

Probiotic strain specificity in formulation, labeling and marketing

by Kristen McPhee

For probiotic formulators, understanding the specific types of live microorganisms and their functions is essential to helping consumers achieve optimal facets of health and consequently, overall health.

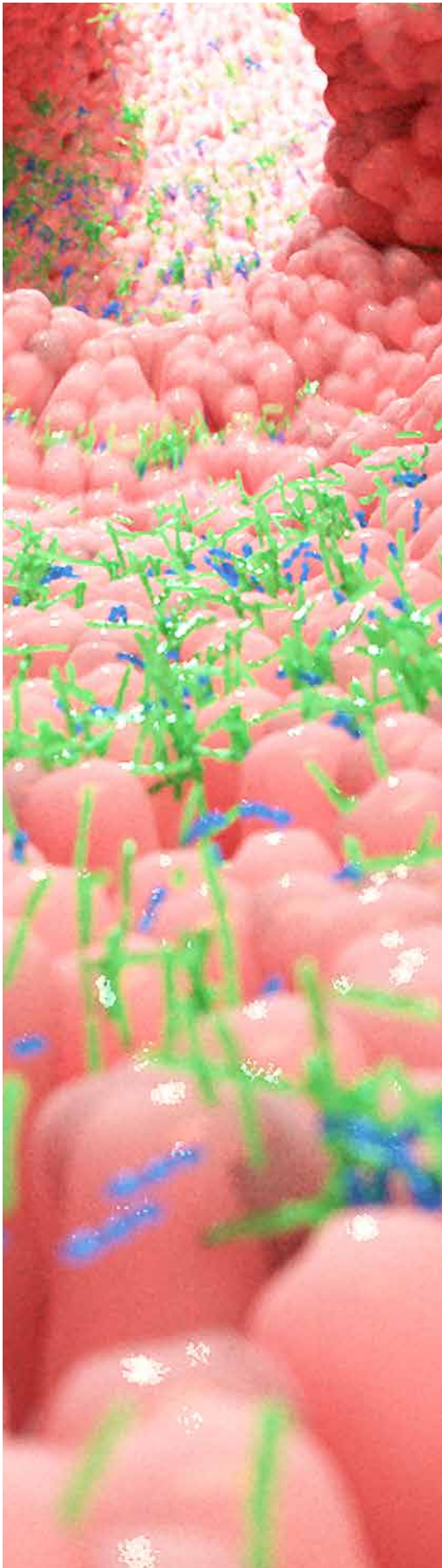
A majority of probiotic strains are derived from the lactic acid-producing genera *Lactobacillus* and *Bifidobacterium*. Clinical trials over the past several decades have shown that the species within these two groups, such as *L. acidophilus*, *L. rhamnosus* or *B. lactis*, offer unique benefits and perform different functions. However, a growing body of research supports the concept that variation exists among strains of the same species—*L. rhamnosus* GG, for example, has been shown to help inhibit traveler's diarrhea.¹

Inter-strain variations can present as differences in growth requirements, shelf-life stabilities, metabolic profiles and clinical efficacy. Probiotic strain selection can influence product formulation, labeling, marketing and, ultimately, consumers.

A 2018 systematic review and meta-analysis of randomized controlled trials explored the potential correlation of strain specificity and probiotic efficacy.² Of 228 studies, 135 examined the efficacy of 17 probiotic products containing designated single or formulated strains in active *Clostridium difficile* infections, inflammatory bowel disease (IBD), irritable bowel syndrome (IBS), *Helicobacter pylori* infections and acute pediatric diarrhea. Sixty-five percent of the probiotics showed strong efficacy. Noteworthy, 63 studies examined the effects of designated strains in acute pediatric diarrhea; 29 of the 63 studies used *S. boulardii* CNCM I-745 as the intervention which showed significant efficacy. The remaining 93 studies examined the efficacy of 10 probiotic products in preventing *C. difficile* infections, antibiotic-associated diarrhea, hospital-acquired infections and traveler's diarrhea, with 70% showing strong efficacy. For both the active and preventive pooled groups, specific designated strains showed clinical efficacy for certain conditions but not others. In other words, the potential efficacy of probiotics for specific health conditions is heavily influenced by the designated strain or strains used; merely sharing the same genus and species alone does not necessitate the same clinical outcomes.

