

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

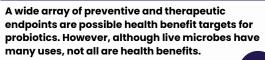
REGULATORY CATEGORY



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

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

HEALTH BENEFIT



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

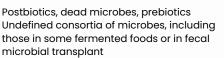
- Dose indicated through end of shelf life (not at time of manufacture)
- What microbial strain(s) is in the product. For example: B. animalis subsp. lactis AB#1

Genus: Bifidobacterium Species: animalis Subspecies* : lactis Strain:

ΔR#1

*not all probiotics require a subspecies designation

NOT PROBIOTIC





Any microbes not meeting stipulated criteria

source IASPP

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