



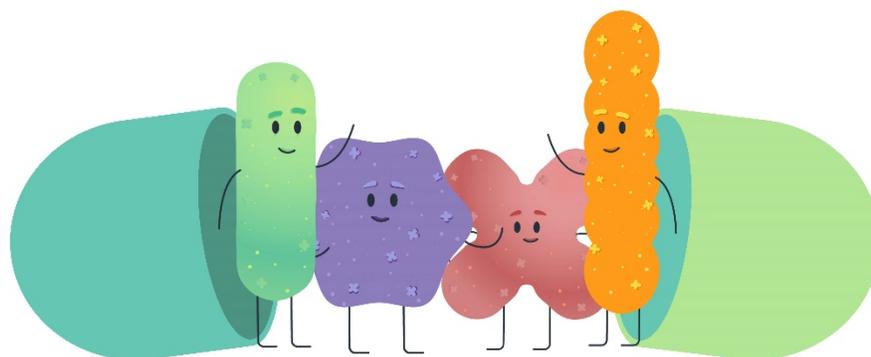
LEARN MORE ABOUT THE INTRICACIES OF PROBIOTICS

Consumer interest in probiotics is growing. So are the advances in science demonstrating expanded health benefits and the innovations delivering probiotics in a broader range of products. More than ever, retailer buyers need to be informed to select the right products for their consumers.

RETAIL BUYER'S GUIDE TO PROBIOTICS

BACKGROUND

Yes, Probiotics are actually alive! Probiotics are unique ingredients that continue to gain popularity with consumers due to growing product innovation and the developing body of scientific research demonstrating a variety of health benefits. Making smarter choices about which products to offer your customers starts with the understanding that products containing probiotics are actually delivering millions, or sometimes billions, of living organisms.

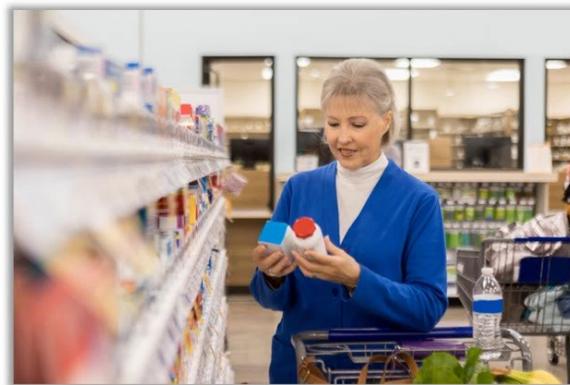
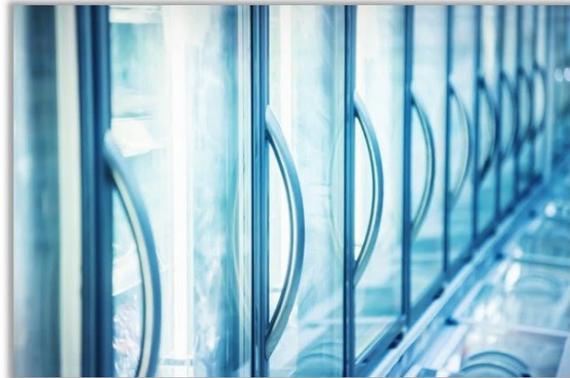


The Food and Agriculture Organization of the United Nations (FAO) and World Health Organization (WHO) define probiotics as “live microorganisms which when administered in adequate amounts confer a health benefit on the host.”¹ The human body plays host to trillions of microscopic live organisms—many are beneficial, though some may be harmful. These organisms, which live on and in the body (such as on the skin and in the gut), comprise the human microbiome. Humans depend on these organisms, interacting with their organs and bodily systems, for a broad range of activities (e.g., digestion, immune health, supporting the gut-brain axis). Probiotics can help the body in a number of ways, including by fighting off excessive “bad” bacteria and restoring a healthy microbial balance.

Retail Buyer's Guide to Probiotics

Given that probiotics are live organisms, these products are different from other dietary supplements and require different labeling practices, as well as unique storage and handling requirements. This Buyer's Guide will help to educate retailers on the intricacies of probiotic products, including their unique bioactivity and various health benefits, labeling issues, storage and handling best practices, and consumer usage data.

Understanding these differences will help retail buyers when purchasing high-quality probiotic products from responsible manufacturers, curating their product offerings, improving handling of these products, and educating customers on the benefits of probiotics.



