium by 20% to 30% in your finished product. Most companies are looking to reduce sodium by 15% to 25%."

Slower calcium acid pyrophosphate/monocalcium phosphate leavenings (CAPP/MCP) can be used as a one-to-one replacement for SAPP 28, since they both have a neutralizing value of 72. The neutralizing value of a leavening acid is the number of pounds of sodium bicarbonate that can be neutralized by 100 pounds of acid. No other changes to the formula will be needed. "Calcium phosphates are bland in taste, so your product's flavor profile will not change," Brodie says. "It is possible to replace sodium bicarbonate with potassium bicarbonate, but you will need to use 19% more, and the cost difference is significant."

Besides a reduced-sodium declaration, an added benefit of using slower calcium phosphates is a boost to the calcium content of a product.

Another option, glucono-delta-lactone (GDL), is a sodium-free leavening agent that "can be used very effectively in bakery leavening systems by replacing the sodium acids typically found in baking powders," say Peter Bradbury, market development manager, Jungbunzlauer, Newton Centre, MA. "Functionally, GDL offers excellent leavening properties, clean taste profile and is a cost-competitive solution for sodium-reduction challenges." It is considered a

time-delayed agent, because carbon dioxide is released over time. Because its reaction rate is accelerated by increased temperature, the rate of leavening can be controlled.

Substituting salt

Benjamin Jones, Ph.D., senior flavor chemist, David Michael & Co., Philadelphia, suggests replacing sodium with other salt compounds that taste "salty." But, these can have limitations. Lithium chloride—tried commercially in a salt substitute in the '40s—is toxic at needed levels. Calcium chloride can be bitter with a sweet-and-sour aftertaste. Magnesium chloride can add bitterness. Potassium chloride has a salty flavor similar to sodium chloride, but has a slightly metallic/bitter note. "Bitterness blockers reduce the metallic/bitter aftertaste of potassium chloride and allow for a slightly higher potassium chloride usage rate," Jones says. Reducing sodium chloride is easier with products that have a strong flavor characteristic compared to relatively bland products. "A 10% to 25% reduction can usually be done without detection," he says. "Any more than 25% should be decreased gradually over time."

Strategies can prove application-specific. Some salt replacers that work well in soups and gravies, "when applied to sausages, result in a sausage with a crumbly texture and premature loss of pink color," cautions Mike Bunczek, principal scientist, innovation, Griffith Laboratories. He finds that reducing sodium in ground meat products is often the most difficult. "Sodium has a strong impact on texture, shelf life and color stabilization," he says. "One suggestion to minimize this issue is to dissolve the salt substitute in water prior to addition to the product to improve distribution throughout the product."

Graham points out that it is also important to remember that optimal compositions of salt replacers usually vary with actual salt level. "A salt replacer that works well at 0.75% salt level does not necessarily work as well when salt level is 1.50%," he explains.

The food scientist should keep in mind that sodium reduction "will involve flavor work, since salt substitutes may accentuate the flavor contributions of other flavor components in the food product," Graham says. "This necessitates working with your seasoning/flavor partner to make sure that the reduced-sodium product matches the current product. Product developers should also consider label, allergen and cost before developing low-sodium products."

As a general guideline, Mariano Gascon, vice president, R&D, Wixon Inc., St. Francis, WI, proposes that small sodium reductions can be achieved by reducing the salt by 5% to 15% without affecting the quality of the product. He recommends adding potassium chloride to compensate for greater reductions.

Although potassium chloride does not contain sodium, "it has a salty component because it stimulates some of the same taste receptor cells as sodium chloride, even though the taste-transduction mechanisms for sodium chloride are different than those engaged by sodium chloride," Gascon says.

When a formula contains 25% less sodium, Gascon generally recommends using potassium chloride as a 1:1 replacement. At reductions of 25% to 50%, potassium chloride can replace sodium at 1.15:1. It's important to remember that actual percentages will be dependent on the end product.

"Sodium reduction is very application-specific," Gascon says. "We classify the challenge on three types: formulating foods with low water activity, formulating foods with high moisture content, and formulating foods with high fat." These three categories have the most effect on salt perception.

Potassium chloride enhances saltiness and "can help restore losses in ionic strength," says Kragt. "Although potassium chloride contributes saltiness, it can also provide a metallic note, so 100% substitution for salt is not advised. In addition, many flavor houses now offer masking agents or bitter blockers that can improve the flavor profile of products formulated with partial potassium chloride substitution."

