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### Probiotics: definition, scope and mechanisms of action



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#### A B S T R A C T

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For a subject area of science, medicine and commerce to be so recently defined and investigated, few can compare to probiotics for the controversy they have incited. Barely a paper is published without the use of a different definition, or challenging the most used one, or proposing a different nuance of it. The situation has become even more surreal with the European Food and Safety Authority banning the word probiotic for use on labels. The reiteration of the FAO/WHO definition by the world's leading group of probiotic experts, should provide relative consistency in the near future, but what are the causes of these aberrations? This review will discuss the rationale for the definition, and the scope of the subject area and why alternatives emerge. While mechanisms of action are not widely proven, *in vitro* and some *in vivo* experiments support several. Ultimately, the goal of any field or product is to be understood by lay people and experts alike. Probiotics have come a long way in 100 years since Metchnikoff and 10 years since their globalization, but their evolution is far from over.

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## Introduction

Definitions for many, are necessary evils, which describe the meaning of a term, and in some cases every object the term describes. But, with differences of opinion of the definition of definition itself, one can appreciate why readers will have already tuned out.

In defining probiotics as “Live microorganisms which when administered in adequate amounts confer a health benefit on the host”, the Expert Panel commissioned in 2001 by the Food and Agriculture Organization of the United Nations, at Argentina’s request, and supported by the World Health Organization, provided clarity and distinctiveness to the term probiotic [1]. While initially this was in relation to food, the Panel was cognisant of the potential for probiotics to be used under many regulatory categories. The wording was carefully chosen to encompass all real or envisaged ways of delivering various types of microbes to a host. Therefore, words like consumption and ingested were too restrictive, and ‘administered’ was chosen. The Panel was clear that there is no such entity as a dead probiotic. If dead organisms convey a benefit, they should be referred to by a different term. Yet to this day, authors continue to misunderstand the term, even when they include the actual reference to the FAO/WHO definition [2]. In this particular example, the author states “Probiotic applications can be either mono or multiple strains, or even in combination with prebiotic, immunostimulants such as synbiotics and synbiotism, and in live or dead forms.” It behoves editors and journals to enforce the proper use of the definition, but this is rarely done.

The conferring of a health benefit has been criticized as being too vague or requiring further clarification. In fact, a Working Group of FAO/WHO was convened in 2002 to provide such clarification [3]. More recently, the FAO/WHO definition has been re-evaluated and supported [4]. Clearly, a benefit to the host must be realized and shown to be above and beyond that placebo, yet the majority of products on the market have not undergone such appropriate testing and verification.

In this review, reasons for misunderstanding probiotic will be explored, as well as mechanisms whereby their effects are conveyed.

## Why the confusion?

It is clear from the literature and conference presentations around the world, that either people want to define probiotics themselves, or they misunderstand what probiotics are. Examples of the former include the FDA which still uses the term biotherapeutics, ostensibly because no one has taken the time to update the field. Terms such as biotherapeutics and pharmacobiotics appear to emerge as a means of specifying an activity rather than being an alternative to the term probiotic and its definition. The very use of the word therapeutic indicates treatment of a disease, and would be specific for only a drug, whereas probiotics can be foods, supplements, drugs, medical foods, medical devices or cosmetics. The term pharma implies pharmaceutical, either as a drug or a chemical component. Factors secreted by probiotic strains have been referred to, by some, as ‘postbiotics’.

The term ‘Novel’ probiotics [5] is simply a qualifier rather than a new definition. The term ‘psychobiotics’ has been propagated since 2012 [6] defined as “a live organism that, when ingested in adequate amounts, produces a health benefit in patients suffering from psychiatric illness”. There are a number of issues with this. Firstly, creating a sub-category of probiotic per se is not necessarily a problem, and in this case, it should be cited as such. Secondly, when introducing a new term and definition, it should be clear and encompassing. In the case of psychobiotics, it seems premature, and requires the type of clarification undertaken for probiotics. For example, must the organism be ingested, or could signalling molecules from bacteria in the oral cavity, skin, urogenital tract influence the brain? Do the patients have to be suffering, and to what extent suffering, or could they be at risk of a psychiatric illness? Would organisms influencing the brain but not psychiatric illness be termed psychobiotics? Such clarifications would be helpful.

Others are dissatisfied with the definition because it does not specify health benefits and is driven by corporate profits [7]. Ironically, the authors believe that the concept of probiotics is inhibiting the field of phamacobiotics. In fact, how probiotics are regulated, sold and marketed has nothing to do with the definition. As already stated, probiotics, unlike pharmacobiotics, can be sold as foods and

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