

What Qualifies as a Probiotic?

Probiotics are live microorganisms that, when administered in adequate amounts, confer a health benefit on the host.

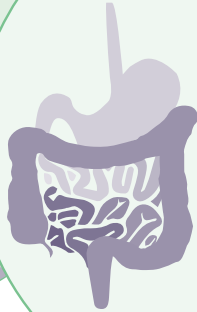
TARGET HOST

Humans
Animals, e.g.:
Companion: dogs, cats, horses
Production: cows, chickens, honeybees, fish
Plants, e.g.:
trees, grass, crops



TARGET SITE OF HOST

Any target site on any host that leads to a beneficial health effect, e.g.: digestive tract, urogenital tract, skin, heart, endocrine system, or oral cavity; roots or leaves



SCIENTIFIC CREDENTIALS

- ✓ Adequate evidence in target host demonstrating health benefit. The evidence must align with any claim made, including comparable study population, study outcomes and the study dose.
- ✓ Safe for intended use
- ✓ High quality genome sequence
- ✓ Assigned to current taxonomic group
- ✓ Deposited in international culture collection

ROUTE OF ADMINISTRATION

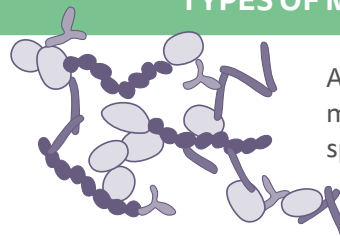
Any route of administration, e.g.:



Oral, nasal
Topical (skin) treatments
Intravaginal instillations
Rectal infusions



TYPES OF MICROBES



Any live microbe, including many different genera, species and strains

REGULATORY CATEGORY



Probiotics can range across diverse regulatory categories, e.g.:

Foods	Drugs/live biotherapeutic agents
Dietary supplements	Medical devices
Infant formula	Animal feed
Medical foods	

HEALTH BENEFIT



A wide array of preventive and therapeutic endpoints are possible health benefit targets for probiotics. However, although live microbes have many uses, not all are health benefits.

For example, the following are not considered health benefits in the context of probiotics:

- Environmental uses such as detoxification or pathogen removal/inhibition
- Improving beauty or odor
- Industrial use to produce endproducts
- Improving nutritional properties of foods or feeds

HEALTHCARE PROVIDERS AND CONSUMERS: WHAT TO LOOK FOR

Quality product [Bonus: Valid third party verification of product quality]

Dose no less than that shown to provide health benefit

On the label:

- Dose indicated through end of shelf life (not at time of manufacture)
- What microbial strain(s) is in the product.
For example: *B. animalis* subsp. *lactis* AB#1

Genus: *Bifidobacterium*

Species: *animalis*

Subspecies*: *lactis*

Strain: AB#1

*not all probiotics require a subspecies designation

NOT PROBIOTIC

Postbiotics, dead microbes, prebiotics

Undefined consortia of microbes, including those in some fermented foods or in fecal microbial transplant

Any microbes not meeting stipulated criteria



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