Speaking of potassium chloride, Chris Warsow, corporate executive chef, Bell Flavors & Fragrances, Northbrook, IL, says: "Many people perceive it as having a bitter-metallic flavor. I work with a number of masking agents that can help to mitigate those off flavors. By using flavor enhancers, you can boost the overall savoriness of the product so the consumer does not miss the salt."

Janice Johnson believes that "potassium chloride is the best substitute for sodium chloride. It works well as a foundation for significantly reducing sodium in processed foods," she says. "It mimics salt in ways such as texture and protein-binding, water-retention capacity, and fermentation control."

One ingredient that can be used in place of sodium chloride "consists of taking potassium chloride and modifying the crystal structure to enhance the flavor to make it taste more like regular salt," says Teresa Isakson, sales and marketing director, Nu-Tek Products, Minnetonka, MN. She suggests using this product at a 1:1 replacement for sodium chloride.

"In a dry application, the salty perception should be slightly more intense, and in a wet application it will be slightly diminished," Isakson says. "In a wet application, any potassium-based salt will have a slightly weaker flavor perception because the potassium molecule is larger than sodium, thus giving less ions to give the salty perception."

This potassium chloride functions well in meat "because it has an ability to hold onto water well in meat applications, thus improving yields," Isakson says. "In a dry-coating application, it has a lot of surface area, giving an enhanced salty perception. You would not need as much of our product as regular salt to get the same salty perception in a dry application."

Because the potassium molecule is larger than the sodium molecule, Warsow cautions that when it comes to binding processed meats, potassium chloride is not as effective as salt on a weight-by-weight basis. "To get the same protein extraction and water-binding capacity, you have to use slightly more potassium chloride," he says.

One salt substitute consists of sodium chloride, potassium chloride and sodium gluconate, notes Bradbury. The latter ingredient is a "metal chelator, which blocks the bitterness of potassium, therefore providing a very clean taste profile and full functionality," he says. The product works well in soups, salad dressings, sweet baked goods, topical applications and meats.

Reduced-sodium solutions

In savory applications, sodium can often be reduced by decreasing salt and increasing other flavors. Kevin McDermott, technical sales manager, Savoury Systems International, Branchburg, NJ, suggests using yeast extracts as a means for reducing the sodium level in the original formulation. He recommends replacing sodium with a flavoring component, such as yeast extract, or developing new products using yeast extracts as a base flavor for flavor development.

"Generally, yeast extracts will have a much lower usage level than added salt, while still providing savory flavor and overall mouthfeel," McDermott says. "With the addition of the savory flavor added by the amino-acid profile of a yeast extract, a developer can reduce the amount of salt that is being added in a finished food product while not turning off the consumer to the product due to loss of the sodium flavoring component."

Well-known flavor enhancers like monosodium glutamate, (MSG), inosinate + guanylate (I+G), hydrolyzed vegetable protein (HVP) and autolyzed yeast extract (AYE) have the ability to boost flavors, including salt perception.

"Flavor enhancers such as MSG and nucleotide can boost overall flavor and salty taste by putting back the enhancement functionality that salt has," says Judy Kim, senior researcher, CJ CheilJedang, Seoul, South Korea. "So they maintain quality, even though salt is reduced in the formulation." She says MSG is most effective in soups, bouillions, sauces and other applications with water in the finished product. "In some applications, a synergistic combination between MSG and other ingredients with sweet, umami and acid taste should be considered."

While some consumers report adverse reactions to MSG—headache, flushing, sweating, heart palpitations and nausea, among them—research has not found a definitive link between MSG and what's referred to as MSG symptom complex. In a review of available literature on the relationship between MSG consumption and MSG system complex, including wheezing, welts, hives, migraine and stuffy nose, researchers concluded that "decades of research have failed to demonstrate a clear and consistent relationship between MSG ingestion and the development of these conditions (*Clinical & Experimental Allergy*, 39:640–646). Further, a 2009 study assessed whether blood pressure (BP) was associated with glutamic acid intake. The researchers found that the more dietary glutamic acid subjects consumed, the more their blood pressure fell, leading them to conclude: "Dietary glutamic acid may have independent BP-lowering effects, which may contribute to the inverse relation of vegetable protein to BP" (*Circulation*, 120:221-228). Nevertheless, there are still a growing number of consumers looking for alternatives to the standard flavor enhancers.