BENEFITS OF PROBIOTICS—BEYOND GUT HEALTH

Not all probiotics are the same—not by a long shot. Probiotics are a category, not a single entity. Just as probiotics are growing in popularity, so is the body of scientific research supporting their use. Different probiotic species and strains have unique bioactivities and provide varied health effects. Some probiotic products contain one strain, while others may have many. Different probiotics (or combinations) may affect different systems in the body (digestive, cognition, immune function, heart health, women's health, etc.), so it is important that retailers understand that not all probiotic products offer the same benefits. **When discussing probiotic use with consumers, your sales staff should understand the differences in probiotic products offered in your store and inquire about the specific needs of the individual before recommending a product.**



**Gut
Health**



**Women's
Health**



**Brain
Health**



**Heart
Health**

Supported by a long history of safe use and rigorous clinical trials, probiotics are most widely known for their role in maintaining digestive health. However, emerging science shows benefits of specific organisms for immune function, brain health, oral health and heart health, among others. According to recent consumer data, 57% of probiotic supplement users take these products for digestive health and general health, and 51% take them for immune system support.²

LABELING PROBIOTIC IDENTITY

Proper labeling of probiotics comprises three components: identity, quantity and viability. Retailers should inquire about all three when curating the products for their shelves.

First, the label should identify the genus, species, and strain for each microorganism in the product. Not all probiotic strains are alike or serve the same function in the human body. Just as different breeds of dogs serve different functions—some are better suited for herding livestock, while others are known for tracking and retrieving—various probiotic strains also may operate differently and affect different bodily systems (digestive, cognition, immune system function, etc.).

So be sure the strain is identified on the product label. Usually, this designation appears after the two-word Latin genus and species identification (such as “GG” or “BI-04”).

The label should identify the genus (e.g. *Lactobacillus*), species (e.g. *acidophilus*), and strain (e.g. La-14) for each microorganism in the product



| Supplement Facts | | |
|---|--------------------------------------|--------|
| Serving Size 1 Capsule | | |
| Servings Per Container 30 | | |
| Amount Per Serving | %DV | |
| Proprietary blend of | 25 Billion CFU* | 125 mg |
| 3 Strains of Probiotic Bacteria: | | |
| <i>Lactobacillus rhamnosus</i> GG, | <i>Bifidobacterium lactis</i> BI-04, | |
| <i>Bacillus coagulans</i> GBI-30, 6086. | | |
| * Daily Value not established | | |

Exp. 12-2024

Retail Buyer's Guide to Probiotics

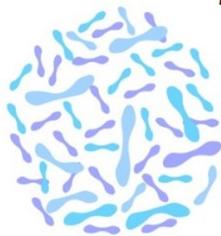
While strain attributes and benefits may overlap, one cannot assume that research on one strain of probiotic applies to another strain, even of the same species. It is important that these living organisms are labeled accurately to ensure that retailers can differentiate the unique bioactivity of different strains and that consumers have the information on the label to choose products to best serve their individual needs.



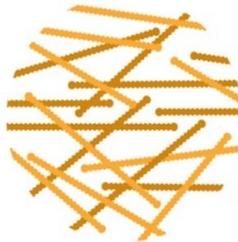
Lactobacillus



Lactococcus



Bifidobacterium



Bulgaricus



Propionibacterium

LABELING PROBIOTIC QUANTITY

Second, the quantitative amount(s) of probiotics in a product should be expressed to reflect live microorganism count, such as Colony Forming Units (CFUs)³. CFU is currently the most prevalent scientifically accepted unit of measure for probiotics.

Measuring probiotic quantity by weight (such as in milligrams), as FDA regulations currently require, does not provide information on the number of live microorganisms in the product. In addition, some of these probiotics may die over their shelf life (see next section for more information on shelf life) so it is not possible to distinguish the weight of live microorganisms from that of dead microorganisms or from that of the fillers used to standardize the probiotic raw materials. Imagine telling someone that a room full of people and furniture weighs 20 tons and asking them to determine how many living people are in the room.

| Supplement Facts | |
|--|------------------------|
| Serving Size 1 Capsule Servings Per Container 30 | |
| Amount Per Serving | %DV |
| Proprietary blend of 3 Strains of Probiotic Bacteria: | |
| | 25 Billion CFU* 125 mg |
| <i>Lactobacillus rhamnosus</i> GG, <i>Bifidobacterium lactis</i> BI-04, <i>Bacillus coagulans</i> GBI-30, 6086. | |
| * Daily Value not established | |

Quantity should be labeled to reflect live microorganism count, such as CFUs. However, current regulations require labeling quantity by weight (mg).

Exp. 12-2024

Listing live microbial dietary ingredient quantity on a label gives consumers the most accurate information about the amount of viable microorganisms present in a product. FDA does not currently require labeling for live organisms but responsible marketers provide this information throughout the shelf life of the product.

