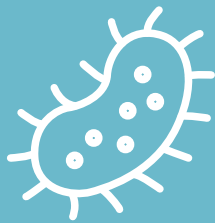


# A GO-TO-GUIDE TO PROBIOTICS

## What is the definition of a probiotic?



**Live microorganisms** that, when **administered in adequate amounts**, confer a **health benefit** on the host<sup>1</sup>

This definition means that,

› Probiotics must be **live**

› Probiotic strains must be **fully characterised**

› Evidence from **well designed clinical trials** in humans is the gold standard to demonstrate a positive effect on health

› These trials should be conducted with a **similar number of live bacteria** as would be found in the probiotic supplement

The human gastrointestinal tract is colonised by many microorganisms, including bacteria, archaea, viruses, fungi, and protozoa. The activity and composition of these microorganisms (collectively known as the gut microbiota or microbiome) can affect human health and disease.

While probiotics may influence the activity and composition of the gut microbiota, certain strains may have effects beyond the gut, for instance on the immune and/or nervous systems. It is an important criterion for probiotics to survive alive through the gut, if that is their target and mode of action. Probiotics may colonise the human gut mucosa in highly individualised patterns, depending on the baseline microbiota, probiotic strain, and gastrointestinal tract region<sup>2</sup>. All probiotics have a transient effect and will never permanently colonise the gut, therefore it is important that a probiotic is taken daily.

### › Probiotics must be fully characterised

Probiotics must be fully classified, which means the microbial strain must be defined using its full name on the product including the genus, species and the strain identified.

Genus	Species	Strain
<i>Bifidobacterium</i>	<i>longum</i>	35624®

### › Scientific evidence of a specific health benefit

Not all probiotics work in the same way; their effects are strain specific. Probiotics should always have evidence from scientific studies demonstrating their benefit on human health<sup>3</sup>. Evidence from well-designed clinical trials in humans is the gold standard to demonstrate a positive effect on health.

### › Survival

Does the strain have evidence to prove it reaches the gut alive? It is important that there is evidence to demonstrate the survival of the strain or strains through the gastrointestinal tract of a human. *In vitro* or model studies are not proof that the strain will survive *in vivo*.

### › Microbial numbers

Ensure that probiotic supplements contain an appropriate number of live bacterial cells, often expressed as CFU (colony forming units). The number in the supplement should be similar to the number used in the clinical trials of the probiotic strain, to ensure efficacy in clinical practice. Note that higher microbial numbers or mixtures of strains does not always mean better or more effective.

### › Safety

It is important that there is evidence to support the safe use of the specific strain or strains in the relevant population group for which you are recommending it<sup>4</sup>. Is there evidence to support the use in the specific health condition?

### › Stability

The probiotic supplement needs to have undergone sufficient quality control measures to ensure the number of live cells of the probiotic in the product at the end of shelf life is as described on the label<sup>3</sup>.

## Regulatory restrictions on probiotics

Currently in the UK and EU there are no approved health claims associated with the term 'probiotic', and even the term 'probiotic' is considered to be a claim of health benefit. The regulations were intended to protect consumers, but the resulting lack of information about probiotics makes it difficult for consumers to make informed choices. Healthcare professionals can access and understand the scientific evidence behind these supplements, in order to help consumers.

#### References:

1. Hill et al. 2014;11(8):506-14 2. FAO/WHO . Online: HYPERLINK "http://www.who.int/foodsafety/fs\_management/en/probiotic\_guidelines.pdf" www.who.int/foodsafety/fs\_management/en/probiotic\_guidelines.pdf
2. Zmora N, et al. Personalized Gut Mucosal Colonization Resistance to Empiric Probiotics Is Associated with Unique Host and Microbiome Features. *Cell*. 2018;174:1388-405.e21.
3. Pinero M, Stanton C. Probiotic Bacteria: Legislative Framework- Requirements to Evidence Base. *Journal of Nutrition*. 2007;137(3):850S-853S.
4. Srinivasan et al. Clinical Safety of Lactobacillus casei shirota as a Probiotic in Critically Ill Children. *Journal of Paediatric Gastroenteral Nutrition*. 2006;42(2):171-173.
5. Glanville et al. A review of the systematic review process and its applicability for use in evaluating evidence for health claims on probiotic foods in the European Union. *Nutrition Journal*. 2015;14(1):16.

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