"With consumers demanding cleaner labels, natural alternatives fit into the equation more than ever," says Joe Leslie, national industrial sales & marketing manager, Kikkoman Sales USA, Inc., San Francisco. "Companies with fermentation technology have met this need by creating new, all-natural products that provide umami and expand flavors," such as a new line of low-cost natural flavor enhancers that increase salt perception in foods without adding their own flavor to the end product. "These can be used by themselves, or be part of a sodium-reduction system—often partnering with potassium," he notes.

MARKET SNAPSHOT

Rising Demand

According to a report from Packaged Facts, New York, "Low- and No-Sodium Foods and Beverages in the U.S.," the market for low-sodium/salt and no-sodium/salt products in the U.S. market reached $22 billion in 2009. Low-sodium/salt foods and beverages comprised $17 billion of the total, and no-sodium/salt products accounted for the remainder. The market research company believes that number will continue to rise as the quality of such products improves.

It's important to consider that some enhancers are not sodium-free. "Yeast extracts act as flavor enhancers, but usually bring along some amount of sodium," cautions Jones. "Yeast extract ranges from 2% sodium chloride (low-sodium versions) up to around 40% sodium chloride. HVPs also act as flavor enhancers, but typically have significant amounts of sodium. HVPs are typically about 40% sodium chloride. Anyone working with YEs or HVPs should check with the vendor for sodium chloride levels of the product."

Warsow keeps umami enhancers in his developer's kit. "The use of herbs and spices can be used to boost overall flavor without adding sodium," he says. This works especially well in processed meats. In various applications, he also suggests using organic acids, such as lactic, citric and malic, to fool the taste buds and boost the salty perception of a product.

"Dried plum ingredients offer food processors opportunities to reduce the amount of added salt in formulations, without negatively impacting formula flavor objectives, while maximizing consumer flavor expectations," says James Degan, consultant, California Dried Plum Board, Sacramento, CA. This is because dried plums naturally contain 1.5% to 2.0% malic acid, an effective flavor enhancer. In bakery and meat applications, added salt can be reduced up to 25% when using dried plums.

Warsow says common American soups are among the most-difficult products when it comes to reducing sodium. "We are all very familiar with the classic tastes of tomato soup, chicken noodle soup and minestrone soup," he says. "Salt is a big flavor driver in all of these products. In the case of a minestrone soup, you can increase that herb profile by using a flavor that will boost and enhance the fresh herb notes in the product. You can also use an umami enhancer to boost the savoriness of the tomato base."

For Gascon, snacks are a big challenge because of the associated sensory phenomena. "When you sample a salty snack, the amount of salt is topical. You will perceive it immediately, so your brain will turn down the volume on the salt message and you will taste less salt each time," he says. "Traditionally, food developers have been forced to add heavy quantities of salt to assure that the intensity of the saltiness is great enough that even with the adaptation phenomena, you still will be able to taste the salt."

Because potassium chloride stimulates some of the same taste receptor cells as sodium chloride, its off-putting qualities are more pronounced in topical applications and can present flavor-modification difficulties.

Sometimes the perception of saltiness—and the resulting level of salt needed—can be adjusted by the choice of salt used. According to Kragt, "a finer salt will impart a rapidly sensed saline taste. Coarser salts deliver a slower, more-lingering saltiness. It is a good idea to consult with your salt supplier to learn about different salt options for specific applications."

One sodium-reduction solution comes via changing the structure of the salt granule. The crystals "are created from a process that starts with a hollow pyramid shape," says Janice Johnson. "This shape has a wide surface area and low bulk density that increases the rate at which the crystals dissolve. When these crystals touch the tongue, the rapid dissolution causes a flavor burst, allowing manufacturers to reduce the amount of salt while maintaining that salty flavor consumers desire." She notes that manufacturers, ingredient suppliers and researchers are diligently working on trying to create new sodium-reduction solutions. "By working together, knowledge transfer from fundamental research to applications occurs more quickly and effectively, thereby resulting in more concrete solutions and better likelihood of commercial success," she says.