LABELING PROBIOTIC VIABILITY

Third, the labeled quantity of probiotics should reflect the quantity of live microorganisms at the end of their stated shelf life (i.e., the expiration or “use by” date), not at the date of manufacture.

Labeling quantity at the time of manufacture may be misleading because, like many other ingredients, probiotics can naturally lose activity over time. This fact is particularly relevant to probiotics that can die in the container over shelf life, so labeling quantity at the time of manufacture may not reflect the number of live microorganisms in the product by the time it reaches the consumer. If the product label only includes the number of organisms at the date of manufacture, consumers will not know whether the probiotics will still be alive in the quantities needed to provide the desired health benefits at the time they take the product.

All dietary supplements that are labeled with an expiration date must contain at least the labeled amount of each dietary ingredient up until the expiration date. It's not uncommon for manufacturers to provide more than the labeled amount of an ingredient that allows for some deterioration over its shelf life. That is true for probiotics too. Based on the strains used, the length of the shelf life, the finished product matrix, and the product packaging, it is not unusual for probiotic quantity at time of manufacture to be significantly higher than the label claim.

| Supplement Facts | |
|--|------------------------|
| Serving Size 1 Capsule Servings Per Container 30 | |
| Amount Per Serving | %DV |
| Proprietary blend of 3 Strains of Probiotic Bacteria: | 25 Billion CFU* 125 mg |
| <i>Lactobacillus rhamnosus</i> GG, <i>Bifidobacterium lactis</i> BI-04, <i>Bacillus coagulans</i> GBI-30, 6086. | |
| * Daily Value not established | |

Retailers should ask their vendors about overages in manufacturing, and not be surprised if a recently produced probiotic actually tests for amounts higher than the labeled quantity at the expiration date.

Exp. 12-2024 → Expiration or “use by” date

PROPER STORAGE AND HANDLING

Ensuring that probiotics remain viable throughout their lifecycle can be a challenge, but it is critical to do so. As live organisms, probiotics are generally sensitive to changes in temperature and humidity. The extent to which an individual product is impacted by temperature and humidity depends on the probiotic strains in the product, formulation matrix and dosage form, manufacturing and packaging conditions, and product packaging, among other factors. Some probiotic products require refrigeration, while others are shelf-stable at room temperature.

Manufacturers should provide storage and handling instructions to their retailer customers, taking into account individual formulations and packaging. Retailers should ensure that the products are stored under the appropriate conditions throughout their lifecycle, including at the warehouse, during shipping, and on retail shelves. Proper storage and handling are critical for the products to maintain the labeled quantity of live organisms through the end of the stated shelf life. Retailers should also advise their customers about the proper storage conditions for the products they purchase, as indicated on the product label.

When defining storage temperatures, firms may consider the following storage conditions from the United States Pharmacopoeia (USP) General Chapter <659> Packaging and Storage Requirements⁴.

| USP General Chapter <659> storage condition definitions | |
|--|--------------------------|
| Storage | Storage condition |
| Refrigerated | 2°C to 8°C |
| Cold | Not exceeding 8°C |
| Cool | 8°C to 15°C |
| Controlled room temperature | 20°C to 25°C |

In addition, room temperature is generally accepted to be 25°C for the Continental US per International Council for Harmonisation stability testing guidelines⁵.

CONSUMER USAGE OF PROBIOTICS

Who takes probiotics?

Three quarters of Americans take dietary supplements. And nearly half of supplement users (46%) take specialty supplements, which include ingredients like probiotics, omega-3s, collagen and melatonin. Probiotics continue to be one of the most widely used supplements in the specialty supplement category.