"There is no guarantee that just because probiotics are from the same species that they will behave or function the same," noted John Deaton, vice president of science and technology of Deerland Probiotics and Enzymes. "Formulators should, therefore, take this into account and consider formulating with strains that have been shown, via strain-specific studies, to function in the desired way. Otherwise, they run the risk of creating products that may not have the desired stability or benefit."

Niklas Larsson, director of scientific affairs of Probi, said the significance of strain specificity in product formulation is "related to the microbiological mechanisms and the associated health benefits. Some mechanisms are widespread/common for a large group of probiotics; some may be related to a species; and some more-specific health benefits can be, and often are, strain-specific."³



When it comes to labeling probiotic dietary supplement products, “It is generally a good idea to indicate the strain name on the label, as [recommended by the IPA](#) [International Probiotics Association], even if there may not be strain-specific clinical data for all strains in a product,” Larsson stated. Indeed, several international probiotic guidelines recommend that strain designation be reported in clinical trials in part to help companies utilize and substantiate strain-specific efficacy.

“I’ve noticed a definite shift in brand owners’ clearly identifying the bacteria’s genus, species and strain on labels,” reported Buffy Stahl, technology scouting and open innovation leader of IFF Health. “This is likely because brands are incorporating quality strains which have been demonstrated in clinical trials to help consumers target specific health needs such as immune, prenatal or brain health. By featuring specific strains on the label, brand owners can highlight the science-backed health benefits these strains can provide consumers. And, in an industry constantly navigating product adulteration, this provides brands with more transparency so they can showcase the quality and efficacy of their strain-specific products compared to placebo.”

One example of a clinically researched strain-specific probiotic that has influenced product formulation and marketing is *L. paracasei* Lpc-37.⁴ The ingredient improved psychological and physiological markers of stress and anxiety in 120 healthy adults after five weeks of supplementation with a daily dose of 1.75×10^{10} colony-forming units (CFUs) in a double-blind, placebo-controlled clinical trial. Taking these findings into consideration, Lpc-37 was selected as the cornerstone designated strain in HOWARU Calm from IFF Health, a novel probiotic dietary supplement geared to promote calmness in adults.

The clinical efficacy of Lpc-37 does not necessarily indicate efficacy for other *L. paracasei* strains, however. “Probiotic species yield great genetic diversity,” Stahl noted. “The specific effects of probiotics are dependent on the type of strains used, as well as the dosage and strains’ potency through end of shelf life.”

In fact, the IPA recommends that product labels include the quantity of live microorganisms in CFUs at the end of the declared shelf life, not at the time of manufacturing. Also, products containing multiple designated strains are recommended to provide the total CFUs on the label; if a product contains a single designated strain, then the total CFUs for that strain is provided.

According to Dawn Jarvis, senior director of nutrition translation and educational content, Garden of Life has fully adopted these best practices. “We believe it is important to demonstrate that our probiotics contain the actual strain in the clinically studied dosage,” she said. “Providing a total CFU count for the entire blend enables manufacturers

Ingredients: Strain-specifics

to avoid disclosing the dosage of each individual probiotic in the formula. We have come a long way as a brand and today, all of our probiotic labels provide a CFU count for the time of expiration.”

What does the industry shift to formulating, marketing and labeling probiotic products with strain specificity for greater efficacy and specific health benefits mean for consumers? According to Deaton, “marketing and labeling with appropriate strain designations helps to empower consumers to choose the probiotic products that will be best for their health. It’s incredibly difficult for a consumer to choose the *L. acidophilus* strain, for example, that would be most beneficial for them, when they have no way of distinguishing *L. acidophilus* strains with specific clinically proven benefits from those that have not yet been tested.”

Elodi Ruffin, digestion and gut health market manager of Gnosis by Lesaffre, added, “Consumers are seeking the science behind everything that they consume, so brands are actively working to improve their transparency and give consumers the information they need to make informed purchase decisions. With probiotics, in particular, they’re beginning to learn the specific health benefits of specific strains and seek out those specific strains in products.”

Jarvis echoed these expert opinions, stating, “Full strain identity enables our consumers to distinguish better quality brands, formulated with clinically researched strains.”

International guidelines and industry experts are recommending integrating strain specificity into published clinical studies. Meanwhile, consumer awareness about the unique health benefits of designated probiotic strains is growing. In response, more companies are creating novel probiotic products and highlighting their strain-specific efficacy through marketing and labeling efforts. ✨



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