Yet even with an industry-wide effort, the biggest obstacle may be getting everyone on the same page at the same time. Can a population adapt at the same pace so that food processors don't lose consumers?

"Salt perception is learned," says Jones. "As consumers become accustomed to lower-salt products, old products are perceived as too salty."

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Natural Product Protection

By Renée Gan
Contributing Editor

It is no secret that consumers today are looking for natural ingredients on their food labels—or perhaps more accurately, the absence of chemical-sounding ones. The natural arena is heating up, buoyed by the growing popularity of the locavore and sustainability movements. In a recent release from the Natural Marketing Institute (NMI), Harleysville, PA, "pure and simple" was listed as one of the top trends for the new decade, with "cleaner labeling" and "less is more" specifically cited. This puts the onus on food scientists to develop products without the old stand-by preservative systems.

Tying up free radicals

Oxidation—particularly of fats—can be one of the biggest issues in manufactured foods. Synthetic antioxidants, such as BHA and BHT, are very effective, but not very natural. Therefore, demand for naturally occurring antioxidants is rising.

First, a quick review of the autoxidation reaction: Oxidation occurs when free radicals formed in the initiation step combine with oxygen to form peroxy radicals. These peroxy radicals yield hydroperoxides in the propagation phase.

Antioxidants act by either inhibiting the formation of free radicals in the initiation phase or hindering the free-radical chain reaction in the propagation phase. The majority of the antioxidants in food act as free-radical scavengers, thereby terminating the chain propagation reaction. In addition, synergists scavenge free radicals along with the primary antioxidant, or metal chelators inhibit the formation of free radicals in the initiation step.

A natural against oxidation

Plant-based antioxidants, such as essential oils, tocopherols and extracts, have shown they are able to stand up with the synthetics when it comes to antioxidant and antimicrobial activity. One such example is rosemary extract, which is quickly becoming one of the go-to natural antioxidants because it contains phenolic compounds that can bind free radicals. Commercial applications have shown protective effects similar to that of BHA and BHT. "Specific rosemary extracts can replace synthetic antioxidants in meat applications," says Jim Bacus, Ph.D., managing partner, Technology Ingredient Solutions LLC, Gainesville, FL. "Carnosic acid is the key indicator for rosemary activity. We evaluated natural pepperoni for 130 days at 36°F, and found that 100 ppm carnosic acid provided the same oxidative inhibition as did a combination of BHA and BHT used at the maximum allowable limit." Similarly, just 50 ppm carnosic acid was able to protect color stability in fresh pork sausage compared to BHA and BHT.

"Successful applications of rosemary extract have been in the preservation of poultry fat without flavor alteration,

and in avoiding warmed-over flavor (WOF) development in precooked meat products," says Samuel Menard, sales director, Naturex, Inc., South Hackensack, NJ. "After having screened multiple botanical and spice extracts for almost 20 years, our technical groups have determined that rosemary has proven to be the most efficient and sustainable product with respect to antioxidant power, abundant raw materials and cost-efficiency."

Spicing up the bac attack

A group at USDA's Agricultural Research Service (ARS), Western Regional Research Center (WRRC), Albany, CA, is evaluating the bactericidal properties of various essential oils and active compounds found in plant extracts. They have shown that carvacrol, an essential oil and an active ingredient in oregano, was found to have a bactericidal effect on *E. coli* O157:H7 and *Salmonella enterica*. The method of delivery to administer the essential oils is novel: edible films made with purées of apple or tomato.

In an earlier study, Mendel Friedman, research chemist, ARS WRRC, performed an exhaustive investigation of more than 200 botanicals for antimicrobial activity (*Journal of Food Protection*, 2002; 66(10):1,811-1,821). Some of the front-runners were oregano, thyme, cinnamon, clove, lemongrass and allspice. That work became the backbone for subsequent edible film studies.

In one of those studies, apple-purée films made with carvacol or cinnamaldehyde at different concentrations (0.5%, 1.5% and 3.0%) were wrapped around raw chicken breast and ham inoculated with *S. enterica* and *E. coli* O157:H7 and held at different temperatures. Researchers observed significant log reductions in both pathogens—from 0.7 all the way up to 7.8 log CFU—with carvacrol showing better activity than cinnamaldehyde under certain conditions. This technology shows promise for controlling surface pathogens on meats.