11%
of supplement users
take probiotics

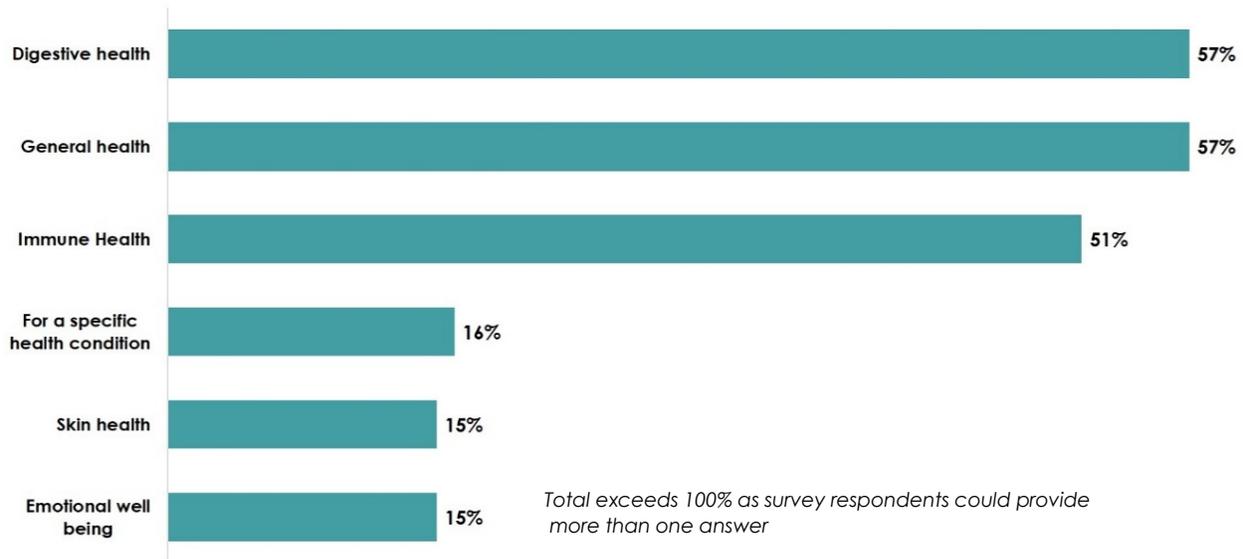
Recent consumer usage data show that 11% of supplement users report taking probiotics, with some slight variation among different demographics.

Historically, probiotics usage has skewed female and to adults aged 35-54.



Why do supplement users take probiotics?

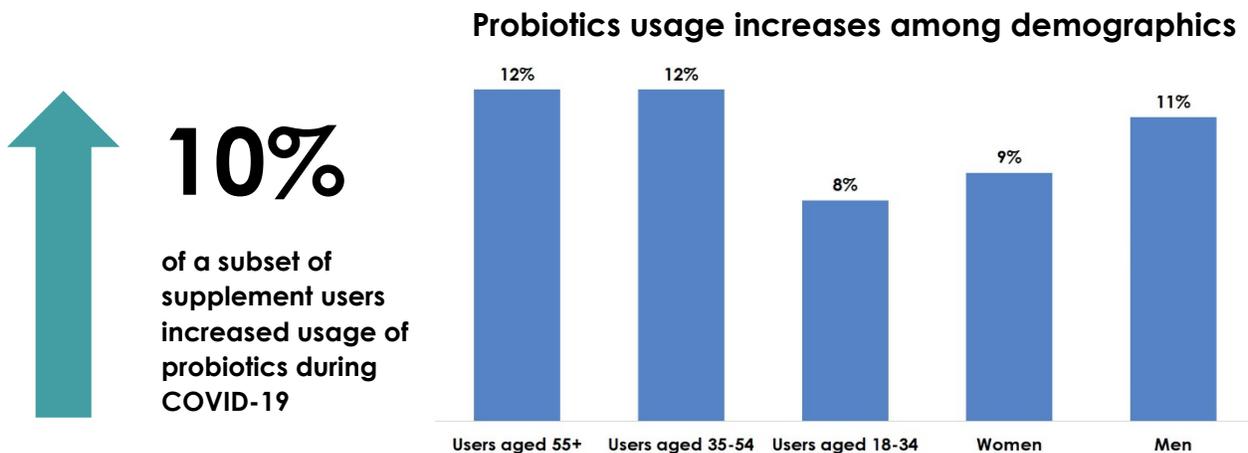
Among those who report taking probiotics, a majority (57%) cite taking this ingredient for digestive health or general health and 51% report taking probiotics for immune system health.



2020 CRN Consumer Survey on Dietary Supplements²

Probiotics usage increases during COVID-19

Since the start of the COVID-19 pandemic, 43% of supplement users reported changing their supplement routine. And of those users who altered their regimen, 91% reported increasing their supplement intake during the health crisis. Data show that of this subset of supplement users, 10% increased their probiotics intake during the pandemic with varied increases across demographics.



