

IPA Europe guidelines to qualify a microorganism to be termed as 'probiotic' in foods, beverages and supplements in commercial communications

In 2001, in a period that marked a rise in interest in probiotics for the clinical and scientific communities, experts convened by the FAO/WHO provided a scientific opinion on "probiotics"¹ and agreed on the following definition (later amended by an expert consensus group): "*live microorganisms that, when administered in adequate amounts, confer a health benefit on the host*"^{2,3}.

This report was followed by the "Guidelines for the Evaluation of Probiotics in Food"⁴ where the FAO/WHO experts made several recommendations. One of these was to officially adopt the definition as well as more specific criteria as a prerequisite to qualify a microbial strain as a "probiotic".

While the definition of probiotics has been widely acknowledged by the scientific community and key players in the field of probiotics, the FAO/WHO guidelines have not been implemented. In Europe, there is neither regulatory status nor guidelines defining the probiotics category, nor a commonly acknowledged list of individual probiotic strains and/or species⁵.

Therefore, it is essential that the industry clarifies specifications for probiotics in foods, in order to ensure the proper use of the term without contradicting national requirements or health claim provisions.

Scope of the IPA Europe guidelines

In accordance with the FAO/WHO guidelines, the scope of this document is limited to the use of probiotics in food, including food supplements (Chapter 3¹).

Drug applications and animal feeds are excluded from the scope of these guidelines.

Probiotic criteria

There have traditionally been many products available in the marketplace carrying the label 'probiotic'. However, there are currently no defined guidelines accepted within Europe on what constitutes a 'probiotic' microorganism.

¹ Health and Nutritional Properties of Probiotics in Food including Powder Milk with Live Lactic Acid Bacteria. Report of a Joint FAO/WHO Expert Consultation on Evaluation and Nutritional Properties of Probiotics in Food including Powder Milk with Live Lactic Acid bacteria. Cordoba, Argentina, 1 - 4 October 2001.

² Note: but restricted its scope to discussion of 'Live microorganisms which when consumed in adequate amounts as part of food confer a health benefit on the host.'

³ The International Scientific Association for Probiotics and Prebiotics consensus statement on the scope and appropriate use of the term probiotic. Hill C *et al* (2014) *Nature Rev Gastroenterol Hepatol* **11**:506-514.

⁴ Joint FAO/WHO Working Group Report on Drafting Guidelines for the Evaluation of Probiotics in Food. London, Ontario, Canada. 30 April – 1 May 2002.

⁵ Note: although some EU Member States have adopted such lists and others have developed certain conditions for qualifying specific strains as probiotic.

⁶ Health Canada (2015). Natural Health Products – Probiotics. <http://webprod.hc-sc.gc.ca/nhp/nd/bdipsn/atReq.do?atid=probio>

⁷ Ministry of Health (2013). Guidelines on probiotics and prebiotics.

http://www.salute.gov.it/imgs/C_17_pubblicazioni_1016_ulterioriallegati_ulterioriallegato_0_alleg.pdf

IPA Europe recommends that, with respect to commercial communications, the term 'probiotic' should only be used to describe microorganisms when a certain combination of requirements is met. No specific authorisation would be required as long as no reference to any specific health effect is made. In accordance with Italian⁶ and Canadian⁷ guidelines, IPA Europe considers that microorganisms described as 'probiotic' should, for example, facilitate a beneficial balance of the intestinal microbiota and/or support desirable gastrointestinal function.

Probiotic strains:

1. Must be taxonomically characterized at species level and identifiable at strain level

- Probiotics are specific strains that need to be well identified at strain level, by using the most current, valid and internationally accepted techniques. This would require using a combination of the most appropriate molecular techniques, according to the LPSN list (List of prokaryotic names with standing in nomenclature <http://www.bacterio.net/>)⁶ or the International Committee on Systematics of Prokaryotes (<http://icsp.org/>).
- Probiotics are classified, as per reference nomenclature, at species level (family, genus and species). IPA Europe recommends that probiotic strains are indicated in the ingredients list with their strain ID.
- IPA Europe recommends that probiotic strains are deposited in an internationally recognised culture collection (<http://wfcc.info/collections>).

2. Must be safe for the intended use (i.e. for the targeted consumer and in the conditions of recommended use)

- Species that are safe for human consumption are listed in the "Qualified Presumption of Safety" (QPS) EFSA reference documents⁷. The EFSA has taken responsibility to launch this European initiative,⁸ which aims to allow strains with an established history and safety status to enter the market without extensive testing requirements. The QPS concept is a fast track approach for species for which there is a sufficient body of knowledge, so that all strains within a species are presumed to be safe for human consumption.
- Safety assessment of strains of QPS-listed species can be limited to aspects that are relevant for the organism in question.

3. Must be alive when consumed

- Probiotic strains must be alive (including in freeze-dried form) in the product throughout shelf life and hence, when consumed.
- On the basis of available literature, it can be assumed that the sufficient amount is at least 10⁹ live cells per daily portion⁹ to ensure an effect. A different daily dose or quantity per strain may be accepted if substantiated by specific studies that have shown the effects.
- Enforcement is under the responsibility of the national authorities.
- Statements with regard to survival of the probiotic through the gastrointestinal tract should be demonstrated by human studies.

When using probiotics, the industry must ensure appropriate consumer information.

⁶ See also http://ijs.sgmjournals.org/content/64/Pt_4/1434.full.

⁷ <http://www.efsa.europa.eu/en/topics/topic/qps.htm#wtr1=01>

⁸ Anon (2005). European Food Safety Authority (EFSA) Scientific Colloquium—Microorganisms in Food and Feed: Qualified Presumption of Safety. 13–14 December 2004, Brussels, Belgium. <http://www.efsa.europa.eu/en/supporting/pub/109e.htm>.

⁹ Lee YL & Salminen S (1996) The coming age of probiotics. *Trends Foods Sci Technol* 6:241-245