However, such approaches might pose a hurdle or two. When incorporated into films at concentrations needed to kill pathogens, notes Tara McHugh, Ph.D., research leader, ARS WRRC, they could adversely affect the sensory properties of the final foods. "We are working on developing films that are also sensorially acceptable," she says.

The somewhat beleaguered, but popular, bagged-salad category could be dealt some relief from recent food-safety issues by utilizing another dimension of this technology. "We have studied the vapor action of natural antimicrobials, and many of these are active in the vapor phase. For products like leafy greens, we feel this offers potential benefits," says McHugh. This may prove an exciting breakthrough, since the vapor phase could work its way into the crevices of leaves where pathogens are hiding—a real issue with bagged salad greens.

To demonstrate vapor-phase efficacy, tomato-purée films laced with oregano oil (carvacrol), allspice oil (eugenol) and garlic oil (high volatiles, sulfides) were pitted against *E. coli* O157:H7, *S. enterica* and *Listeria monocytogenes*. "These tests were performed in Petri dishes containing bacteria, not on actual spinach," notes McHugh. "However, the results are promising. We are performing tests on produce now, and results will be completed in the near future." Researchers envision squares of the edible films placed in the bag with the lettuce to do their thing. The vapor action could add another much-needed layer of protection for bagged leafy greens.

Natural 'cures'

For natural salami and sausage, alternatives to adding synthetic nitrate are employed. Plant sources like spinach and celery, which have inherently high amounts of nitrate, can be substituted.

"We are trying to find natural ingredients that will contribute to control of bacterial growth, and for those that do, trying to determine how much help they may offer for 'naturally cured' processed meats," says Joseph Sebranek, Ph.D., professor, Iowa State University, Ames.

Sebranek cautions that consumers may expect natural meat products to be able to withstand the same handling and temperature abuse as a conventionally cured product from a microbial standpoint, which is not always the case. "The most-meaningful comparison is the in-going, or added, nitrite or nitrate, because curing reactions reduce the nitrite concentrations in both cases," he says. "This makes the residual nitrite a relatively poor indicator of how much was initially added or generated from nitrate. The added nitrite for sausage products in conventional curing is limited to 156 ppm, and that is what is most often used. The 'natural cure' with celery powder adds the equivalent of 40 to 80 ppm, depending on

the form and amount used. So, the concentration is about 25% to 50% of the conventional curing approach."

Natural vinegar, lactate and lemon powder have also shown an ability to fight bacteria. "The effective ingredients help by increasing the lag phase by anywhere from a few to several days, but temperature plays a major role, as you would expect," says Sebranek. "Several of the major meat processors are using high-pressure pasteurization to improve the bacterial control of the naturally cured products, and thus provide the added protection that is achieved in the conventional curing process."

Regarding their research, Sebranek notes that "the general effects that we have seen seem to apply to several pathogens. We have measured responses for *L. monocytogenes* and *Clostridium perfringens*, and have collaborated with another laboratory for work on the same products with *C. botulinum*."

Fermented protection

Bacterial fermentates can also serve as natural preservatives and are growing in popularity along with the natural product category; examples are nisin, natamycin and several cultured products with label-friendly names such as cultured cane or corn sugar, cultured dextrose, and cultured skim milk. When using these antimicrobials, product developers should know what organisms they want to fight: gram-positive or gram-negative bacteria, molds, yeasts or different combinations thereof.

"Natamycin is a surface-active direct antimycotic and, therefore, will prohibit fungi growth by exerting an inhibition area around each particle of natamycin," says Jit Ang, executive vice president, International Fiber Corporation, North Tonawanda, NY. "When enough particles are present, these growth-free areas will be abundant enough that they overlap, thereby preventing yeast and mold growth in the food to which natamycin is applied. Natamycin functions by distorting the cell membrane of fungi, thereby creating 'leaky' membranes."

Certain factors should be taken into account when using natamycin. "Natamycin is most stable around neutral pH," says Ang. "High and low pHs will reduce its stability. It is not very sensitive to heat, but UV light will degrade natamycin.

"For normal natamycin to work, literature has reported that a minimum of 7 ppm must be present on the surface of cheese or food," continues Ang. "However, recent innovations have improved upon this, and new forms of patented natamycin have been shown to be significantly more effective. In the United States, food regulations will permit not more than 20 ppm natamycin to be present on the surface of shredded and grated natural cheeses. In Canada, the permitted level is 10 ppm. Normally, natamycin is more effective against mold, and higher concentrations may be required for yeast inhibition."