10%
of a subset of supplement users increased usage of probiotics during COVID-19

CRN COVID-19 Consumer Survey on Dietary Supplements⁴

ADDITIONAL TOOLS AND RESOURCES

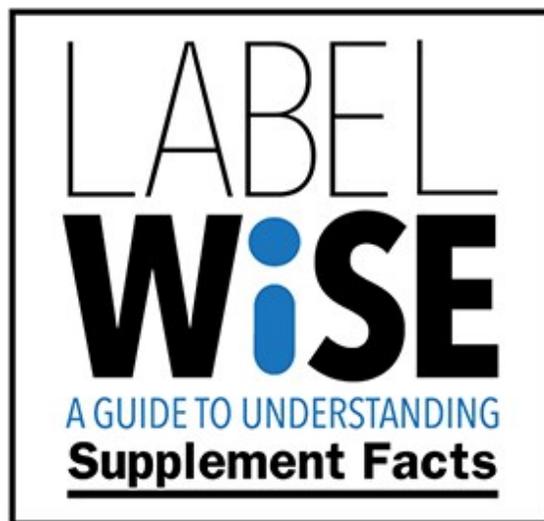
Supplement OWL

The Supplement OWL is a self-regulatory initiative of CRN that provides a resource for regulators, retailers, and industry to identify dietary supplements, their ingredients and the companies who market them. Users can examine and evaluate labels and other product information. The [Supplement OWL](#) provides retailers with an authoritative database to examine and evaluate labels of products in the market.



Label Wise

FDA has mandated new label requirements for dietary supplement products to provide consumers with better information they need to make informed choices about their health. The agency has extended its policy of enforcement discretion in response to COVID-19, giving large companies through the remainder of 2020 to come into compliance. In the meantime, CRN's [LabelWise campaign](#) offers a suite of educational materials to help retailers and consumers understand changes they will see on dietary supplement labels. Retailers can use these resources in their own communications with customers.



CRN and IPA's Best Practices for Probiotics

The Council for Responsible Nutrition (CRN) and the International Probiotics Association developed scientifically-based [voluntary best practices](#) that address the labeling, stability testing, and storage recommendations for probiotic-containing dietary supplements and functional foods. These best practices are intended to facilitate transparency and consistency.



Roadmap for Retailers

The Council for Responsible Nutrition created this guide to assist its members, their customers, and retailers selling dietary supplements with meeting their obligation under the law. Dietary supplements may not be marketed to prevent, treat, mitigate or cure any disease. As manufacturers and marketers of supplements are limited by law as to the claims they can make about their products on the labeling, in print or broadcast advertising, similar requirements and restrictions apply to retailers and distributors who speak directly with consumers. This [guide](#) supports individuals assisting consumers at the point of purchase to discuss dietary supplements accurately and legally.



SOURCES

1. Joint FAO/WHO Expert Consultation on Evaluation of Health and Nutritional Properties of Probiotics in Food including Powder Milk with Live Lactic Acid Bacteria. (2001). Health and nutritional properties of probiotics in food including powder milk with live lactic acid bacteria. Available at: <ftp://ftp.fao.org/docrep/fao/009/a0512e/a0512e00.pdf>.
2. [2020 CRN Consumer Survey on Dietary Supplements](#), Council for Responsible Nutrition, conducted among U.S. adults by Ipsos, August-September 2020
3. CFU is the scientifically accepted unit of measure for probiotics. Labeling quantity in CFUs provides meaningful information to consumers about the quantity of viable microorganisms present in the product throughout shelf life. However, 21 CFR 101.36(b)(3)(ii)(A) requires that the quantity of probiotic dietary ingredients be declared in metric units. FDA issued draft guidance in September 2018 contemplating a policy of enforcement discretion for those firms that declare the quantitative amount of live microbial ingredients in the Supplement Facts label in CFUs in addition to the required metric weight (See draft guidance at: <https://www.fda.gov/regulatory-information/search-fda-guidancedocuments/draft-guidance-industry-policy-regarding-quantitative-labeling-dietary-supplementscontaining-live>). Additionally, the draft guidance states that live microbial dietary ingredients in a proprietary blend should be listed in descending order of predominance by weight. CRN disagrees with the draft guidance because listing quantitative amount in CFUs and by metric weight is not feasible since CFUs do not directly correlate directly with weight (See CRN's comments at: https://www.crnusa.org/sites/default/files/pdfs/commentspdfs/CRN_Comments_FDA_DraftGuidance_Probiotic-Labeling_110618.pdf).
4. *The Council for Responsible Nutrition* and the International Probiotics Association. "Best Practices Guidelines for Probiotics." Accessed at: <https://www.crnusa.org/self-regulation/best-practices-guidelines-probiotics>
5. [CRN COVID-19 Consumer Survey on Dietary Supplements](#), Council for Responsible Nutrition, conducted among U.S. adults by Ipsos, July-August 2020
6. ICH. (2003). Harmonised Tripartite Guideline. Stability testing of new drug substances and products Q1A (R2) (Section 2.2.7). Available at: http://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Quality/Q1A_R2/Step4/Q1A_R2_Guideline.pdf.