



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