Cultured-sugar preservation products provide a broad spectrum of activities against bacteria, yeasts and molds, and contribute to clean labels by allowing the removal of chemical additives such as benzoate and sorbate. "We have generated data across a wide range of food products, including soups, entrées and pasta; refrigerated deli salads (meat and non-meat); refrigerated dips, including salsa, sour cream and hummus; shelf-stable sauces and dressings; and bakery items, that shows cultured-sugar products are effective antimicrobials compared to the control and, in many cases, compared to other commercial fermentates and chemicals," says Jarret Stopforth, technical services manager, Purac America, Lincolnshire, IL. "In addition, such fermentates were highly effective against most pathogens, including *Listeria monocytogenes*, *E. coli* O157, *Salmonella* and *Staphylococcus* in various food matrices."

Stopforth also notes that, aside from their role in preservation and food safety, these ingredients "have demonstrated enhancement of flavors already present, such as spices, color protection, thickening properties, and creaminess and smoothness in various food applications."

Keep in mind, however, any legal definition of "natural," particularly in USDA-regulated products might disallow the use of any additives for preservation—natural or not—so make certain you know what rules pertain to your specific product.

As the food industry increasingly moves toward natural preservation, product developers must act as guardians to make sure it is not at the expense of food safety. Everyone should be cognizant of differences in mechanisms and efficiencies of natural preservative alternatives compared with conventional, proven product protection. Work in this area is quite active, so new research is continually being completed, and current solutions are being refined to meet the natural category's growing needs.

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Natural History

Natural products are growing increasingly popular with consumers. When designing products that fit into this category, it's important to understand federal perspectives on the subject.

To navigate the natural claim landscape depends first on the type of food product one is designing. Is it USDA or FDA governed? In what context is the claim being made? How is the food processed? Even with clear answers to those questions, the waters are still a little murky.

In 1982, the Food Safety and Inspection Service (FSIS) of the USDA published Policy Memo 55. This memo provided guidance to manufacturers wishing to make natural claims on their label to include a brief statement that the product is "a natural food because it contains no artificial ingredients and is minimally processed. This statement needs to appear contiguous to, or linked to, the term 'natural' on the label." It also allowed for FSIS to approve or deny claims based on their context. The guidance has been modified from time to time to reflect recent decisions and to be consistent with current policies.

In 2005, sodium lactate, along with natural flavorings from oleoresins and sugar, were added to the guidance as acceptable in products with a natural claim. FSIS indicated that the modifications were meant to reflect decisions that had already been made by the agency on a case-by-case basis. A veritable uproar ensued, mostly concerning the inclusion of added sodium lactate. FSIS backpedaled on their initial allowance of sodium lactate and stated that it would define "natural" through the rulemaking process. A public meeting was subsequently held in Dec. 2006, soliciting comments regarding the "natural" claim.

Fast-forward to Sept. 11, 2009. FSIS issued an Advance Notice of Proposed Rulemaking (ANPR) to assist the agency in defining the conditions under which it will permit the voluntary claim "natural" to be used in the labeling of meat and poultry products. A comment period was opened for two months. When asked for an update on the timing of a ruling, a source at FSIS replied: "The purpose of the ANPR is to solicit more focused comments on several issues. We will analyze the comments and, based on that analysis, we will determine the next steps. FSIS is taking the necessary time to carefully consider issues related to industry use of 'natural' claims and to decide upon the most-appropriate course of action."

Until the rulemaking is finalized, the current approval process still applies. Our FSIS source states: "FSIS has made every effort to address stakeholders' divergent views about how the word 'natural' should be defined, including seeking a discrete set of alternatives. While FSIS decides how it will proceed, companies are still free to submit labels for consideration, and each label will be judged on a case-by-case basis."

FDA, on the other hand, made a decision to not formally define "natural," but defers to guidance given in 1988 which states that no artificial or synthetic ingredient can be added to the product that would not generally be expected to be in the food. Furthermore, even if the ingredient source is considered natural—for example, turmeric added to baked goods for color, not as a flavoring—that food still cannot be called natural. FDA will continue to hear protests to specific cases as they are presented.

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